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Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States

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Österreichisches Bundesinstitut für Gesundheitswesen

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Country Profiles

Claudia Habl
Katja Antony
Danielle Arts
Michael Entleitner
Barbara Fröschl
Christine Leopold
Heidi Stürzlinger
Sabine Vogler
Marion Weigl

assisted by
Romana Landauer

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Abbreviations

A.S.SO.FARM	Federazione aziende e dei servizi farmaceutici pubblici / Association of Public Pharmacies Public Pharmaceutical Services (Italy)
ABPI	The Association of the British Pharmaceutical Industry (United Kingdom)
AC	Autoridade Concorrência / Portuguese Competition Authority (Portugal)
ACD	Appraisal Consultation Document (United Kingdom)
ADEFARMA	Associacíon de Farmacéuticos de Madrid / Association of Pharmacists in Madrid (Spain)
ADF	Associazione Distributori Farma-Ceutici / Association of Wholesalesr (Italy)
AEMPS	Agencia Espanola del Medicamento y Productos Sanitarios / Spanish Medicines Agency (Spain)
AESEG	Asociacion Espanola de Fabricantes de Sustancias y Especialidades Farmaceuticas Genericas / Association of Generic Industry (Spain)
AFR	Annual financial return
AFSGP	Association Francaise des Producteurs de Spécialités Grand Public / French Association of Self-Medication Industry (France)
AFSSAPS	Agence Francaise de Sécurité Sanitaire des Produits de Santé / Medicines Agency (France)
AGES	Österreichisches Institut für Gesundheit und Ernährungssicherheit / Austrian Agency for Health and Foodsafety (Austria)
AIC	Autorizzazione all'immissione in commercio / Market Authorisation (Italy)
AIFA	Agenzia Italiana del Farmaco / Medicines Agency (Italy)
AIM	Autorização de Introdução no Mercato / Market Authorisation (Portugal)
AIPM	Association of Innovative Pharmaceutical Companies (Hungary)
ALP	Association of Lithuanian Pharmaceutical Wholesalers (Lithuania)
AMG	Arzneimittelgesetz / German Medicines Act (Germany)
AMGROS	Hospital Purchasing Agency (Denmark)
AMMD	Association des Médecins et des Médecins-Dentistes du G.D.de Luxembourg / Chamber of Doctors and Dentists (Luxembourg)
AMR	Arzneimittel-Richtlinien / Prescribing Guidelines (Germany)
AOPP	Asociácia na ochranu práv pacientov / Association for the protection of patients' rights (Slovakia)
APB	Association Pharmaceutique Belge / Pharmaceutical Association (Belgium)
APBI	Association of the British Pharmaceutical Industry (United Kingdom)
Apifarma	Associação Portuguesa da Indústria Farmacêutica / Association of the Research-oriented Industry (Portugal)
ARGE	ARGE Pharmazeutika / Association of the Austrian Pharmaceutical Wholesalers (Austria)
ARSZMP	Agencija Republike Slovenije za zdravila in medicinske pripomocke / The Agency of Medicinal Products and Medical Devices (Slovenia)
Art.	Article
ASL	Aziende Sanitarie Locali / Health care provision is organised by regional authorities (Italy)
ASMR	Amélioration du Service Médical Rendu / Improvement in medical benefit (France)
ASSR	Agenzia per i Servizi Sanitari Regionali / Agency for Regional Health Services (Italy)

ASUSALUD	National Association of Consumers and Users of Healthcare Services (Spain)
ASVG	Allgemeines Sozialversicherungsgesetz / Austrian Social Insurance Law (Austria)
ATC	Anatomic, therapeutic, chemical classification of the WHO
BAH	Bundesfachverband d. Arzneimittel-Hersteller / Association of Pharmaceutical Industry (Germany)
BAK	Bundesarbeiterkammer / Federal Chamber of Labour (Austria)
BAPW	British Association of Pharmaceutical Wholesalers (United Kingdom)
BASG	Bundesamt für Sicherheit im Gesundheitswesen / Austrian Federal Agency for Saftey in Healthcare (Austria)
BCFI	Centre Belge d'Information Pharmacothérapeutique / Belgian Center for Pharmacotherapeutic Information (Belgium)
BEK	Executive Order (Denmark)
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte / Federal Institute for Drugs and Medical Devices (Germany)
BG Pharma	Bond van Groothandelaren in het Farmaceutische Bedrijf / Umbrella organisation for pharmaceutical wholesalers (Netherlands)
BGBI	Bundesgesetzblatt / Official Gazette (Austria)
BGMA	British Generic Manufacturers Association (United Kingdom)
BIFA	Bundesinstitut für Arzneimittel / Federal Institute of Medicine (Austria)
BMA	British Medical Association (United Kingdom)
BMF	Bundesministerium für Finanzen / Federal Ministry of Finance (Austria)
BMG	Bundesministerium für Gesundheit / Ministry of Health (Germany)
BMGF	Bundesministerium für Gesundheit und Frauen / Federal Ministry of Health and Women's Issues (Austria)
BMSGK	Bundesministerium für Soziale Sicherheit, Generationen und Konsumentenschutz / Federal Ministry of Social Security, Generations and Consumer Protection (Austria)
BMWA	Bundesministerium für Wirtschaft und Arbeit / Federal Ministry for Economy and Labour (Austria)
Bogin	Bond van de Generieke Geneesmiddelenindustrie Nederland / Dutch Federation for Generics Manufacturers (Netherlands)
ČAFF	Česká asociace farmaceutických firem / Association of Generic Industry (Czech Republic)
CANAM	Caisse Nationale d'Assurance Maladie des Professions Indépendantes / (Health Insurance Fund for self-employed (France)
C.A.S	Legislation sur l' assurance maladie (Luxembourg)
CBB	College van Beroep voor het Bedrijfsleven / Trade and Industry Appeals Tribunal (Netherlands)
CBG	College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board (Netherlands)
CBIP	Centre Belge d'Information Pharmacothérapeutique / Belgian Centre for Pharmacotherapeutic Information (Belgium)
CBS	Centraal Bureau voor de Statistiek / Statistics' Office (Netherlands)
CCA	Cyprus Consumer Association (Cyprus)
CEE	Central and Eastern European Countries
CEM	Comité Economique du Médicament / Pharmaceutical Pricing Committee (France)

CEPS	Comité Economique des Produits de Santé / Medical Products' Pricing Committee (France)
CFH	Commissie Farmaceutische Hulp / Pharmaceutical Care Committee (Netherlands)
CGR	Code geneesmiddelenreklame / Code on Public Advertising of Pharmaceuticals (Netherlands)
CIF	Cost, Insurance and Freight (Incoterm, relevant, e.g. in Cyprus)
CIP	Carriage and Insurance Paid (Incoterm)
CIPE	Comitato Interministeriale per la Programmazione Economica / Interministerial Pricing Committee (Italy)
CIS	Commonwealth of Independent States
CMU	Couverture Maladie Universelle / Coverage of all citizens (France)
CNAMTS	Caisse Nationale de l'Assurance Maladie des Travialleurs Salariés / Health Insurance Fund at the national level (France)
CNOM	Conseil National de l'ordre des Médecins / NationalMedical DoctorsAssociation / (France)
CODEM	Comité de Evaluación de Medicamentos de Uso Humano / Committee for the Evaluation of Medicinal Products for Human Use (Spain)
Cofares	Cooperativa Farmaceutica Espanola / Spanish Pharmaceutical Cooperation (Spain)
CPA	Cyprus Pharmaceutical Association
CPCRP	Comité Permanent de la Commission pour la Régulation des Prix / Standing Commission for Price Regulation (Belgium)
CPCRP	Comité Permanent de la Commission pour la Régulation des Prix / Standing Committee of the Commission for Price Regulation (Belgium)
CPL	Comptoir Pharmaceutique Luxembourgeois
CPP	Certificate of Pharmaceutical Product (Malta)
CPR	Comitato Prezzi e Rimborso / Pricing and Reimbursement Committee (Italy)
CPSP	Commission des Prix des Spécialités Pharmaceutiques / Medicines Pricing Commission (Belgium)
CRM	Commission de Remboursement des Médicaments / Medicines Reimbursement Commission (Belgium)
CSRP	Chambre Syndicale dela Répartition Pharmaceutique / Union of Pharmaceutical Distribution (France)
CTG/ZAio	College Tarieven Gezondheidszorg / Zorgautoriteit in oprichting / National Health Tariffs Authority Board (Netherlands)
CTS	Commissione Tecnico Scientifica / Scientific-Technical Commission (Italy)
CUF	Commissione Unica del Farmaco / Drugs Committee (Italy)
CVZ	College voor Zorgverzekeringen / Health Care Insurance Board (Netherlands)
CYP	Cyprus Pound
CZK	Czech Koruna
DDD	Defined Daily Doses
DG	Directorate-General
DGCC	Direcções-Gerais do Comércio e da Concorrência / Directorate-General of Commerce and Competition (Portugal)
DGE	Direcção-Geral da Impresa / Directorate-General Enterprise (Portugal)

DGFPS	Direccion General de Farmacia y Productos Sanitarios / Directorate General of Pharmacy and Health Products (Spain)
DGV	Deutscher Generikaverband / Association Generic Industry (Germany)
DH	Department of Health (United Kingdom)
DKK	Danske Kroner
DMA	Lægemiddelstyrelsen / Danish Medicines Agency (Denmark)
DoHC	Department of Health and Children (Ireland)
DP(S)	Drug Payments Scheme (Ireland)
DRGs	Diagnosis Related Groups
DTC	Drugs and Therapeutics Committee (Malta)
€	Euro
EAEPC	European Assiciation of Euro-Pharmaceutical Compenies
EC	European Community
EEA	European Economic Area
EEK	Estonia Kroon (Estonia)
EFA	Etiniu Farmacijos Kompaniju Atstovybiu Asociacija / Association of Representative Offices of Ethical Pharmaceutical Manufacturers (Lithuania)
EFEX	Greek Proprietary Association (Greece)
EFG	Especialidad Farmacéutica Genérica / Generic Pharmaceutical (Spain)
EFP	Especialidades Farmaceuticas Publicitarias / Over-the-Countes Pharmaceuticals (Spain)
EFPIA	European Federation of Pharmaceutical Industries' Associations
EGA	European Generic Medicines Association
EGRAL	Eesti Geneeriliste Ravimite Liit / Estonian Generic Medicines Association (Estonia)
EHIF	Haigekassa / Estonian Health Insurance Fund (Estonia)
EKO	Erstattungskodex / Reimbursement Code (Austria)
EMEA	European Medicines Agency
EOF	National Organisation for Medicines (Greece)
ERHL	Estonian Association of Pharmaceutical Wholesalers (Estonia)
ESKI	Egészségügyi Stratégiai Kutatóintézet / National Institute for Strategic Health Research (Hungary)
ESY	National Health System (Greece)
EU	European Union
EüM	Egészségügyi Minisztérium / Hungarian Ministry of Health (Hungary)
EVS	Elektronisch Voorschrijf Systeem / Electronic prescribing system (Netherlands)
FAD	Final Appraisal Determination (United Kingdom)
FB	Fellebbviteli Bizottság / Appeal committee (Hungary)
FD	Farmacijos Departementas / Department of Pharmacy (Lithuania)
Fedichem	Association Génénerale de l'Industrie du Médicament, pharma.be / Federation of the Chemical Industry of Belgium (Belgium)
FIMMG	Federazione Italiana Medici di Famiglia / Association of Family Doctors (Italy)
FnomCeO	Federazione Nazionale degli Ordini de Medici Chirurghi e degli Odontoiatri / National Federation of Doctors, Surgeons and Dentists / (Italy)

FOFI	Federazione Ordini Farmacisti Italiani / Federation of Italian Pharmacists (Italy)
FPS	Federal Public Service
FSPF	Fédération des Syndicats Pharmaceutiques de France / Federation of the Pharmacy Unions of France (France)
FTO	Farmacotherapeutisch overleg / Pharmacotherapeutic forums (Netherlands)
FTTO	Farmacotherapeutisch transmuraal overleg / Interdisciplinary pharmacotherapeutic forums (Netherlands)
G-BA	Gemeinsamer Bundesausschuss / Federal Joint Committee (Germany)
GBP	British Pounds
GDP	Gross Domestic Product
GEMME	Association Générique Méme Médicament / Association of Generics (France)
GFB	Gedragscode Farmaceutische Bedrijfstak / Pharmaceutical Branch (Netherlands)
GGKA	General Secretariat of Social Security (Greece)
GHS	General Health System (Cyprus)
GISF	Gruppo Italiano per gli Studi di Farmacoeconomia / Expert Group for Pharmaco-economic Evaluations (Italy)
GIZ	Mednarodni forum znanstveno raziskovalnih farmacevtskih druzb / Slovenian Forum of International Research and Development Pharmaceutical Industries (Slovenia)
GKM	Gazdasági és Közlekedési Minisztérium / Ministry of Economy and Transport (Hungary)
GKV	Gesetzliche Krankenversicherung / Statutory Health Insurance (Germany)
GMS	General Medical Services
GP	General Practitioner / Family Doctor
GPS	Government Pharmaceutical Services (Malta)
GSL	General Sales List (United Kingdom)
GVS	Geneesmiddelenvergoedingssysteem / Pharmaceutical reimbursement system (Netherlands)
HA	Håndkøb/OTC for sale in pharmacy only (Denmark)
HAPW	Hungarian Association of Pharmaceutical Wholesalers
HAS	Haute Autorité de Santé / High Authority for Health (France)
HEK	Heilmittel-Evaluierungskommission / Pharmaceutical Evaluation Board (Austria)
HF	Frisalg / OTC for general free sale
HILA	Lääkkeiden hintalautakunta / Pharmaceutical Pricing Board (Finland)
HIO	Health Insurance Organisation
HIQA	The Health Information and Quality Authority
HOM	Hospital-only Medicines
HPSS	Health Care Procurement and Supplies Services (Malta)
HSE	Health Service Executive
HTD(S)	High Tech Drugs Scheme
HVB	Hauptverband der österreichischen Sozialversicherungsträger / Federal Association of Social Insurance Institutions (Austria)
HWG	Gesetz über die Werbung auf dem Gebiet des Heilwesens in Deutschland / Pharmaceutical Advertising Law (Germany)

HX	Håndkøb / OTC for limited free sale (Denmark)
IAP	Istituto dell'Autodisciplina Pubblicitaria / Self-Disciplinary Advertising Institute (Italy)
ICEG EC	International Centre for Economic Growth - European Centre
IDTS	Indicative Drug Target Scheme
IFET	Institute of Pharmaceutical Research and Technology (Greece)
IFPMA	International Federation of Pharmaceutical Manufacturers Association
IGL	Industriforeningen for Generiske Lægemidler / The Danish Generic Medicines Industry Association (Denmark)
IHE	Institutet för Hälso- och Sjukvårdsekonomi / Institute for Health Economics (Sweden)
IKA	National Social Insurance Institute (Greece)
IM	Indenrigs- og Sundhedsministeriet / Ministry of the Interior and Health (Denmark)
IMB	Irish Medicines Board
IMO	Irish Medical Organisation
INAMI	Institut National d'Assurance Maladie Invalidité / National Institute for Sickness and Invalidity Insurance (Belgium)
INASTI	Institut National d'Assurance Sociales pour Travailleurs Independents / National institute for Social Insurance for the Self-Employed (Belgium)
INFARMED	Instituto Nacional da Farmácia e do Medicamento / Medicines Agency (Portugal)
INN	International Non-Proprietary Name (Generic or active ingredient name)
IPHA	Irish Pharmaceutical Healthcare Association
IPU	Irish Pharmaceutical Union
IQWiG	Institut für Qualtität und Wirtschaftlichkeit im Gesundheitswesen / Institute for Quality and Efficiency in Health Care (Germany)
IRF	Institut for Rationel Farmakoterapi / Institute for Rational Pharmacotherapy (Denmark)
ISPEL	Istituto Superiore per la Prevenzionee la Sicurezza del Lavoro / High Institute of Prevention and Security of Work Italy)
ISS	Istituto Superiore di Sanità / High Institute of Health (Italy)
KEB	Kommunikációs Etikai Bizottságot / Communication Ethics Committee (Hungary)
KELA	Kansaneläkelaitos / Finnish Health Insurance Institution (Finland)
KME	Central Prescription Processing Unit (Greece)
KNMP	Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie / Royal Dutch Pharmaceutical Society (Netherlands)
LAB	Latvijas Arstu Biedriba / Latvian Physicians Association (Latvia)
LEEM	Les Entreprises du Médicament / Pharmaceutical Industry Association (France)
LFB	Latvijas Farmaceitu Biedriba / Latvian Pharmaceutical Society / (Latvia)
LGS	Lietuvos Gydytoju Sjunga / Lithuanian Medical Doctors Association (Lithuania)
LIF	Lægemiddel Industri Foreningen / Danish Association of the Pharmaceutical Industry (Denmark)
LIF	Lægemiddelidustrifoeningen / Danish Association of the Pharmaceutical Industry (Denmark)
LIF	Lääkemedelinsdustriforeningen / Association of Pharmaceutical Industry (Sweden)
LSE	London School of Economics

LNF	Läkemedelsförmånsnämnden / Pharmaceutical Benefits Board (Sweden)
LTI(S)	Long Term Illness Scheme (Ireland)
LVL	Latvian Lats (Latvia)
MA	Medicines Authority respectively Marketing Authorisation
MAFS	Mezinárodní asociace farmaceutických společností / Association of International Research Based Pharmaceutical Industry (Czech Republic)
MAGYORSZ	Pharmaceutical Manufacturers Association (Hungary)
MAM	Medical Association of Malta
MF	Ministerstvo finance / Ministry of Finance (Czech Republic)
MF SR	Ministry of Finance / Ministerstva Financií (Slovakia)
MG	Medicamento Generico / Generic Medicinal Product (Portugal)
MGYK	Magyar Gyógyszerész Kamara / Hungarian Chamber of Pharmacists (Hungary)
MHRA	Medicines and Healthcare Products Regulatory Agency (United Kingdom)
MKEH	Magyar Kereskedelmi Engedélyezési Hivatal / Hungarian Trade Licensing Office (Hungary)
MNSRM	Medicamentos Não Sujeitos a Receita Médica / Prescription-only Medicines and Non-prescription Products (Portugal)
MoH	Ministry of Health, the Elderly and Community Care (Malta) / Ministry of Health (Cyprus)
MOK	Magyar Orvosi Kamara, MOK / Hungarian Chamber of Doctors (Hungary)
MOTESZ	Magyar Orvostársaságok és Egyesületek Szövetségének / Member nominated by the Association of Hungarian Medical Societies (Hungary)
MPA	Läkemedelsverket / Medical Products Agency (Sweden)
MRU	Medicines Regulatory Unit (Malta)
MS	Member States
MSA	Mutualité Sociale Agricole / Health Insurance Fund for farmers (France)
MZ	Ministrstvo za zdravstvo resp. Ministerstvo zdravotnictvi / /The Ministry of Health (Slovenia, Czech Republic)
MZ SR	Ministerstvo Zdravotnicta Štátny ùstav pre kontrolu lieciv / Ministry of Health (Slovakia)
N.a.	Not available
N.app.	Not applicable
NAM	Lääkelaitos / Finnish National Agency for Medicines (Finland)
NCPE	Irish National Centre for Pharmacoeconomics St. James's Hospital
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence(United Kingdom)
NMIC	National Medicines Information Centre
NPCF	Nederlandse Patienten en Consumenten Federatie / Dutch patients and consumers federation (Netherlands)
NVGV	Nationale Vereniging van de Groothandelaars-Verdelers in farmaceutische specialiteiten / National Association of Wholesalers and Distributers of Pharmaceutical Specialties (Belgium)

OAEE	Fund for Merchants, Manufacturers and Small Industries (Greece)
ÖAK	Österreichische Apothekerkammer / Chamber of Pharmacists (Austria)
ÖÄK	Österreichische Ärztekammer / Austrian Chamber of Physicians (Austria)
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (Austria)
OCU	Organización de Consumidoies y usarios / Organisation of Users and Consumers (Spain)
OECD	Organisation for Economic Co-operation and Development
OEGV	Österreichischer Generikaverband / Sustrian Association of Generic Trade (Austria)
OEP	Országos Egészségbiztosítási Pénztár / National Health Fund (Hungary)
OGA	Organisation on Agricultural Insurance (Greece)
OGYI	Országos Gyógyszerészeti Intézet / National Institute of Pharmacy (Hungary)
ONDAM	Objectif National des Dépenses d'Assurance Maladie / Annual ceiling for health expenditure (France)
OsMED	Osservatorio Nazionale sull'Impiego dei Medicinali / National Observatory on the Use of Pharmaceuticals (Italy)
OTC	Over-the-Counter
P	Pharmacy-Only List (United Kingdom)
PA	Product Authorisation
PA	The Patient's Association (United Kingdom)
PAPW	Pan Hellenic Pharmacist's Association (Greece)
PCRS	Product Committee of Department
PDF	Pharmaceutical Distributors Federation
PFL	Parallelimportor foreningen af Laegemidler / Association of Parallel Importers (Denmark)
PFM	Postos Farmacêuticos Móveis / Medicinal Chests (Portugal)
PGEU	Pharmaceutical Group of the European Union
Phargro	Bundesverband des pharmazeutischen Grosshandels Phargro / Association of the German Pharmaceutical Wholesalers (Germany)
PHARMIG	Österreichische Vereinigung pharmazeutischer Unternehmen / Austrian Association of Pharmaceutical Companies (Austria)
PIF	Lääketietokeskus / Pharma Industry Finland (Finland)
PIL	Patient Information Leaflets
PK	Preiskommission / Pricing Committee (Austria)
PM	Pénzügyminisztérium / Ministry of Finance (Hungary)
PMA	Provisional Market Authorisation (Malta)
PME	Prezzo Medio Europeo / Average European Price (Italy)
POM	Prescription-only Medicines
PPA	Prescription Pricing Authority (United Kingdom)
PPC	Prescription Pre-payment Certificate (United Kingdom)
PPR	Pharmig Pricing & Reimbursement
PPP	Pharmacy Purchasing Price = Wholesale Price
PRODIGY	Prescribing Rationally with Decision Support in General Practice (United Kingdom)
PRP	Pharmacy Retail Price

PSI	Pharmaceutical Society of Ireland
PVA	Preço de Venda ao Armazenista / Manufacturer Price (Portugal)
QALY	Quality Adjusted Life Year Gained
R & D	Research and Development
RFV	Riksförsäkringsverket / National Social Insurance Board (Sweden)
RMO	Réferences Médicales Opposables / Medical guidelines (France)
ROC	Return on Capital (United Kingdom)
RöV	Richtlinie über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen / Guideline on economic prescribing of pharmaceuticals and medicinal products (Austria)
RPSGB	Royal Pharmaceutical Society of Great Britain (United Kingdom)
RRLE	Rahvusvaheliste Ravimitootjate Liit Eestis / Association of International Pharmaceutical Manufacturers (Estonia)
RS	Republic of Slovenia
SA	Statistik Austria / Statistics Austria
SAFS	Slovenská Asociácia Farmaceutických Spoloèností / Association of Research-Based Pharmaceutical Companies (Slovakia)
SAM	Sveikatos apsaugos ministerija / Ministry of Health (Lithuania) resp. Ravimiamet / State Agency of Medicines (Estonia)
SBU	Statens beredning för medicinsk utvärdering / Council on Technology Assessment in Health Care
SD-doctor	Self-dispensing doctor
SECM	Service d'évaluation et de contrôle médicaux / Service for Medical Evaluation and Control (Belgium)
SEK	Svenska Kroner
SFEE	Association of Pharmaceutical Manufacturers (Greece)
SFK	Stichting Farmaceutische Kengetallen / Foundation for Pharmaceutical Statistics
SIFO	Società Italiana di Farmacia Ospeda-Liera / Association of Hosptial Pharmacies (I-taly)
SKK	Slovak Koruna
SKL	Sveriges Kommuner och Landsting / Swedish Association of Local Authorities and Regions (SALAR)
SLeK	Slovenská Lekárnická Komora / Pharmacists' Association (Slovakia)
SLS	Selected List Scheme (United Kingdom)
SM	Sotsiaalministeerium / Ministry of Social Affairs (Estonia)
SmPC	Summary of Product characteristics
SMR	Service Médical Rendu / Medical Benefit (France)
SNS	Service National de Sáude / National Health Service (Portugal)
SOP	Farmaci senza obbligo di prescrizione medica / OTC products (Italy)
SPC	Supplementary Protection Certificates (Hungary)
SPF	Santé Publique, Sécurité de la Chaîne Alimentaire et Environnement - Direction Générale Médicaments) / Health, Food Chain Safety and Environment - Directorate-General Medicines (Belgium)

SPMA	Lekova Domaca Lekarna / The Slovenian Pharmaceutical Manufacturers Association (Slovenia)
SSN	Servizio Sanitario Nazionale / National Health Service (Italy)
SST	Sundhedsstyrelsen / National Board of Health (Denmark)
STM	Sosiaali- ja terveysministeriö / Ministry of Social Affairs and Health (Finland)
SUKL	Státní Ústav pro Kontrolu Léčiv / State Institute for Drug Control (Czech Republic) resp. Štátny Ústav pre Kontrolu Liečiv / State Institute of Drug Control (Slovakia)
TÉB	Technológia Értékelő Bizottság / Technology Evaluation Committee (Hungary)
TFR	Tarif Forfaitaire de Responsabilité / Reference Price System (France)
UCM	Union des Caisses de Maladie
UHK	Unabhängige Heilmittel-Kommission / Independent Pharmaceutical Committee (Austria)
UNCAM	Union Nationale des Caisses d'Assurance Maladie / National Union of Health Insurers (France)
UR	Uitsluitend recept / Prescription-only (Netherlands)
VAT	Value added tax
VBR	Voorbereidingscommissie Richtlijnontwikkeling / Preparatory Committee on Guideline Development (Netherlands)
VGA	Vaistu gemintoju asociacija / Association of Generic Manufacturers (Lithuania)
VLK	Valstybinė ligonių kasa / State Sickness Fund (Lithuania)
VM	Latvijas Republikas veselibas ministrija / Ministry of Health (Latvia)
VOAVA	Veselibas obligetas apdrošinašanas valsts agentura / State Compulsory Health Insurance Agency (Latvia)
VO-EKO	Verfahrensordnung zur Herausgabe des Erstattungskodex nach Art. 351g ASVG / Rules of Procedure for publication of the Reimbursement Code according to Art. 351g ASVG (Austria)
VsZP	Všeobecná zdravotni pojišťovna / General Health Insurance(Czech Republic)
VsZP	Vseobecná Zdravotná Pois-tovňa / General Health Insurance (Slovakia)
VVKT	Valstybinė vaistų kontrolės tarnyba / State Medicines Control Agency (Lithuania)
VWS	Volksgezondheid, Welzijn en Sport / Ministry of Health, Welfare and Sport (Netherlands)
VZA	Valsts zalu agentura / State Agency of Medicines (Latvia)
w.y.	without year (Bibliography)
WGP	Wet Geneesmiddelenprijzen / Law on pharmaceuticals' prices (Netherlands)
WHO	World Health Organisation
WKÖ	Wirtschaftskammer / Federal Chamber of Commerce (Austria)
WVZ	Warenverzeichnis / Medicines price Register (Austria)
YPAN	Ministry of Development (Greece)

ZAF	Zavod za farmacijo in za preizkusanje zdravil / Institute of Pharmacy and Drug research (Slovenia)
ZCA	Zalu Cenu Valsts Agentura / State Medicines Pricing and Reimbursement Agency (Latvia)
ZZZS	Zavod za zdravstveno Slovenjie / National Health Insurance Fund (Slovenia)

Glossary

ATC (Anatomic Therapeutic Chemical Code)	=	In this classification system pharmaceuticals are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties.
Claw-back	=	A system allowing health insurance/national health service to recoup (part of the) discounts/rebates granted in a reimbursement system between various stakeholders, e.g. wholesalers and pharmacists.
Co-payment	=	Out-of-pocket payments of patients for pharmaceuticals within the reimbursement system. They appear in different forms: Fixed co-payments: a fixed amount (like for example a prescription fee) to be paid for a service, a pharmaceutical or a medical device. Percentage co-payment: a certain fixed proportion of the cost of a service or pharmaceutical, with the social health insurance/national health service paying the remaining proportion. Deductible: a fixed amount which must be paid for a service or of total cost incurred over a defined period by a covered person beforehand a social health insurance/national health service, then all or a percentage of the rest of the cost is covered.
Cost-containment Measures	=	Measures like price freezes taken to reduce expenditure or the rate of growth of expenditure, or the unit cost of services.
DDD (Defined Daily Dose)	=	Technical unit developed in the early 1970's used to measure the consumption of pharmaceuticals in a comparable way. The DDD is the assumed average maintenance dose per day for a pharmaceutical used for its main indication in adults.
De-listing	=	Exclusion of a pharmaceutical from a pharmaceutical list (e.g. positive list), often resulting in exclusion from reimbursement.
External Price Referencing / Cross Country Referencing	=	The practice of comparing pharmaceutical prices across countries. There are various methods applied and different country baskets relevant.
Generic Substitution	=	Practice of substituting a pharmaceutical, whether marketed under a trade name or generic name (branded or unbranded generic), by a pharmaceutical, often a cheaper one, containing the same active ingredient(s). Generic substitution may be performed by doctors and in some countries also by pharmacists.
INN (International Non-proprietary Name)	=	A pharmaceutical is normally identified by either its chemical or „generic“ name, which often is referred to as INN or its brand name, which is the trade or marketing name.
Internal Price Referencing	=	A method to compare prices of pharmaceuticals in a country with the price of identical pharmaceuticals (ATC 5 level) or similar pharmaceuticals (ATC 4 level) or even with therapeutical equivalent treatment (not necessarily a pharmaceutical) in a country. Often performed in the course of a reference price system.
Manufacturer Price	=	The manufacturer’s posted price, in some countries also referred to as list price. This price does not include any discounts or other incentives offered by manufacturers.
OTC (Over-the-Counter)		Pharmaceuticals which may be dispensed without a doctor's prescription being submitted and which are in some countries available via self-service in pharmacies a/o other retail outlets (e.g. drug stores). Selected OTC may be reimbursed for certain indications in some countries.

Pharmaceutical Budget	=	Pharmaceutical budgets are a cost-containment measure of health insurance/national health service. The maximum amount of money to be spent on pharmaceuticals in a specific region or period of time is fixed ex-ante.
Pharmaco-economic Evaluation	=	The comparative analysis of alternative courses of action in terms of both their costs and consequences.
Pharmacy Retail Price (gross)	=	The price charged by pharmacists to the general public. It includes any pharmacy mark-ups or dispensing fees and VAT.
POM (Prescription-only-Medicine)	=	Pharmaceuticals that may be dispensed only on a doctor's prescription.
Positive List	=	List of pharmaceuticals that may be prescribed more or less without further conditions at the expense of a health insurance/national health service.
Price Freeze	=	A popular cost-containment method. The price of a pharmaceutical is fixed at a given level, mostly for a predetermined period of time. Price freezes are sometimes based on agreements between pharmaceutical industry and authorities but in most cases it is done by law.
QALY (Quality-adjusted-life year)	=	A QALY is a measure of the value of health outcomes. Since health is a function of length of life and quality of life, the QALY was developed as an attempt to combine the value of these attributes into a single index number. The change in utility value induced by the treatment is multiplied by the duration of the treatment effect to provide the number of QALYs gained.
Reference Price System	=	The health insurance/national health service determines a maximum price (= Reference Price) to be reimbursed for certain pharmaceuticals. On buying a pharmaceutical for which a fixed price (~ the so-called reimbursement price) has been determined, the insured person must pay the difference between the fixed price and the actual pharmacy retail price of the pharmaceutical in question, in addition to any fixed co-payment or percentage co-payment rates. Usually the reference price is the same for all pharmaceuticals in a given ATC 4 level and/or ATC 5 level group.
Reimbursement Categories	=	Pharmaceuticals eligible for reimbursement are often grouped according to selected characteristics, e.g. route of administration (oral, etc.), main indication (oncology, paediatric, etc.), ATC level, classification (hospital-only, etc.). In many countries different reimbursement rates are determined for different reimbursement categories.
Switch	=	Reclassification of prescription-only-medicines to over-the-counter pharmaceuticals.
Therapeutic Benefit	=	Synonym to therapeutic value. The effect conveyed on a patient following administration of a pharmaceutical which either restores, corrects or modifies a physiological function(s) for that patient.
Wholesale Price	=	The price charged by wholesalers to the retailers (usually pharmacies). It includes any wholesale mark-up.

1 Introduction

The Austrian Health Institute (Österreichisches Bundesinstitut für Gesundheitswesen, ÖBIG) was commissioned by the European Commission, Directorate-General (DG) Competition/ Unit B-2 Basic Industry, Chemicals and Pharmaceuticals in Brussels to provide an in-depth and comprehensive description of the pharmaceutical system in each of the 25 Member States. The project started end of December 2005, and the report of the study "*Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*" was submitted to the European Commission in July 2006.

1.1 Background

Within the framework of the EU Transparency Directive 89/105/EEC[1], pharmaceutical pricing and reimbursement systems are national affairs. Consequently, these systems may differ widely throughout the 25 Member States. Key regulations of the European Union (EU) in the field of pharmaceuticals concern mainly the market authorisation and the distribution of pharmaceuticals.

The pharmaceutical pricing and reimbursement systems are often very complex, being customised to the specific economic and health needs of a country, and often having a long tradition. Furthermore the systems are adjusting continuously as Member States are in the process of reviewing their health care systems, searching for strategies to increase the efficiency of pharmaceutical services, or keeping their pharmaceutical budget under control. These efforts often lead to a reaction by other players in the market such as pharmaceutical manufacturers, wholesalers, doctors, pharmacies or patients. Examples of these reactions may be changes in pricing strategies or in consumption patterns. In return, authorities might respond to these developments for example by means of new cost containing measures, thus creating a "pendulum" of action and counter action.

These developments lead to comprehensive and up-to-date information being rather hard to gain, but nonetheless very import in order to monitor the conditions of competition in pharmaceutical markets. The demand for accurate information is further accelerated by the enlargement process of the European Union as the pharmaceutical systems in the ten new Member States are still in the process of adjusting to community provisions.

The DG Competition of European Commission the has therefore identified the need for comprehensive and detailed information on pharmaceutical systems in the EU Member States, allowing to identify similar cost drivers and policy measures, to maintain the monitoring and enforcement of competition rules by the Commission.

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[1] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance system, http://pharmacos.eudra.org/F2/eudralex/vol-1/new_v1/890105en.pdf#search='89/105/EECeudra'

1.2 Objectives

The aims of the current study "*Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*" are

- to gather available information and knowledge on the pharmaceutical systems in the Member States of the enlarged European Union, thus contributing to increase transparency and allowing to enforce competition rules;
- to identify the relevant players in the pharmaceutical market of each Member State;
- to investigate regulatory measures as well as demand side and supply side strategies adopted with regard to cost-containing effects in the pharmaceutical market;
- to provide information for policy-makers on European Union level, with regard to mechanisms on pricing, reimbursement and dispensing of pharmaceuticals
- to provide an in-depth, comprehensive description of the pharmaceutical system in each of the 25 Member States by developing comparable country reports.

1.3 Methodology

In the current study, ÖBIG undertakes a review of the pharmaceutical regulation, reimbursement and pricing systems in the 25 Member States of the enlarged European Union. Both the pricing and the reimbursement system of pharmaceuticals have been included as, whereas all countries, pursuant to EU legislation, have separate authorisation and pricing procedures, many countries combine pricing and reimbursement in one parallel process. Furthermore, in order to provide a complete overview on pharmaceutical systems, it is important to identify the relevant stakeholders, such as authorities, national institutes and umbrella organisations, and their respective roles within the system.

A detailed survey of the above defined topics was carried out through a review of available relevant literature and through internet research. Up-dates on latest cost-containment measures as well as necessary validation of existing data and information was achieved through an international network of cooperation partners maintained by ÖBIG, which includes representatives from national authorities, supporting agencies or institutions (e.g. National Health Institutes), universities and research institutes.

Based on the gathered information the regulatory measures as well as demand side and supply side strategies adopted with regard to cost-containing effects in the pharmaceutical market were investigated. The gathered information for all Member States is presented in 25 comprehensive up-to-date country profiles describing the pharmaceutical systems. Within the country profiles references have been made to relevant European directives and national laws, decrees and other types of regulations.

1.4 Outline

All individual country profiles within this report follow the same outline. Each country profile contains three main sections: 1) Pharmaceutical system, 2) Pricing and 3) Reimbursement. Within these sections, the same subsections are applied in each country profile. At the end of each country profile, a table summarising the most important characteristics of the system is provided.

The content of each of the three main sections is as follows:

1.4.1 Pharmaceutical System

In the first section of each country profile the regulatory framework of the pharmaceutical systems, as well as the roles of the relevant authorities and market players are accurately described in text. In addition, for each country a table will be provided containing the correct names, in country language and in English, and the contact details of all relevant stakeholders. For each country, this section closes with a chart, providing a clear visualisation of the connections between and the order of the processes for authorisation, pricing, reimbursement and distribution of pharmaceuticals.

1.4.2 Pricing

In each country profile, the pricing section describes the dominating pricing policies and the scope of statutory price control at the manufacturer level, the wholesale level and at the pharmacy retail level.

In addition for each country an overview of implemented price related cost-containment measures, such as internal or external price referencing, margin cuts or prize freezes is provided. An extra subsection describes the extent to which co-payments are applicable in a country.

1.4.3 Reimbursement

The third and final section of a country profile gives an overview of the reimbursement system of a country, by describing for instance which reimbursement categories are defined (and in which way), by whom decisions concerning reimbursement eligibility of a pharmaceutical are taken and how reimbursement prices are determined.

In this section special attention is paid to reference price system, which are in place in many Member States, but may be differently implemented. Finally, in this section the implementation of volume control oriented cost-containment measures, such as pharmaceutical budgets, prescription monitoring and substitution are discussed.

AUSTRIA

2 Austria

2.1 Pharmaceutical System

2.1.1 Regulatory Framework and Authorities

98% of Austrian's eight million inhabitants are covered by statutory health insurance characterized by income-related health insurance contributions, benefits in kind, unrestricted access to primary, secondary and tertiary care accompanied by co-payments on all levels of care.

The most relevant players in the Austrian pharmaceutical system are

- the Austrian Federal Ministry of Health and Women's Issues (Bundesministerium für Gesundheit und Frauen, BMGF), which is responsible for the strategic planning in terms of pharmaceuticals,
- the 21 Austrian Sickness Funds (Krankenkassen) with their umbrella organisation, the Federation of Austrian Social Insurance Institutions (Hauptverband der Österreichischen Sozialversicherungsträger, HVB) and
- the newly established Federal Agency for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen, BASG) supported by the AGES PharmMed Austria (see below) acting as the Austrian Medicines Agency

Due to the new Law on Food and Health (Gesundheits- und Ernährungssicherungsgesetz, GESG[2]) since 2.1.2006 the BASG has taken over the responsibility for granting market authorisation, classification and vigilance agenda for human and veterinary medicines as well as medical devices from the BMGF, thus acting as Medicines Agency like in many other European countries. A limited liability company owned by the Republic of Austria was founded by the same law - the Austrian Agency for Health and Foodsafety (Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH, AGES). A subdivision of this Agency, the AGES PharmMed, supports the BASG in its work.

Pricing activities remain in the hands of BMGF assisted by the Austrian Pricing Committee (Preiskommission, PK), especially in terms of the EU Average Pricing System which was introduced in 2004 (cf. 2.2.1.1).

The PK consists of one representative by each of the following institutions besides the BMGF itself who also acts as chairman of the committee: the Federal Ministry of Finance (Bundesministerium für Finanzen, BMF), the Federal Ministry for Economy and Labour (Bundesminis-

[2] Law on Food and Health 2002, amended [Bundesgesetz, mit dem die Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH errichtet und das Bundesamt für Ernährungssicherheit sowie das Bundesamt für Sicherheit im Gesundheitswesen eingerichtet werden (Gesundheits- und Ernährungssicherheitsgesetz - GESG 2002) i.d.F. BGBl. I No. 153/2005]

terium für Wirtschaft und Arbeit, BMWA), the Federal Ministry for Agriculture, Forestry, Environment and Water Management (Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft, Lebensministerium), the Federal Chamber of Labour (Bundesarbeiterkammer, BAK), the Federal Chamber of Commerce (Wirtschaftskammer, WKÖ) and the Presidential Conference of the Chambers of Agriculture (Präsidentenkonferenz der Landwirtschaftskammern Österreichs).

According to the Price Act (Preisgesetz[3]) the BMGF - assisted by the PK - is entitled to set a economically justified price for pharmaceuticals; nonetheless manufacturer prices of new pharmaceuticals need not be approved by the BMGF to enter the market as it is rather a notification procedure.

In contrary the maximum mark-ups for wholesalers and pharmacies are statutorily regulated. Separate rules are in place for the pricing of pharmaceuticals applying for reimbursement; these pharmaceuticals have to be priced according to the EU Average Price. The PK collects price notifications from companies and assesses them; furthermore the PK does the actual calculation of the EU Average Price, for details see also section 2.2.1.1.

Decisions on reimbursement status are made by the HVB on the basis of recommendations of the Pharmaceutical Evaluation Board (Heilmittel-Evaluierungskommission, HEK), a body consisting of 20 experts nominated by several Austrian public bodies, 10 of which are social health insurance representatives. Among other parameters, like the therapeutic value of a product and its efficacy also economic criteria (like the price requested by the company, cf. 2.3.1 for details) are taken into consideration. The actual process of reimbursement of pharmaceuticals to patients is duty of the 21 Austrian sickness funds.

The appeal body to whom manufacturers may turn in case of negative reimbursement decisions, etc. is the the Independent Pharmaceutical Committee (Unabhängige Heilmittelkommission, UHK). The UHK has the function of a appeal court. All committee members are independent experts nominated by several public bodies in Austria like the Federal Chamber of Commerce (Wirtschaftskammer, WKÖ), the Federal Chamber of Labour (Bundesarbeiterkammer, BAK), the Chamber of Medical Doctors (Österreichische Ärztekammer, ÖÄK), various sickness funds, the Chamber of Pharmacists (Österreichische Apothekerkammer, ÖAK) etc., and/or the Ministry of Finance (Bundesministerium für Finanzen, BMF and the Ministry of Labour and Economy (Bundesministerium für Wirtschaft und Arbeit, BMWA).

Further bodies dealing with pharmaceuticals on a federal level are the Prescription Committee (Rezeptpflichtkommission) as well as the Restriction Committee (Abgrenzungskommittee). The Prescription Committee meets on an annual basis and makes general suggestions for changes in the prescription status. The Restriction Committee is an advisory body to the BMGF and is responsible for decision on pharmaceutical distribution channels

[3] Art. 3.1. Price Act 1992, amended [Bundesgesetz, mit dem Bestimmungen über Preise für Sachgüter und Leistungen getroffen werden (Preisgesetz 1992), i. d. F. BGBl. I Nr. 151/2004]

The Official Medicines Control Laboratory (Bundesinstitut für Arzneimittel, BIFA) which used to support the work of the BMGF by revising the information and sample molecules handed in by the companies with regard to quality, safety and efficacy standards has also become part of the AGES PharmMed.

Table 2.1 contains an overview of relevant Austrian stakeholders introduced in sections 2.1.1 and 2.1.2.

Table 2.1: Austria - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Bundesministerium für Gesundheit und Frauen (BMGF) / Federal Ministry of Health and Women's Issues	Regulatory Body for Pharmaceuticals, Pricing	BMGF (Department III/B/7) Radetzkystraße 2 A-1030 Vienna, Austria Tel.: +43 1 71100 Fax: +43 1 715 73 12 buergerservice@bmgf.gv.at www.bmgf.gv.at	Mr. Gernot Spanninger Head of Department III/B/7 Radetzkystraße 2 A-1030 Vienna, Austria Tel.:+43 1 71100-4657 or 4680 Fax:+43 1 715 73 12 gernot.spanninger@bmgf.gv.at
Hauptverband der österreichischen Sozialversicherungsträger (HVB) / Federation of the Austrian Social Insurance Institutions	Pricing and Reimbursement, Association of the Third Party Payers	HVB Kundmanngasse 21 A-1030 Vienna, Austria Tel.: +43 1 711 32 Fax: +43 1 711 32 3777 postein-gang.allgemein@hvb.sozvers.at www.hauptverband.at	Mr. Peter Wieninger Head of Pharmaceutical Department Kundmanngasse 21 A-1030 Vienna, Austria Tel.: +43 1 711 32 3801 Fax. +43 1 71132 3782 peter.wieninger@hvb.sozvers.at
Bundesamt für Sicherheit im Gesundheitswesen (BASG) - Agentur für Gesundheit und Ernährungssicherheit (AGES PharmMed) / Austrian Medicines Agency - Federal Agency for Safety in Health Care	Medicines Agency (Registration, Vigilance, etc.)	BASG / AGES PharmMed Schnirchgasse 9 A-1030 Vienna, Austria Tel. +43 1 505550 Fax: http://www.ages.at/	Ms. Christa Wirthumer-Hoche Head of Department Registration & Lifecycle Management Schnirchgasse 9 A-1030 Vienna, Austria Tel. +43 1 50555 36500 Christa.wirthumer-hoche@ages.at

Institution	Task	Contact details/URL	Responsible person
Vereinigung Pharmazeutischer Unternehmen (PHARMIG) / Austrian Association of Pharmaceutical Companies	Association of Pharmaceutical Industry	PHARMIG Garnisongasse 4/1/6 A-1090 Vienna, Austria Tel.: +43 1 4060290 Fax: +43 1 4060290 9 kommunikation@pharmig.at www.pharmig.at	Mr. Jan Oliver Huber General Manager Garnisongasse 4/1/6 A-1090 Vienna, Austria Tel.: +43 1 4060290 Fax: +43 1 4060290 60 Jan.huber@pharmig.at
Österreichischer Generikaverband (OEGV) / Austrian Association of Generic Trade	Association of Generic Manufacturers and Traders	Österreichischer Generika-verband Wiedner Hauptstraße 90-92/1/12 A-1050 Vienna, Austria Tel.: +43 1 544 92 91 office@generikaverband.at www.generikaverband.at	Mr. Wolfgang Andiel Wiedner Hauptstraße 90-92/1/12 A-1050 Vienna, Austria Tel.: +43 1 544 92 91
ARGE Pharmazeutika / Association of the Austrian Pharmaceutical Wholesalers	Wholesaler Association	ARGE Pharmazeutika Türkenstraße 25/8 A-1090 Vienna, Austria Tel.: +43 1 409 44 86 Fax: +43 1 409 44 87 40 office@argepgh.at www.argepgh.at	Mr. Heinz Krammer General Manager Türkenstraße 25/8 A-1090 Vienna, Austria Tel.: +43 1 409 44 86 Fax: +43 1 409 44 87 40 hk@causa.at
Apothekerkammer (ÖAK) / Austrian Chamber of Pharmacists	Association of Pharmacists	Apothekerkammer Spitalgasse 31 A-1090 Vienna, Austria Tel.: +43 1 404 14 100 Fax: +43 1 408 84 40 info@apothker.or.at www.apotheker.or.at	Mr. Herbert Cabana President Mr. Josef Fasching Head of Economic an Financial Department Spitalgasse 31 A-1090 Vienna, Austria Tel.: +43 1 404 14 198 Fax: +43 1 408 84 40 josef.fasching@apotheker.or.at her-bert.cabana@apotheker.or.at
Ärztekammer (ÖÄK) / Austrian Chamber of Physicians	Medical Doctors' Association	Ärztekammer Weihburggasse 10-12 A-1010 Vienna, Austria Tel.: +43 1 514 06 0 post@aerztekammer.at www.aerztekammer.at	Mr. Reinhard Brettenthaler President Weihburggasse 10-12 A-1010 Vienna, Austria Tel.: +43 1 514 06 43 r.brettenthaler@aek.or.at

Institution	Task	Contact details/URL	Responsible person
Österreichische Wirtschafts-kammer (WKÖ) / Federal Chamber of Commerce	Representa-tives of Employers and Trade	Wirtschaftskammer Österreich Abt. Sozialpolitik und Gesundheit Wiedner Hauptstraße 63 A-1045 Vienna, Austria Tel: +43 1 501 05-0 Gesund@wko.at http://portal.wko.at	Mr. Wolfgang Königshofer Wiedner Hauptstraße 63 A-1045 Vienna, Austria Tel: +43 1 501 05 5034 Fax: +43 1 501 05 5037 wolfgang.koenigshofer@wko.at
Bundesarbeiter-kammer (BAK) / Federal Chamber of Labour	Employees Association	Bundesarbeiterkammer Österreich Arbeit und Gesundheit Eugen-Straße 22 A-1040 Vienna, Austria Tel:+43 1 501 65 0 www.arbeiterkammer.at/www-5335.html	Ms. Vera Lacina Prinz Eugen-Straße 20-22 A-1040 Vienna, Austria Tel: 43 1 501 65 2235 Fax: +43 1 501 65 2532 Vera.lacina@akwien.or.at

Source: ÖBIG 2006

2.1.2 Market Players

2.1.2.1 Pharmaceutical Industry

There are approximately 120 pharmaceutical companies based in Austria[4]. This number includes 24 manufacturing companies[5] but also companies only trading with pharmaceuticals. The Austrian Association of Pharmaceutical Companies (Österreichische Vereinigung pharmazeutischer Unternehmen, PHARMIG) represents the interests of the Austrian pharmaceutical industry. Generic manufacturers or generic trading companies (which are included in above number of 120) like the Austrian based company Lannacher or the German based Stada are organised in a separate association, the Austrian Association of Generic Trade (Österreichischer Generikaverband, OEGV).

The local pharmaceutical industry in Austria is characterised by small and medium sized enterprises. Approximately half of the companies are employing up to 9 persons, another 40% having 10-250 employees. Only the remaining 10% are large companies with more than 250 employees, the biggest manufacturer in Austria being Baxter. Furthermore there are 2 bigger local Austrian generic manufacturers, though the generic market share is comparatively low with about 7.8% of the market in terms of turn-over at pharmacy level (cf. also section 2.3.4.2 on generic promotion).

4 PHARMIG 2003

5 Statistik Austria, personal communication, 2005

Pharmaceutical production in Austria amounted in 2003 to € 1,325 million, a significant reduction compared to the year 2001 when production was € 1,660 million.[6]

In general Austria is an import country rather than an export country, though in terms of parallel trade Austria is more a source for parallel export than the other way round. Consequently, there is no Association of Parallel Traders present in Austria (cf. 2.2.2.8).

2.1.2.2 Distribution

On wholesale level in Austria there is a multi-channel system and most wholesalers are full-ranged, i.e. providing a full assortment of pharmaceuticals on the market. In 2006 there are eight full-line wholesalers, who are member of the Association of the Austrian Pharmaceutical Wholesalers (ARGE Pharmazeutika). About 95% of all deliveries to pharmacies are supplied by wholesalers, direct supply by pharmaceutical companies is allowed (provided that the company has obtained a wholesaling licence from the federal authorities) although not general practice. Self-dispensing doctors (SD-doctors) may only procure pharmaceuticals from pharmacies, this provision is evaded in practice by wholesalers holding a pharmacy concession.

Pharmaceuticals in Austria are mainly sold through pharmacies or branch pharmacies operated by pharmacists. Only pharmacists are allowed to own pharmacies, whose establishment is regulated by law.[7] In addition, medicines may be dispensed through above mentioned SD-doctors, who are allowed to dispense both prescription-only (POM) and Over-the-Counter (OTC) medicines, in municipalities without a pharmacy. Drugstores are only allowed to sell dietary supplements etc..

On 1 September 2005, there were 1,178 pharmacies (18 of which are branch pharmacies) and 992 SD-doctors in Austria. This corresponds to 1 POM-dispensary per 3,835 inhabitants.

In 2005 a total of 12,140 pharmaceuticals (including homeopathic pharmaceuticals, excluding pharmacy preparations) have a market authorisation in Austria (counting different pharmaceutical forms and dosages, but excluding different pack sizes). Of these, 8,188 (67.5%) were prescription-only medicines. Currently, about 5,350 pharmaceuticals (counted including different pack sizes) are included in the Reimbursement Code (Erstattungskodex, EKO), cf. 2.3.1 for details. In Austria, only approximately 60% of the registered pharmaceuticals are on the market.

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6 EFPIA 2005

7 Art. 12, 47, 49 and 51 of Austrian Pharmacy Act, amended [Gesetz vom 18. Dezember 1906, betreffend die Regelung des Apothekenwesens (Apothekengesetz), i.d.F. BGBl. I No. 1/2006]

2.1.2.3 Patients

The role of the patients in the choice of a medication is rather minor for POM, in fact there the patient has no "formal" role. Furthermore patients are usually not informed on products and their prices and have to pay a fixed fee per pack dispensed on expense of the sickness funds, independent of the type of product or it's pack size (cf. 2.2.3 on co-payments).

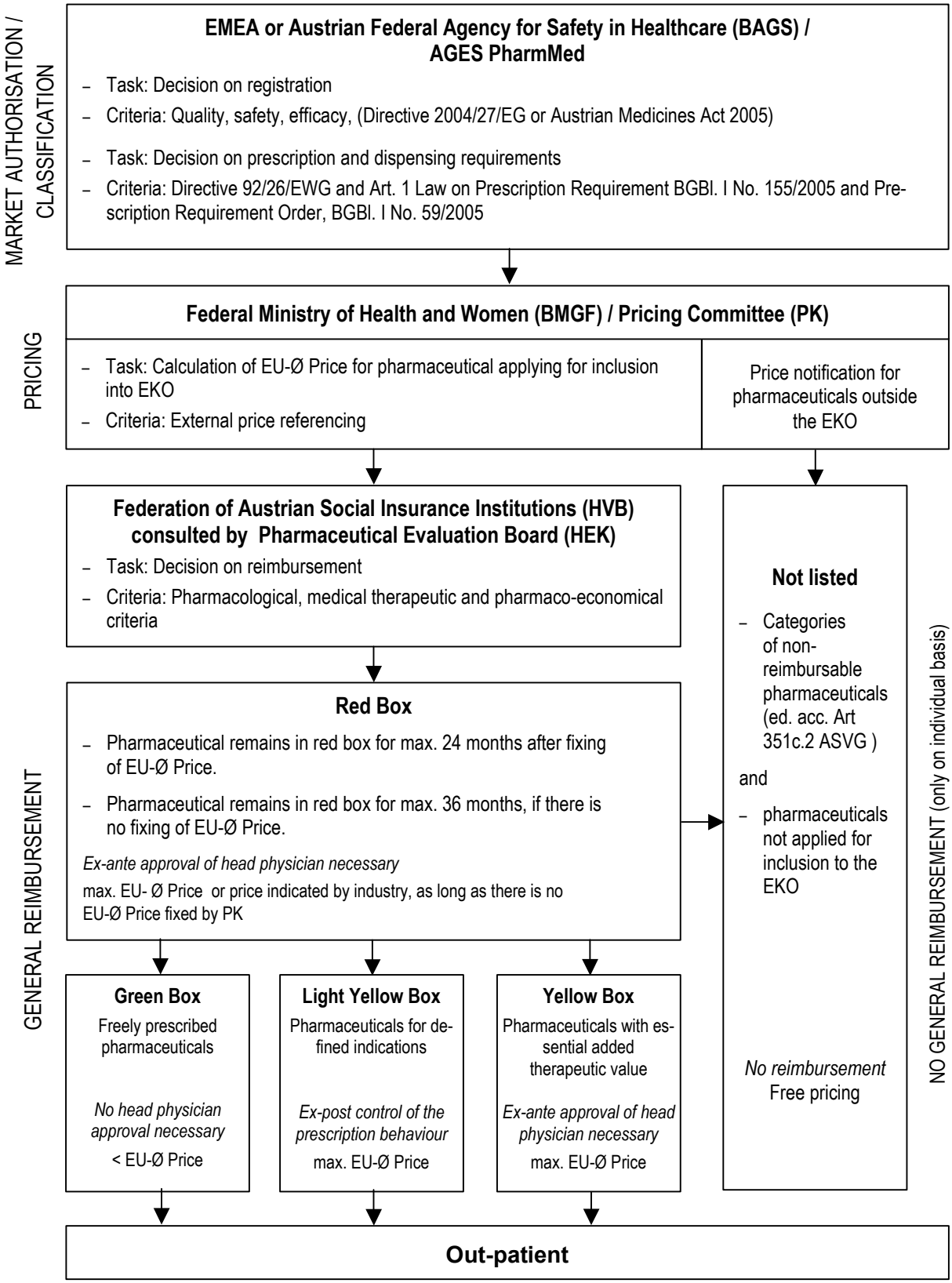
But of course doctors are interested in establishing a good cooperation with their clients so the patient has a chance to express his/her wishes. Thus the “preferences” of patients may be incorporated in the decision of the doctor as well. E.g. there are 12 different simvastatin 20mg f/c tablets in the same pack size listed in the green box of the EKO besides the originator Zocord®, which also may be freely prescribed on the expense of the sickness funds (cf. 2.3).

According to the Guideline on economic prescribing of pharmaceuticals and medicinal products (Richtlinie über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen, RöV)[8], only the pharmaceutical prescribed by the doctor may be dispensed on expense of the sickness funds (thus the patient may request a generic from the doctor or a parallel traded pharmaceutical from the doctor or the pharmacy - but he/she has no incentive to do so).

Figure 2.1 shows an overview of the pharmaceutical system in Austria.

[8] Art. 10.2 Guideline on economic prescribing of pharmaceuticals and medicinal products [Richtlinie über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005), published by the Hauptverband der österreichischen Sozialversicherungsträger (Verlautbarung Nr. 5/2005)]; www.avsv.at

Figure 2.1: Austria - Pharmaceutical System, 2006



Source: ÖBIG 2006

2.2 Pricing

2.2.1 Scope of Price Control

In Austria all pharmaceuticals, i.e. POM and OTC fall by law under a sort of statutory price regulation and the reimbursement system and the pricing system are very closely linked. Since 1999 the former pricing system was replaced by an agreement of the Federal Chamber of Labour (BAK) and the Federal Chamber of Commerce (WKÖ) by a price notification process.

Besides, there are additional pricing rules for pharmaceuticals applying for inclusion in the Reimbursement Code (EKO) in place. Pharmaceuticals included in the EKO have to be priced either according to the EU Average Price as established by the pricing committee (PK) (cf. 2.2.2.3) or below this price. The pricing scheme is therefore very much linked with the EKO, which is discussed in more detail under section 2.3.1. Table 2.2 provides a concise overview of the Austrian pricing system.

The current statutory mark-up schemes for wholesalers (cf. Table 2.3 and Table 2.4) and for pharmacies (cf. Table 2.5) are applicable to all pharmaceuticals.

Table 2.2: Austria - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Non-reimbursable products, mostly OTC	Not applied	Not applied
Statutory Pricing	For pharmaceuticals applying for reimbursement, mostly POM	All products regulated via a regressive mark-up scheme	All products regulated via a regressive mark-up scheme
Price Negotiations	Prices for pharmaceuticals in EKO can be further negotiated with HVB	Not applied	Not applied
Price / volume agreements, discounts / rebates	Yes (Contribution to secure affordability of pharmaceuticals 2004-2006)	No	Yes (Solidarity contribution of pharmacists 1'2000-12'2003; discount for "privileged customer" i.e. social health insurance)
Institution in charge of pricing	- BMGF advised by PK - Manufacturers prices for reimbursable pharmaceuticals fixed by HVB advised by HEK on basis of the EU Average Price or other pricing regulation (generics), price negotiations take place		
Legal Basis	- Price Act 1992, amended; - Enactment of the BMGF on the maximum mark-ups in pharmaceutical wholesale 2004; - Austrian Pharmaceutical Taxe Enactment (Arzneitaxe); - Art. 351c.6 and Art. 351c.10 ASVG and Art. 609.14 ASVG; - BMGF Regulation on Procedural Rules for Calculation of EU Average Price, published 1.10.2005		

Art. = Article, ASVG = Allgemeines Sozialversicherungsgesetz (Austrian Social Insurance Law), BGBl. = Bundesgesetzblatt (Official Gazette), BMGF = Bundesminsterium für Gesundheit und Frauen (Federal Ministry of Health and Women), EKO = Erstattungskodex (Austrian Reimbursement Code), HVB = Hauptverband der Sozialversicheurngsträger (Federation of Austrian Social Insurance Institutions), HEK = Heilmittel-Evaluierungskommission (Pharmaceutical Evaluation Board), PK = Preiskommission (Pricing Committee), OTC = Over-the-Counter medicines, POM = Prescription-only medicines

Source: ÖBIG 2006

2.2.1.1 Manufacturer Price

In accordance with the Price Act of 1992[9] the BMGF is entitled and obligated to set a "national price justified in terms of the national economy". The pricing committee (PK) has been established to act as an advisory body to the BMGF[10]. The PK consists of representatives of Ministries and of the so-called social partners (i.e. representatives of employers, employees, farmers and free professions) (cf. 2.1.1).

[9] Art. 3.1 Price Act 1992, amended [Bundesgesetz, mit dem Bestimmungen über Preise für Sachgüter und Leistungen getroffen werden (Preisgesetz 1992), i. d. F. BGBl. I Nr. 151/2004]

[10] Art. 9.3 Price Act 1992, amended

Since 1.9.1999 an agreement of the Federal Chamber of Labour (BAK) and the Federal Chamber of Commerce (WKÖ) has changed the procedure of price setting. Since that time a price notification system came into effect, meaning that manufacturers have to notify the manufacturer price for new products or price changes to the BMGF. This pricing procedure is applied on all pharmaceuticals (on- and off-patent, POM or OTC).

Still the Price Act is effective, so if the price is deemed too high from an Austrian economy perspective the BMGF has, generally speaking, the opportunity to start an official price fixing process. However, this has not occurred during the last years. If no such process is started within six weeks the sought price is automatically granted. As the Price Act does not only apply to pharmaceuticals but also to other society-relevant products like energy, it states rather general criteria for the pricing of pharmaceuticals. Criteria listed are the affordability of consumers and the economic circumstances of the industry, for other branches international price comparisons are enlisted as a criterion.

Additional to the Price Act, which is still valid as a sort of back-up regulation, in 2004 a new procedure for pricing at manufacturer level was introduced for those pharmaceuticals which apply for inclusion to the EKO, i.e. for reimbursement. The manufacturer price of pharmaceuticals in the red box of the EKO (cf. 2.3.1) is set at the EU Average Price, which is the arithmetic average of the manufacturer price of the product (without the VAT) in all Member States. For the calculation of the EU Average Price, pharmaceuticals with the same active ingredient, the same strength, the same dosage form and a comparable package size are taken into account.

A BMGF Regulation on procedural rules for calculation of EU Average Price, published 1.10.2005[11] specifies the procedure. It says that the holder of a marketing authorisation applying for inclusion of a product to the EKO has to provide information, whether the product is on the market in the EU Member States and if so has to submit the manufacturer and wholesale price of the product in each of these countries. By doing so the companies have to use a form, which was developed by the PK.[12] The Austrian Health Institute (Österreichisches Bundesinstitut für Gesundheitswesen, ÖBIG) is responsible for checking the prices submitted by the industry on a random basis.

Considering the price consultation of the ÖBIG the PK computes and sets the EU Average Price of the products applying for inclusion in the reimbursement system (cf. 2.3.1) in the following way: The Regulation on procedural rules for calculation of EU Average Price holds, that a EU Average Price can be established, if the product is marketed in at least half of the EU member states for on-patent products and for at least two member states for generics. Otherwise the EU Average Price can not be established and a price evaluation will be carried

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11 Regulation on procedural rules for calculation of EU Average Price [Regelung für die Vorgehensweise der Preiskommission bei der Ermittlung des EU-Durchschnittspreises acc. to Art. 351c.6 ASVG; http://www.bmgf.gv.at/cms/site/detail.htm?thema=CH0008&doc=CMS1078931881119]

12 Price notification form according to Regulation on Procedural Rules for Calculation of EU Average Price, http://www.bmgf.gv.at/cms/site/attachments/0/7/8/CH0008/CMS1078931881119/preismeldung-roter-bereich.xls

out every six months. Should the information criteria not be met at the second re-evaluation, the EU Average Price will be established on the basis of information available, i.e. the available countries.

The manufacturer price is then set at the level of the EU Average Price and the product is allowed to enter the red box of the EKO. The EU Average Price is further the maximum limit for products in the yellow box of the EKO, green box products must always be priced below the EU Average Price.

Besides the limits of the EU Average Price, further pricing rules are applicable for pharmaceuticals applying for reimbursement, e.g. for off-patent pharmaceuticals. Furthermore the HVB may negotiate manufacturers prices with pharmaceutical companies, if an agreement is found the manufacturer price is binding for the whole market. (Further details on prices of reimbursable pharmaceuticals may be found in section 2.3.1.

Price setting for parallel traders is shortly explained in section 2.3.1.

2.2.1.2 Wholesale Price

In Austria the wholesale margins for all products are regulated by the state[13]. From 1.1.2004 on, there are different mark-up schemes valid for pharmaceuticals included in the yellow or green box of the EKO and for all other pharmaceuticals.

The regulations are displayed in detail in Table 2.2 and Table 2.3. The wholesale mark-ups as regulated are maximum mark-ups and are always applied. However, wholesalers may grant discounts to pharmacies. In practice allowances (Skonti) are rather common and sometimes promotional activities (promoting a certain pharmaceutical form of a product etc.) are set.

[13] Enactment of the BMGF on the maximum mark-ups in pharmaceutical wholesale 2004 [Verordnung des BMGF über Höchstaufschläge im Arzneimittelgroßhandel 2004] , http://www.bmgf.gv.at/cms/site/attachments/0/3/3/CH0008/CMS1071504141891/vo_hoechstaufschlaege_am.pdf

Table 2.3: Austria - Wholesale Mark-up Scheme for Yellow and Green Box of Reimbursement Code, 2006

Manufacturer Price in €	Maximum Mark-up in % of Manufacturer price	Wholesale price in €
0.00 - 6.06	15.5%	-
6.07 - 6.22	-	7.00
6.23 - 12.11	12.5%	-
12.12 - 12.32	-	13.62
12.33 - 53.78	10.5%	-
53.79 - 54.77	-	59.43
54.78 - 181.68	8.5%	-
181.69 - 184.22	-	197.12
184.23 - 339.14	7.0%	-
Over 339.15	Fixed amount € 23.74	

Source: Enactment of the BMGF on the maximum mark-ups in pharmaceutical wholesale 2004

Table 2.4: Austria - Wholesale Mark-up Scheme for Products not Included in Green and Yellow Box of Reimbursement Code, 2006

Manufacturer Price in €	Maximum Mark-up in % of Manufacturer price	Wholesale price in €
0.00 - 6.06	17.5%	-
6.07 - 6.21	-	7.12
6.22 - 12.11	14.5%	-
12.12 - 12.33	-	13.87
12.34 - 53.78	12.5%	-
53.79 - 54.74	-	60.50
54.75 - 181.68	10.5%	-
181.69 - 184.17	-	200.76
184.18 - 339.14	9.0%	-
Over 339.15	Fixed amount € 30.52	-

Source: Enactment of the BMGF on the maximum mark-ups in pharmaceutical wholesale 2004

2.2.1.3 Pharmacy Retail Price

Pharmacy margins are also statutorily fixed for all pharmaceuticals (on- and off-patent, POM and OTC), the legal basis being the Austrian Pharmaceutical Taxe Enactment (Österreichische Arzneitaxe)[14].

Like wholesale margins, they are regressively staggered and are based on the wholesale price (= pharmacy purchasing price). Since 1.1.2004 there are two different schemes applied: one scheme using reduced mark-ups for "privileged customers", i.e. such as the Austrian sickness funds, the state, the Austrian provinces or communities and funds and institutions held by these as well as non-profit hospitals[15] (cf. Table 2.5) and another basic scheme for "private customers" (cf. Table 2.5), on which an additional flat “private customer mark-up” of 15% is added.[16] The latter scheme is valid since 1.2.1997.

[14] Austrian Pharmaceutical Taxe 1962, amended [Österreichische Arzneitaxe, 1962 i.d.F. BGBl. II Nr. 433/2005]

[15] Enactment of the Minister of Health and Women, changing the Austrian Pharmaceutical Taxe (107. Change) 30.12.2003 [Verordnung der Bundesministerin für Gesundheit und Frauen, mit der die österreichische Arzneitaxe geändert wird (107. Änderung der Arzneitaxe) vom 30.12.2003]

[16] Enactment of the Minister of Health and Women, changing the Austrian Pharmaceutical Taxe (99. Change) 14.07.2000 [Verordnung der Bundesministerin für Gesundheit und Frauen, mit der die österreichische Arzneitaxe geändert wird (99. Änderung der Arzneitaxe) vom 14.07.2000]

Table 2.5: Austria - Pharmacy Mark-up Scheme for Privileged Customers, 2006

Wholesale Price in €	Mark-up in % of wholesale price	PRP in €	Margin in % of PRP
0.00 - 10.00	37.0%	-	27.0%
10.01 - 10.15		13.70	-
10.16 - 20.00	35.0%	-	25.9%
20.01 - 20.45		27.00	-
20.46 - 30.00	32.0%	-	24.2%
30.01 - 30.94		39.60	-
30.95 - 60.00	28.0%	-	21.9%
60.01 - 62.44		76.80	-
62.45 - 100.00	23.0%	-	18.7%
100.01 - 104.24		123.00	-
104.25 - 120.00	18.0%	-	15.3%
120.01 - 124.21		141.60	-
124.22 - 150.00	14.0%	-	12.3%
150.01 - 155.45		171.00	-
155.46 - 200.00	10.0%	-	9.1%
200.01 - 207.55		220.00	-
207.56 - 350.00	6.0%	-	5.7%
350.01 - 357.07		371.00	-
ab 357,08	3.9%	-	3.8%

PRP = Pharmacy Retail Price

Source: Austrian Pharmaceutical Taxe Enactment, 30.12.2003

Pharmacy mark-ups applicable to reimbursed pharmaceuticals are thus lower than those applied to end consumers (i.e. in case a patient buys a pharmaceutical on his/her own expense, which is common e.g. for contraceptives or many OTC).

The Austrian Pharmaceutical Taxe furthermore officially regulates that above mentioned privileged customers are granted discounts. The levels of these discounts depend on the respective annual sales of the pharmacy in question (the higher the sales volume, the higher the discount). Details on the discounts are explained in point 2.2.2.6.

Prices of products are published by the Chamber of Pharmacists (Österreichische Apothekerkammer, ÖAK) in a medicines price register (Warenverzeichnis; WVZ), which is updated monthly and available against subscription in paper and electronic form.

Table 2.6: Austria - Basic Pharmacy Mark-up Scheme for Private Customers, 2006

Wholesale Price in €	Mark-up in % of wholesale price	PRP in €	Margin in % of PRP
0.00 - 7.29	55%	-	35.5%
7.30 - 7.58		11.30	-
7.59 - 15.70	49%	-	32.9%
15.71 - 16.25		23.40	-
16.26 - 26.25	44%	-	30.6%
26.26 - 27.19		37.80	-
27.20 - 63.09	39%	-	28.1%
63.10 - 65.44		87.70	-
65.45 - 90.74	34%	-	25.4%
90.75 - 94.26		121.60	-
94.27 - 108.99	29%	-	22.5%
109.00 - 113.38		140.60	-
113.39 - 130.80	24%	-	19.4%
130.81 - 135.73		162.20	-
135.74 - 203.43	19.5%	-	16.3%
203.44 - 211.39		243.10	-
211.40 - 363.30	15%	-	13.0%
363.31 - 371.37		417.80	-
ab 371.37	12.5%	-	11.1%

PRP = Pharmacy Retail Price

Source: Austrian Pharmaceutical Taxe Enactment,14.07.2000

To calculate the actual Pharmacy Retail Price valid for private customers, on top of the prices calculated from the regressively staggered margin scheme in Table 2.5, a flat 15% mark-up ("Privatverkaufszuschlag") is added.

Besides the pharmacies, self-dispensing doctors supply patients with pharmaceuticals. Self-dispensing doctors have to procure the pharmaceuticals through a pharmacy. In practice some wholesalers also have a pharmacy licence thus supplying pharmaceuticals to self-dispensing doctors (cf. 2.2.2.6 and 2.1.2.2).

2.2.1.4 Value Added Tax (VAT)

Since 1997 the sale of pharmaceuticals is liable to the standard Austrian 20% VAT rate. VAT is paid by the private customers for non-reimbursable pharmaceuticals but also by the sickness funds for reimbursable pharmaceuticals and is calculated in terms of the pharmacy retail prices. The Ministry of Finance (BMF) refunds part of the VAT on reimbursed products to the sickness funds.

2.2.2 Price related Cost-containment Measures

2.2.2.1 Pharmaco-economic Guidelines

There are no explicit pharmaco-economic guidelines in place for Austria, though there has been a proposal of the HVB been put up for discussion.[17]

Still the evaluation of the HEK regarding the inclusion of a pharmaceutical into the EKO comprises a health economic evaluation. The Procedural rules for publication of the Reimbursement Code (Verfahrensordnung Erstattungskodex, VO-EKO) holds requirements which should be fulfilled by pharmaco-economic evaluation, in the annexes of this Regulation the health economic data, which shall be included, is specified in very detailed way (cf. 2.3.1).[18]

Furthermore the VO-EKO holds that pharmaceuticals applying for inclusion to the yellow box of the Reimbursement Code have to proof cost-effectiveness for selected patient groups by means of pharmaco-economic studies.[19]

2.2.2.2 Internal Price Referencing

The health economic evaluation of products to be accepted in the EKO includes a comparison of its cost based on manufacturer prices with existing treatment alternatives. In this comparison the treatment cost of the product is pitted against that of the cheapest alternative treatment already included in the EKO. The products potential sales and the product price in other European countries (see next point) may also be taken into consideration.

Internal referencing is mainly relevant for the reimbursement price of green box products and thereof off-patent products.[20] As soon as a generic (defined as a bio-equivalent copy product of an originator brand) becomes available, the HVB re-initiates price negotiations over the price of the original product (cf. 2.3.1.4). Industry is obliged to notify the HVB of patent expiries (cf. 2.2.1.1). If no generic is launched in Austria in the wake of a patent expiry, the HVB may - on recommendation of the Pharmaceutical Evaluation Board (HEK) - initiate tenders for the off-patent active ingredient.

But also for products applying for inclusion to the yellow box, internal price referencing is applied if comparable treatment alternatives are available.[21] If no comparable treatment is available cost effectiveness may be proofed by pharmaco-economic studies (cf. 2.2.2.1).

However, compared to a lot of other European countries like e.g. Germany, internal price referencing plays a minor role in Austria.

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17 Wieninger, P., Führlinger, S. 2005; http://www.hauptverband.at/mediaDB/93784.PDF

18 Art. 25 Procedural rules for publication of the Reimbursement Code acc. to Art. 351g ASVG [Art. 25 Verfahrensordnung zur Herausgabe des Erstattungskodex nach § 351g ASVG (VO-EKO)], www.avsv.at

19 Art. 25.4 VO-EKO

20 Art. 25.2 VO-EKO

21 Art. 25.5 VO-EKO

2.2.2.3 External Price Referencing / Cross Country Referencing

HVB has been comparing prices of pharmaceuticals in Austria with those in other European Countries in the course of the reimbursement decision for more then 10 years on an irregular basis.

With the introduction of the EU Average Price system in 2004 (cf. 2.2.1.1) the comparison method and the relevant country basket - in the meantime all EU Member States - has been fixed in the Regulation on Procedural Rules for Calculation of EU Average Price, published 1.10.2005[22]. The EU Average Price system is explained in detail in section2.2.1.1.

2.2.2.4 Price Freezes / Stops

There have been no direct statutorily introduced price freezes during the last five years in Austria, however the introduction of the EU Average Price system together with the new VO-EKO in July 2004 has led to price reductions in some market segment, for example in high priced products (the formerly so-called "Schwarzpunkt" products") which were formerly not included in the old reimbursement list (Heilmittelverzeichnis). Those "Schwarzpunkt" products could be only reimbursed with ex-ante approval of the so-called head physician (cf. 2.3).

In the course of the introduction of the new reimbursement scheme (EKO) the government postulated that public pharmaceutical expenditure should only be allowed to grow in a range of 3 to 4% annually. This goal has been reached in 2004 with a growth of public pharmaceutical expenditure of 3.5%; the corresponding figure for 2005 is 2.2%.

2.2.2.5 Margin Cuts

Wholesale and pharmacy margins on pharmaceuticals are regulated through a regressive mark-up scheme (cf. 2.2.1.2 and 2.2.1.3). In 1995, 1997 and 2004 pharmacy margins were lowered by law. In 2004, the aggregate pharmacy margin amounted to 28.2%.

Wholesale margins have also been reduced by law in 1995, 1997 and in 2004. Additionally they have also been statutorily cut from 1.6.2000 on, as the Association of Wholesalers did not - in contrary to the Pharmacists' Association (cf. 2.2.2.6) accept the voluntary "Solidarity Contribution" as suggested by the HVB.

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[22] Regulation on Procedural Rules for Calculation of EU Average Price [Regelung für die Vorgehensweise der Preiskommission bei der Ermittlung des EU-Durchschnittspreises acc. to Art. 351c.6 ASVG; http://www.bmgf.gv.at/cms/site/detail.htm?thema=CH0008&doc=CMS1078931881119]

2.2.2.6 Discounts and Rebates

The HVB and the Chamber of Pharmacists (ÖAK) have agreed that from the year 2000 on pharmacies will pay a "Solidarity Contribution" of 13% of their individual increase in sales compared to the previous year to the sickness funds. The agreement was negotiated for a five year period.

Growing pharmaceutical expenditure led to another agreement between the HVB, pharmacists, wholesalers, and the industry to further cut margins effective from 1.1.2004. As the former rebate for "privileged customers" was incorporated in the margin scheme, the "Solidary Contribution" ended with 31.12.2003. In addition to the margin cuts a further 2.5% rebate for "privileged customers" on turnover with privileged customers above the nationwide mean turnover with privileged customers of all pharmacies was introduced payable by pharmacies. Products whose wholesale price is above € 200.- are exempt from the rebate calculation.[23] This has resulted in differential margins for "privileged customers" (i.e. sickness funds) and private customers. Similar regulations apply to SD-doctors.

The share of pharmaceutical companies to cost-containment measures in the last few years is the so-called "Contribution to secure affordability of pharmaceuticals" (Finanzierungs-Sicherungs-Beitrag)[24], a sort of ex-post discount, which is due for the years 2004 to 2006. In 2004 HVB and the Association of the Pharmaceutical Industry (PHARMIG) agreed on a flat rate payment of € 23 million plus 20% VAT. In 2005 and 2006 the contribution will amount to 2% of the annual sales plus 20% VAT, for sales above a threshold of € 2 million per company.

There has been a wide discussion on rebates in kind ("natural rebates") granted by the pharmaceutical industry to SD-doctors in summer 2005. Adjacent to the public discussion these kinds of rebates were explicitly prohibited in an amendment to the Austrian Medicines Act[25] to counteract even the possibility to influence the prescribing decision of SD-doctors by rebates in kind. Though as stated above (cf. 2.2.1.3) rebates in cash are not prohibited - especially as the acquisition price (~ wholesale price) for SD-doctors is not fixed by law.

Manufacturers and wholesalers are neither allowed to dispense pharmaceuticals to patients nor to grant them direct discounts. Still, they may provide doctors with free samples ('Ärztemuster') which these may hand out to patients. Doctors are not allowed to sell such products. In the contrary pharmacies are allowed to grant discounts to their clients, but only in the private retail market.

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23 Art. 3a Austrian Pharmaceutical Taxe 1962, amended [Österreichische Arzneitaxe 1962, festgelegt in der 107. Änderung der Arzneitaxe, 30.12.2003 BGBl. II Nr. 629/2003]

24 Art. 52 to 55 VO-EKO on the Contribution to maintain the financial balance of the social security system according to Art. 609.19 ASVG [Art. 52 to 55 VO-EKO; Beitrag zur Wahrung des finanziellen Gleichgewichts des Systems der sozialen Sicherheit gemäß §609 Abs. 19 ASVG]

25 Art. 55b Austrian Medicines Act 2005 [Arzneimittelgesetz 2005; i.d.F. Bundesgesetz, mit dem das Arzneimittelgesetz, das Rezeptpflichtgesetz, das Medizinproduktegesetz, das Tierarzneimittelkontrollgesetz, das Gesundheits- und Ernährungssicherheitsgesetz und das Arzneiwareneinfuhrgesetz 2002 geändert werden, BGBl. 153/2005 of 28.12.2005]

2.2.2.7 Company Profit Controls

The profits of pharmaceutical companies are indirectly influenced by the above mentioned "Contribution to secure affordability of pharmaceuticals" (cf. 2.2.2.6) and are capped through the EU Average Price system in the following way: In the case the EU Average Price established by the pricing committee lies below the price indicated by the manufacturer, the difference must be paid back to the sickness funds at the end of the year. This case is only relevant for products listed in the red box of the EKO.

However, the average manufacturer price level in Austria is rather low compared to other western EU Member States.

2.2.2.8 Parallel Trade

Parallel trade only plays a minor role as on the one hand the overall manufacturer price level in Austria is rather low compared to other countries and there are no incentives for doctors, patients or pharmacists to use parallel imports. In fact for some products Austria is more an export (e.g. to UK) than an import country.

Parallel importers do not need to file an own price application (like manufacturers have to, cf. 2.2.1.1) to enter the market as their price is the same as the original one. But if they want their product explicitly to be included in the EKO (e.g. because of different pack size) they have to negotiate the price with the HVB. For parallel traded goods the same wholesale and pharmacy margins are applicable as for other pharamceuticals.

To make pharmacists replace the prescribed brand by the parallel imported one parallel importers grant discounts to wholesalers and especially to pharmacists.[26] Currently parallel traders lobby in Austria to oblige pharmacists to always dispense the cheapest available product (on basis of brand names).

[26] Usually it is the doctor who decides, if he prescribes a parallel traded product or a original (directly imported) product by making a note on the prescription. But some years ago the BMGF has stated that the pharmacist may also decide to dispense a parallel imported brand instead the direct import, if not opposed by the doctor. However the legal situation is not very clear, which perhaps is also a reason why parallel imports play a minor role in Austria.

2.2.3 Co-Payments

For pharmaceuticals sold at the expense of the sickness funds patients have to pay a flat-rate fee per prescription. In 2006 the prescription fee amounted to € 4.60 as it is annually adjusted by the inflation rate (in 2005 it was € 4.45). [27] The latest extra-ordinary rise happened in October 2000 when it was changed by 22.2% to € 4.0. There are no additional payments due for patients.

The pharmacies collect this amount on behalf of the sickness funds and pass it on to them. Socially disadvantaged persons like e.g. old-age pensioners with an income below a certain threshold and persons with communicable diseases like tuberculosis or HIV are exempt from prescription fees.[28]

With a co-payment in form of a fixed fee there are no incentives for patients in place to opt for cheaper pharmaceuticals or treatment alternatives, especially as neither a reference pricing system (cf. 2.3.2) nor generic substitution (cf. 2.3.4.2) is relevant in Austria. Also no special co-payment rules apply for parallel traded products.

There have been plans to lower prescription fees for generics thus encouraging the demand of patients but currently there is no decision whether this reduced fee will come into place.

2.2.4 Information Transparency

In Austria prices of pharmaceuticals are hard to access by patients and in former times also by doctors or other health experts, as there is no public information on prices like a general public price database.

The best widely available expert information source for pharmaceuticals is the EKO which is published as paper version two times a year (on 1. January and 1. July) and is up-dated monthly via internet (www.avsv.at). The paper version contains only the green, yellow and light-yellow box of the EKO, whereas the red box is only available via internet as it may change daily. Besides information on the ATC code, brand name, available pharmaceutical forms, dosage and pack size the Reimbursement Code also contains prescription restrictions (e.g. may only be prescribed by a paediatricians for children <12 years) and the social insurance (reimbursement) price of the product.

Other price registries like the above mentioned medicines price register (Warenverzeichnis; WVZ) published by the Chamber of Pharmacists (ÖAK) are not available to the broad public neither is this information available for free.

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[27] Art. 136.2 and 3 Austrian Social Insurance Law (ASVG 1955), amended [Art. 136.2 und 3 Allgemeines Sozialversicherungsgesetz (ASVG 1955), i.d.F. BGBl. II Nr. 446/2005]

[28] Art. 136.4 and 5 ASVG 1955, amended [Art. 136.2 und 3 ASVG 1955, i.d.F. BGBl. II Nr. 446/2005]; The current values for exemption of social reasons are published on the webpage of the HVB: http://www.hauptverband.at/mediaDB/108932.PDF

Advertising and industry behaviour towards health professionals is regulated by the Austrian Medicines Act[29], which is in line with the Directive 2001/83/EC. The BASG is the competent institution in charge of supervising pharmaceutical advertising activities.

Advertising in media (broadcasting) is not allowed for POM, but companies may provide patients with product-specific information if this information is personally requested by the patient. There are no "formal" incentives in place to encourage doctors to provide their patients with information on products. The HVB together with the Austrian Chamber of Physicians (Österreichische Ärztekammer, ÖÄK) and the Austrian Chamber of Pharmacists (ÖAK) have a cooperation to inform patients on pharmaceutical treatment of certain diseases in form of patient leaflets (Initiative “Arznei & Vernunft”), which are provided in practices and pharmacies.[30]

There is a code of conduct issued by PHARMIG[31], this self regulatory industry code also lays down financial penalties up to € 100.000 in case of breach with the code. According to PHARMIG the code exceeds the provisions made by the law and holds that employees of PHARMIG-members may not offer or take any kind of benefits in cash or kind to or from health professionals.

Furthermore the Austrian Chamber of Physicians (Österreichische Ärztekammer; ÖÄK) has issued a code of conduct[32] which is in line with the one set up by the industry. This code regulates the attendance to scientific congresses, workshops and presentations organised or financed by the pharmaceutical industry, the acceptance of gifts or other benefits, the acceptance of professional samples of pharmaceuticals, the cooperation in clinical trials as well as research and (post-marketing) observational studies.

However, pharmaceutical industry is still the main source of pharmaceutical information for physicians in Austria and physicians are in the end the persons who decide on which medical treatment a patient will receive. The role of patients and social health insurance is rather small in this process. However the sickness funds have influence on the prescribing habits of doctors in terms of economic guidelines (cf. 2.3.4).

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29 Austrian Medicines Act 2005 [Arzneimittelgesetz 2005; i.d.F. BGBl. 153/2005 of 28.12.2005]

30 http://www.hauptverband.at/esvapps/page/page.jsp?p_pageid=219&p_menuid=58369&p_id=5

31 http://www.pharmig.at/upload/Arzneimittelrecht/Pharmig_Code_of_Conduct_2004_English.pdf?&SESS=c886236529a3ab699df491fc5c9edfe4 - Changes in the Austrian Medicines Act as of December 2005 are not incorporated in this version

32 http://www.aerztekammer.at/service/Code_of_Conduct.pdf

2.3 Reimbursement

According to the Austrian Social Insurance Law (Allgemeines Sozialversicherungsgesetz, ASVG) patients must be granted all necessary forms of medicinal and medical treatment in a sufficient and appropriate way as long as adequacy of resources is guaranteed.[33]

Reimbursement of pharmaceuticals in Austria is therefore characterised by reimbursement in kind and on a very general level all duly registered pharmaceuticals in Austria are reimbursable by social health insurance for certain diseases if there is no treatment alternative.[34] The latter is called *individual reimbursement* but is only rarely applied (< 1% of prescriptions).

All pharmaceuticals listed in the so-called Reimbursement Code (Erstattungskodex, EKO) may be prescribed by contracting doctors on behalf of the sickness funds (*general reimbursement*). In specific cases (cf. Table 2.7) ex-ante or ex-post approval of a "head physician" (Chefarzt) of the contracting sickness fund is necessary.

The Guideline on economic prescribing of pharmaceuticals and medicinal products (Richtlinie über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen, RöV[35], published by the HVB on basis of ASVG[36]) sets criteria for coverage of pharmaceuticals by sickness funds. Thus even pharmaceuticals not listed in the EKO have to be reimbursed by the sickness funds on individual application, if treatment is necessary for therapeutic reasons and no medication for treatment of the disease is available in the EKO. The RöV-Guideline also sets general criteria on approval by the head physician for pharmaceuticals in the EKO, where mandatory.

The legal basis for current reimbursement scheme (valid from 1.1.2005) is Art. 31.3 para 12 of the ASVG published in 2003 (61. Amendment of ASVG)[37] and the procedural rules for publication of the Reimbursement Code are fixed by decree (Verfahrensordnung Erstattungskodex, VO-EKO)[38].

The basis for the price reimbursed by the sickness fund (~ reimbursement price) is the pharmacy retail price under application of the mark-up scheme for "privileged" customers (cf. 2.2.1.2). In Austria, in contrary to many other European countries the reimbursed price is always the full price of the product. However, patients have to pay a small fixed co-payment per prescription (cf. 2.2.3).

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33 Art. 133 ASVG 1955, regulating the extent of medical treatment [Art. 133 ASVG 1995; BGBl. No. 189/1955]

34 Art. 136.1 and 2 ASVG 1955, amended [Art. 136.1 und 2 ASVG 1995 i.d.F. BGBl. II No. 446/2005]

35 Guideline on economic prescribing of pharmaceuticals and medicinal products [Richtlinie über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005)], www.avsv.at

36 Art. 31.5.13 ASVG 1955, amended [Art. 31.5.13 ASVG, i.d.F. BGBl. I No. 71/2005]

37 Art. 31.5.12 ASVG 1955, amended [Art. 31.5.13 ASVG, i.d.F. BGBl. I No. 71/2005]

38 Procedural rules for publication of the Reimbursement Code acc. to Art. 351g ASVG [Verfahrensordnung zur Herausgabe des Erstattungskodex nach § 351g ASVG (VO-EKO)], www.avsv.at

Besides rebates apply to pharmaceuticals reimbursed by sickness funds (cf. 2.2.2.6).

The EKO is only relevant for primary and secondary care, i.e. all treatment performed out-of-hospital. Pharmaceuticals used in hospital care are covered by diagnosis related remuneration of hospitals, i.e. there is no separate reimbursement of pharmaceuticals in hospital. There is no separate co-payment for pharmaceuticals used with in-patient treatment.

Private insurance only plays a minor role in reimbursement of pharmaceuticals.

2.3.1 Pharmaceutical Lists and Reimbursement Categories

In Austria there is a **positive list**, the already mentioned Reimbursement Code (Erstattungskodex, EKO) in use. All pharmaceuticals included in the EKO qualify for general reimbursement though prescribing doctors have to consider their prescribing habits in accordance with the Guideline on economic prescribing of pharmaceuticals and medicinal products (RöV) and an ex-ante or ex-post approval of sickness fund "head physician" might be required.

The pharmaceuticals in the EKO are categorised in accordance with the World Health Organisation's (WHO) ATC-Code (anatomical, therapeutic and chemical classification). The EKO has three main segments: the red, the yellow (subgroup: light yellow) and the green box (cf. Table 2.7).

According to the VO-EKO[39] starting from the complete application of pharmaceutical companies for reimbursement a pharmaceutical is included in the red box of the EKO, thus qualifying for full reimbursement. Nonetheless its reimbursement status hinges on authorisation from a "head physician" of the sickness funds.

2.3.1.1 Reimbursement Price

Pharmaceuticals are reimbursed in kind; patients only have to pay a fixed fee at the pharmacy. The pharmacy settles its account directly with the sickness funds. Pharmaceuticals dispensed on behalf of the sickness funds are charged at a price (reimbursement price, Kassenpreis) according to the lower pharmacy mark-up scheme for "privileged customers". This mark-up scheme is applicable to all pharmaceuticals dispensed on behalf of the sickness funds regardless of prescription or reimbursement status, i.e. regardless if included in the red box or reimbursed on individual application (cf. 2.2.1.3).

Based on current legislation[40] the pricing committee (PK) of the BMGF is required to calculate the EU Average Price at manufacturer level for pharmaceuticals which apply for inclusion to the EKO (cf. 2.2.1.1). From the time this price has been established by the PK and the HVB has been informed, the product remains in the red box for a maximum of 24

[39] Art. 18 and Art. 20 VO-EKO

[40] Art. 351c.6 ASVG 1955, amended [Art. 351c.6 ASVG 1955, i.d.F. BGBl. I No. 145/2003]

months, within this time span the HVB has to make the decision whether the product will remain in the EKO and if whether it will be classified to the yellow or the green box.

If no EU Average Price can be established (cf. 2.2.1.1) the manufacturer's notified price will be used for reimbursement purposes. In this case the pricing committee carries out a price evaluation every six months. If a price established in this way lies below the one indicated by the manufacturer, the difference must be paid back to the sickness funds. In the case that the EU Average Price cannot be established at the time of application the 24 month period will start only 12 month after inclusion of the product in the EKO.[41]

In case of applications of companies for price increments HVB has to decide within 90 days of receipt of the complete application by the market authorisation holder (in exceptional cases it may take a further 60 days to deliberate).[42] If a pharmaceutical company wants its product to be reimbursed, but does not apply at the Ministry of Health, the BMGF starts to work ex officio and checks if the price is justified in terms of economics (cf. 2.2.1).

[41] Art. 351c.7 ASVG

[42] Art. 32, 33 and 34 VO-EKO

Table 2.7: Austria - Current Reimbursement Code (EKO)

Boxes	Products and guidance
Red	Scope: • Newly launched products and all products (including off-patents) that have applied for inclusion in the yellow or green box Procedure: • Stay in box for a period of maximum 24 (to 36) months o Max. 24 months from the establishment of the ø EU-price o Max. 36 months for products where no ø EU-price can be established, price as indicated by manufacturer will be used for reimbursement purposes; Pricing Committee (PK) performs price evaluation every six months (any difference between industry indicated and established ø EU-price must be paid back to the social health insurance ex-post) o Until decision of HVB on inclusion into yellow or green box • Pharmaceutical Evaluation Board (HEK) studies the therapeutic benefits of the product, basing their analysis on pharmacological, medical-therapeutic and health economic data, then recommends inclusion or not into the yellow or green box Conditions for reimbursement: • Ex-ante approval of head physician sought by the doctor prescribing the pharmaceutical to the patient is needed for reimbursement Price: • Priced at the ø EU-price or price indicated by market authorisation holder (if no ø EU-price has been established); applications for price increments are decided upon by HVB within 90 days of receipt of the PK recommendations
Yellow	Scope: • Products with fundamental therapeutic benefits or considered important therapeutic innovation ("essential added therapeutic value") Conditions for reimbursement: • Products are only reimbursed o for specific disease or age group or o if prescribed by specialist doctor or o in limited quantities (e.g. only for 2 weeks) or for a specific method of application • Ex-ante approval of head physician sought by the doctor prescribing the pharmaceutical to the patient is needed for reimbursement Price: • Price must not exceed ø EU price, applications for price increments are decided upon by HVB within 90 days
Light Yellow	Scope: • Same as for other yellow box products Conditions for reimbursement: • Same conditions as for other yellow box products are applied but for indications as defined in EKO products may be "freely" prescribed by doctors on expense of sickness fund

Boxes	Products and guidance
	• Ex-post volume control by head physician possible, i.e. doctor has to keep a record of the reason for such prescriptions Price: • Same as for other yellow box products
Green	Scope: • "Standard" pharmaceuticals (all pharmaceuticals originally listed in the old Reimbursement List (Heilmittelverzeichnis) and pharmaceuticals prepared by pharmacists (unless registered in the yellow box) • Pharmaceuticals considered medically and health-economically sound, identical or similar therapeutic effects to already available drugs - many generics and off-patent products Conditions for reimbursement: • In general no conditions, product may be prescribed by any contract physician • Restrictions concerning specialist prescription or age of patient are possible Price: • Price must be below ø EU price • Special pricing rules for generic products apply • Prices are usually set after price negotiations, applications for price increments are decided upon by HVB within 90 days

Not listed pharmaceuticals"	Scope: • Contains products that are deemed unsuitable for use in ambulant medical care e.g. because they are used in a hospital setting under constant medical supervision or used for preventive purposes[43] • Conditions for reimbursement: • No general reimbursement possible • In very selected cases (e.g. for hospital products in cases when the patient re-enters primary care setting) reimbursement on individual basis possible, but ex-ante approval by head physician is required Price: • The manufacturer price of such products is freely determined by industry whereas the respective statutory wholesaler and pharmacy margins (“privileged customers”) are applied

Source: ÖBIG 2006

[43] List of non-reimbursable pharmaceutical categories acc. to Art. 351c.2 ASVG [Liste nicht erstattungsfähiger Arzneimittelkategorien nach Art. 351c.2 ASVG], www.avsv.at

2.3.1.2 Selection Criteria

The HVB decides within 90 days from the complete application on recommendation of the HEK whether the pharmaceutical qualifies for inclusion into the EKO at all. Criteria for this decision are held in Art. 351c.2 (for non-reimbursable pharmaceutical categories) and Art. 351c.4 (pack sizes) ASVG.

If the pharmaceutical qualifies for inclusion on this rather formal criteria the Pharmaceutical Evaluation Board (Heilmittel-Evaluierungskommission, HEK) will study the therapeutic benefits of the product in question, basing their analysis on pharmacological, medical-therapeutic, and health economic data.[44]

- The pharmacological analysis is mainly aiming at the classification and evaluation of the pharmaceutical in the context of available therapeutic alternatives, determination of comparable therapeutic alternatives if appropriate on ATC 4 Level, and determination of the degree of innovation for the applied pharmaceutical.
- Medical-therapeutic evaluation is aiming at determination and quantification of groups of patients which could be treated with the new medication, determination and quantification of the added therapeutic value of the new treatment compared to alternatives and the verification of the validity of medical effectiveness as used in pharmaco-economic evaluation. Expected duration of treatment and frequency of administration are also taken into account. The single criteria / data which are evaluated can be found in the Annexe of the VO-EKO.
- As for health economic aspect: according to the Procedural Rules for Publication of the Reimbursement Code (VO-EKO)[45] pharmaco-economic evaluations have to be submitted by the marketing authorisation holder if applying for inclusion to the EKO for a innovative product, providing an substantial therapeutic benefit or if applying for inclusion to the yellow box, if no comparable medicinal preparation is listed in this box.

Although there are no explicit pharmaco-economic guidelines enacted in Austria, some rules and criteria are fixed for the so-called health-economic evaluation in the VO-EKO. [46] The rules e.g. state that only studies published in peer-reviewed journals qualify to prove cost-effectiveness unless the study is approved by an independent scientific or public institution, furthermore on a general level it is defined from which perspective (third-party payer) cost-effectiveness analysis should be done. More detailed pharmaco-economic guidelines have been put up for discussion by the HVB[47] and also by PHARMIG.

As part of the current health economic evaluation clear pricing rules, based on the EU Average Price are fixed, one major point being an internal price referencing especially for generics (cf. 2.2.1.1). Inclusion into the EKO can be restricted to certain indications.

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[44] Art. 351g.2 ASVG

[45] Art. 24.2 para 5 and 6 and Art.25.4 VO-EKO

[46] Art.22 and Art. 25 VO-EKO as well as Annex 4 of VO-EKO

[47] Wieninger, P., Führlinger, S. 2005; http://www.hauptverband.at/mediaDB/93784.PDF

A higher price compared to therapeutic alternatives must be justified by proof of its superior therapeutic value.

After assessment of above 3 categories the HEK then recommends the inclusion or not into the yellow or green box.

The green box comprises those products that can be "freely" prescribed without the need for prior authorisation of a "head physician". Pharmacy-manufactured products are also in the green box, unless HEK has come to a different verdict.

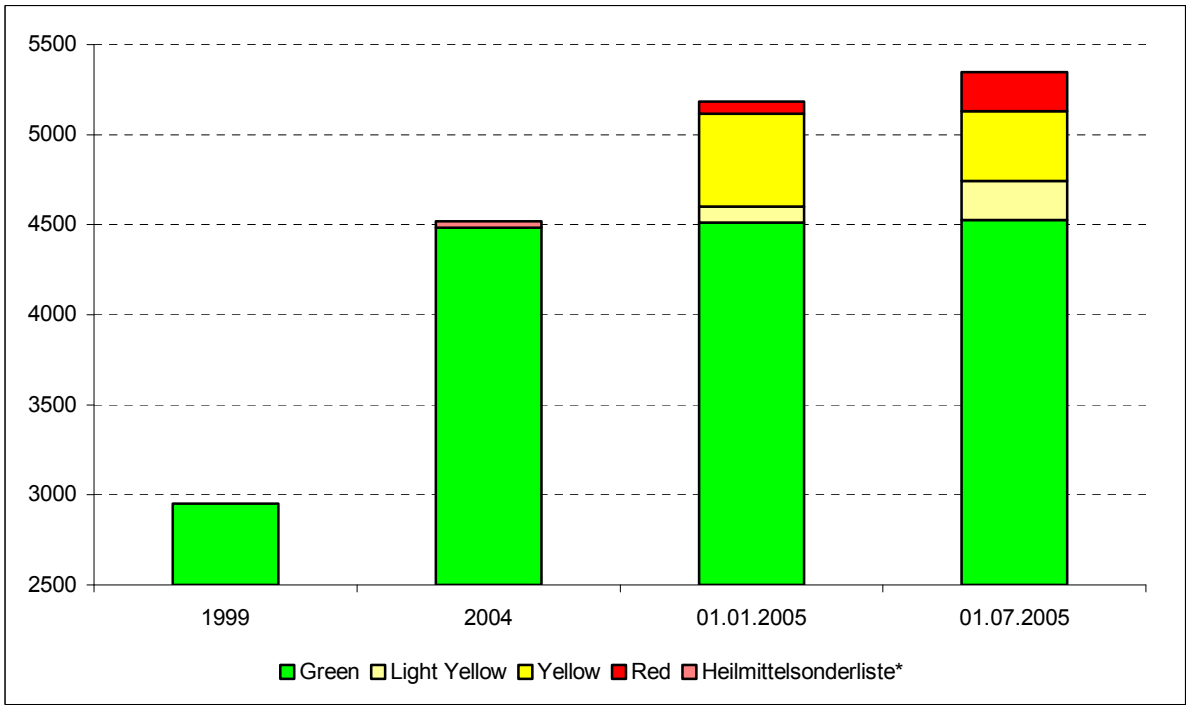
The free prescription of drugs in the green box is considered medically and health-economically sound. On the other hand, the condition of approval by a head physician for the prescription of drugs in the yellow and red boxes is designed to ensure the sickness funds control the volume of prescriptions.

2.3.1.3 Pharmaceuticals on Positive List

The number of pharmaceuticals included in the new Reimbursement Code (EKO) has substantially increased since it was introduced. At the beginning of 1999 there were approximately 2.950 products listed in the old reimbursement list (Heilmittelverzeichnis), by the end of the year 2004 4,518 pharmaceuticals (counted by packs) qualified for automatic reimbursement, whereas from 1 January 2005 5,184 products (counted by packs) were included in the EKO (cf. Figure 2.2).

On 1.7.2005 162 more products have already been listed, totalling 5,346. However, most of the pharmaceuticals that have been added to the EKO can only be prescribed under very specific circumstances (e.g. only by a specialist or as a second line therapy). Thus the need of individual reimbursement applications is reduced and access for patients becomes less bureaucratic.

Figure 2.2: Austria - Development of Positive List



Please note that the number of packs is higher than the number of reimbursable packs as many pharmaceuticals are sold in several pack sizes

* Pharmaceuticals being reimbursed under special conditions

Source: HVB 2005

2.3.1.4 Generics

For generics different pricing rules for inclusion in EKO apply. Generics are usually included in the green box, however prior to the formal decision of HEK they are firstly included in the red box. Social Insurance Law (ASVG)[48] and the Procedural Rules for publication of the Reimbursement Code[49] hold that in this case economic efficiency of the first generic product is given, if the price is at least 48% (2006) below the price of the originator (now off-patent) brand. Economic efficiency is assumed if the second and each subsequent generic "follower" offer a sufficiently large price difference to the previous included generic. The price of the originator has to be reduced by at least 30% within 3 months of the inclusion of the first generic into the green box to ensure economic efficiency of the orignator.

This means that the price of the first generic has to be 25.7% below the price of the discounted original product. The value was 20% in 2004 and 22.9% in the year 2005. At latest three month after the inclusion of the third generic product with the same active ingredient to the EKO the price of the originator has to be further reduced to remain in the EKO.

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48 Art. 351c.10 ASVG

49 Procedural rules for publication of the Reimbursement Code acc. to Art. 351g ASVG [Verfahrensordnung zur Herausgabe des Erstattungskodex nach § 351g ASVG (VO-EKO)], www.avsv.at

2.3.1.5 Non-reimbursable Pharmaceuticals

Pharmaceuticals not listed in the red, yellow or green box of the EKO do not qualify for general reimbursement.

Selection criteria for exclusion of pharmaceuticals from general reimbursement are[50,]

- that the product categories are deemed unsuitable for use in ambulant medical care, either
  - because they are used in a hospital setting under constant medical supervision or
  - because they are used for preventive purposes.
- Further product categories are: Nicotine Replacement Drugs, Nootropics, medical wines, contraceptives, obesity treatment drugs, some homoeopathic products and products used to stimulate or increase the sexual drive.

However, under very special circumstances (e.g. for hospital products in cases when the patient re-enters primary care setting like it is often the case for oncology drugs) and with the ex-ante approval of a "head physician" also these pharmaceuticals may be prescribed and may be reimbursed on an individual basis. In this occasion the reimbursement price (Kassenpreis) again is calculated on basis of the mark-up scheme for "privileged" customers.

Thus a not listed product, e.g. hormonal pharmaceuticals for contraception may be reimbursed on a individual basis for dermatological treatment although in general contraceptives are not reimbursed.

However, if a product does not qualify for reimbursement on general or individual basis e.g. because a medicinal-therapeutically equal but cheaper treatment alternative is available, which the patient refuses; doctors still may prescribe it and patients may purchase it at their own expense or at expense of private insurers. In average 45,000 prescriptions per month were approved via individual reimbursement procedure in 2005.[51]

2.3.1.6 Change in Approval by Head Physician

From January 2005 on patients no longer have to seek an ex-ante (= prior) approval of a prescription by the "head physician" of the sickness fund - if necessary - but the prescribing doctor (both in primary and in secondary care) has to do so. There are plans to introduce a system of electronically approval of prescriptions which have to be approved by the head doctors (Arzneimittelbewilligungssystem, ABS) in July 2006 but there are still discussions on the cooperation of doctors and sickness fund with this system. In one Austrian province, Upper Austria, ex-ante approval of the head physician was completely abolished in 2005, there are only ex-post controls of the prescribing habits of contract physicians possible.

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[50] List of non-reimbursable pharmaceutical categories acc. to Art. 351c.2 ASVG [Liste nicht erstattungsfähiger Arzneimittelkategorien nach Art. 351c.2 ASVG], www.avsv.at

[51] Calculation by HVB, basing on January - October 2005 data

2.3.1.7 Appeal Procedure

HVB decides in accordance with the Transparency Directive[52] within 90 days (180 days in the case of an application to have a product's status changed) from the date it receives the recommendation of HEK. In the case of a negative decision, the manufacturer may appeal to the Independent Pharmaceutical Commission (Unabhängige Heilmittelkommission, UHK)[53]. The UHK has been established in the course of the 60. amendment to the ASVG in 2002 as an appellation court to assess the decision of the HVB on the inclusion of a pharmaceutical to the EKO. There are monthly sessions which are open to the public.

The Association of pharmaceutical industry (PHARMIG) complains that the timeline for the reimbursement decision in accordance with the Transparency Directive are not met.

2.3.1.8 Delisting

The HVB can decide to take medicines out of the Reimbursement Code (= delist them), change their assignation to a box, or impose restrictions, in the wake of new pharmacological, medical-therapeutic or economic findings.[54] The manufacturer has a right to comment or complain against any such decision to the UHK.

Also the manufacturer may apply for delisting.[55]

2.3.2 Reference Price System

In Austria no reference price system is applied (cf. 2.2.2.2).

2.3.3 Pharmaceutical Budgets

In Austria there are no pharmaceutical budgets being applied for doctors or other health care providers, meaning there is no fixed prescribing budgets in terms of money for health care professionals.

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[52] Council Directive 89/105/EEC

[53] details on UHK, e.g. Procedure regulations and topics may be found on www.bmgf.gv.at/cms/site/detail.htm?thema=CH0008&doc=CMS1096983721392

[54] Art. 35 VO-EKO

[55] Art. 28 VO-EKO

Still the prescription volume or prescription habits of general practitioners and specialists are monitored by the individual sickness funds as to compliance with the HVB Guidelines on Economic Prescribing (RöV)[56] in which doctors are encouraged to prescribe the most economical product out of several therapeutically similar alternatives, meaning they should preferably prescribe products from the green box, and thereof the cheapest generic or parallel imports if available. Details can be found in point 2.3.4.1.

2.3.4 Other Volume Control Oriented Measures

2.3.4.1 Prescription Monitoring and Other Doctors-related Measures

The sickness funds monitor to a greater or lesser extent the prescription patterns of their contracted general practitioners and specialists as these are obliged to comply in prescribing with the HVB Guidelines on Economic Prescribing (RöV). These Guidelines intend to safeguard the appropriate and economical prescribing of pharmaceuticals by e.g. stating that in case of several similar therapeutic options a doctor has to choose the most cost-effective one. This system is also called "Red-Light"-System (Ampelsystem), meaning that the first therapeutic option should be a green box, followed by a (light) yellow box product. Red box products should be used only under special circumstances.

The most common way of sickness funds to monitor contract doctors is to benchmark the prescription volume of a given doctor to others in the same region, e.g. focusing on the share of generics or red box products compared to others.

According to the contracts between the sickness funds and the Austrian Chamber of Physicians, in case of non-adherence, as a first measure the doctor will get information followed by a talk to sort out possible solutions. In case of serious discrepancies doctors have to report to the head physician of the contracting sickness fund and - as last option - might be obliged to pay back the difference between the price of the prescribed products and the average prescription price. However, the latter case is very rare and most critical cases can be solved through discussions in the arbitration board (Schlichtungsstelle).

2.3.4.2 Generics and Parallel Trade

The share of generic products in Austria has been rather low for a long time. According to figures of IMS the share of generics in terms of value was 4.5% on the total pharmaceutical market in the year 2000, in 2004 the corresponding figure was 7.8%. In terms of volume the generic market share amounted to 7.4% in 2000 and 12.3% in 2004.[57]

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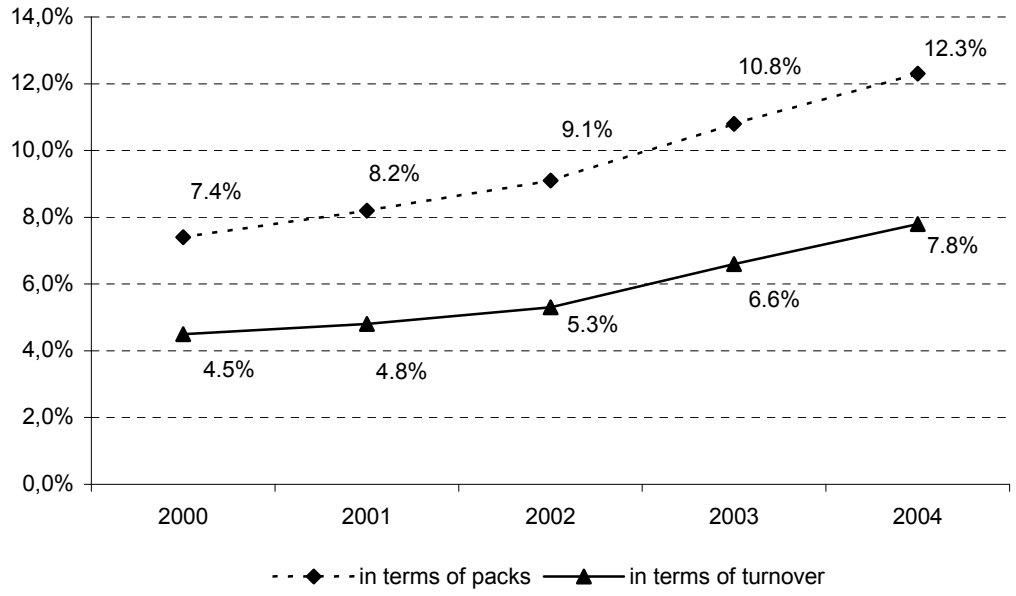
[56] Guideline on economic prescribing of pharmaceuticals and medicinal products [Richtlinie über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005)], www.avsv.at

[57] EGA 2005

If only looking at the reimbursement market the share is slightly higher, the HVB stated that the generic market share in terms of volume on the reimbursement market grew from 11.0% in 2002 to 15.4% in 2004.

One of the reasons for the relatively low market share of generics is that neither voluntary nor obligatory generic substitution is allowed for pharmacists. There are no plans to introduce generic substitution in near future. Furthermore there are no financial incentives for the patient to ask the doctor for prescribing a generic, but information campaigns are promoted by the OEGV in cooperation with the HVB and by individual sickness funds.

Figure 2.3: Austria - Market Shares Generics at the Pharmacy Market According to Value and Volume, 2000 - 2004



Source: OEGV 2005

By the RöV-Guideline medical doctors are obliged to prescribe the cheapest of medically equal effective therapeutic alternatives. Thus the prescription of generics is encouraged.

Still there is room for the medical doctor in this decision - also by the fact that not only one generic product but in most cases a range of products is listed in the “green box”. Yet physicians in Austria are not allowed to only prescribe by INN (~ active ingredient name) but always have to use a brand name or the generic product name.

2.4 Overview of the Reimbursement Market in Austria

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Public Authorities				
Decide on prescription status	X		Prescription Committee (Rezeptpflichtkommission) decides on prescription status of INN; BASG classifies according to legal regulations with market authorisation	Law on Prescription Requirement 1972, amended by BGBl. I No. 153/2005 and Prescription Requirement Enactment, amended by BGBl. II No. 39/2006
Decide on manufacturer price	(X)		BMGF / PK Calculate on maximum manufacturer price according to international price comparisons for reimbursable pharmaceuticals (EKO) Prices are free for non-reimbursable pharmaceuticals	- Price Act 1992, BGBl.Nr. 145/1992 - Art. 351c.6 and Art. 351c.10 ASVG, BGBl. I 145/2003 - BMGF Regulation on Procedural Rules for Calculation of EU Average Price, published 1.10.2005
Agree on manufacturer price		X	BMGF / PK Agree on prices of non-reimbursable pharmaceuticals in so far, as they have to be notified by the manufacturers and the BMGF could theoretically intervene if the price was deemed to high.	Price Act 1992, BGBl.Nr. 145/1992
Fix wholesale margin	X		BMGF Two maximum wholesale mark-up schemes for all pharmaceuticals (depending on whether the pharmaceutical is in the green and yellow box of the EKO or not)	Enactment of the BMGF on Maximum Wholesale Mark-ups for Pharmaceuticals 2004
Fix pharmacy retail price	X		BMGF Via mark-up for all pharmaceuticals; Two mark-up schemes apply: one for preferred customers (e.g. sickness funds) = reimbursed pharmaceuticals; and one for private customers =non-reimbursed pharmaceuticals	Austrian Pharmaceutical Taxe Enactment, amended by BGBl. II Nr. 629/2003 and BGBl. II Nr. 210/2000

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Decide on reimbursement status	X		HVB	- Art. 31.3.12 ASVG - Procedural rules for publication of the Reimbursement Code (VO-EKO) according to Art. 351g ASVG
Decide on reimbursement price	X		Besides regulations on maximum prices (international price referencing for pharmaceuticals in red and yellow box of the EKO, pricing rules for generics in the EKO) the HVB negotiates prices with manufacturers Special mark-up schemes apply to preferred customers (e.g. sickness funds)	
Use pharmaco-economic guidelines		X	No explicit guidelines. With reimbursement decision the Evaluation of the HEK includes a health economic evaluation according to stated requirements	Procedural rules for publication of the Reimbursement Code (VO-EKO) according to Art. 351g ASVG
Use Internal reference pricing	X		HVB With reimbursement decision: In general comparison to costs of treatment alternatives; Explicitly for generics	- Procedural rules for publication of the Reimbursement Code (VO-EKO) according to Art. 351g ASVG - Art. 351c.10 ASVG, BGBl. I 145/2003
Use External reference pricing	X		BMGF / PK With pricing of pharmaceuticals applying for inclusion to positive list (EKO)	Art. 351c.6 ASVG, BGBl. I 145/2003
Price freezes		X		
Margin cuts	X		Wholesale margins for all pharmaceuticals are set by the BMGF. 1995, 1997, 2000 and 2004 they have been statutorily reduced. Also pharmacy margins for all pharmaceuticals are set by BMGF; they were statutorily reduced in 1997 and 2004.	- Enactment of the BMGF on Maximum Wholesale Mark-ups for Pharmaceuticals 2004 - Austrian Pharmaceutical Taxe Enactment, amended by BGBl. II Nr. 629/2003 and BGBl. II Nr. 210/2000

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Discounts and Rebates	X		Pharmaceutical Industry: "Contribution to secure affordability of pharmaceuticals" (2004-2006) Wholesale: not applicable Pharmacies: 2.5% rebate on turnover with privileged customers above the mean turnover of all pharmacies with privileged customers ("Rebates for privileged customers")	Art. 52 to 55 VO-EKO - Contribution to maintain the financial balance of the social security system according to Art. 609.19 ASVG Art. 3a Austrian Pharmaceutical Taxe Enactment, BGBl. II Nr. 629/2003
Company profit control		X	Company profits are not directly controlled - but company profits are influenced above mentioned pricing regulations and rebates	
Country specific:				
Pharmaceutical Industry				
Sets manufacturer price freely		X	For non-reimbursable pharmaceuticals	Price Act 1992, BGBl.Nr. 145/1992
Notifies manufacturer price	X		Notifies price to BMGF / PK for all pharmaceuticals; Pharmaceuticals applying for inclusion to EKO may not exceed the EU Average Price	Art. 351c.6 ASVG, amended by BGBl. I 145/2003
Negotiates manufacturer price		X	Only for reimbursable pharmaceuticals with HVB	
Is free to set price below fixed manufacturer price	X		Free to set price below maximum EU Average Price	
Decides on application for reimbursement	X			
Negotiates reimbursement price	X		Negotiates price with HVB for some pharmaceuticals (mainly with yellow and green box).	
Free to keep manufacturer price above reimbursement price			Not applicable	
Free to grant rebates / discounts to wholesalers	X			
Free to grant rebates / discounts to pharmacies	X		No rebates in kind for reimbursable pharmaceuticals	

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Can engage in marketing towards doctors	X		In line with code of conduct	- Austrian Medicines Act 2005, amended by BGBl. I No. 153/2005 - Code of Conduct (PHARMIG)
Can engage in public advertising		X	Only for authorised OTC products	Austrian Medicines Act 2005, amended by BGBl. I No. 153/2005
Can provide information toward patients		X	Only for OTC pharmaceuticals	
Applies for switches and de-listing	X		May be initiated by manufacturers or by public bodies	
Country specific:				
Distribution Chain				
Wholesaler				
Margins are fixed by statute	X		Statutory maximum mark-up schemes; Two schemes for all pharmaceuticals depending on whether the pharmaceutical is in the green and yellow box of the EKO or not	Enactment of the BMGF on Maximum Wholesale Mark-ups for Pharmaceuticals 2004
Margins are subject to statutory discounts / rebates		X		
Free to grant discounts / rebates to pharmacies	X		Skonti, promotional activities	
Pharmacists				
Margins are fixed by statute	X		Statutory maximum mark-up scheme Two mark-up schemes apply: one for privileged customers (e.g. sickness funds) and one for private customers	Austrian Pharmaceutical Taxe Enactment, amended by BGBl. II Nr. 629/2003 and BGBl. II Nr. 210/2000
Free to set retail price		X		
Obliged to inform patient on cheaper product		X		
Obliged to substitute by a generic		X		
Allowed to substitute by a generic		X	If a substituted pharmaceutical is dispensed, the sickness fund does not cover the cost.	Art. 10.2 Guideline on economic prescribing of pharmaceuticals and medicinal products (RöV)
Obliged to substitute by a parallel import		X	Only if remark on prescription	

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Allowed to substitute by a parallel import	X		Except if opposed by doctor	
Therapeutic / analogous substitution is allowed		X		
Are subject to statutory discounts / rebates	X		2.5% discount for sales with privileged customers above the mean sales with privileged customers of all pharmacies	Austrian Pharmaceutical Taxe Enactment, amended by BGBl. II Nr. 629/2003
Claw back system exists		X		
May grant rebates to customers		X	Not for reimbursable pharmaceuticals (not allowed to deviate from fixed fee co-payment) Are free to grant discounts to private customers	
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X		Contract governing medical treatment; documentation of treatment and information provided to patients is obligatory	Indirectly regulated via various laws e.g. Art. 51 Law for Medical Doctors (Ärztegesetz) regulating the need to document treatment; and by the contract governing medical treatment between the patient and the doctor
Are obliged to inform on co-payment / deductibles		X	Co-payment in form of a fixed fee; information only necessary, if not-reimbursed Doctors are obliged to seek prior approval from head physician for certain treatments (red, yellow box of EKO and pharmaceuticals not listed in EKO)	
Prescription habits are monitored	X		By sickness funds e.g. prescription volume is benchmarked to others on local level	
Are subject to prescription guidelines	X			Guideline on economic prescribing of pharmaceuticals and medicinal products (RöV)
Budgets are controlled		X		
Allowed to prescribe INN		X		

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Obliged to prescribe INN		X		
Can oppose generic substitution			Not applicable	
Can oppose therapeutic substitution			Not applicable	
Can oppose substitution by parallel import	X		By writing a remark on the prescription	
Country specific:	X		Doctors have to get prior approval of head physician when prescribing pharmaceuticals of the yellow or red box or products not listed in the EKO on expense of sickness funds	
Patients				
Can shop for cheapest price of the product		X	PRP are uniform throughout the country; discounts may be granted only on non-reimbursable pharmaceuticals	
Pay a flat rate per prescription / pack	X		Fixed fee of € 4.60 per pack dispensed	Art. 136.3 ASVG
Pay a certain percentage per prescription / pack or a deductible		X		
Annual minimum co-payment		X		
Annual maximum co-payment		X	No, but exemptions for low income patients	
May ask for substitution by a generic		X	May ask only the doctor when prescribing; not substitution allowed in the pharmacy	
May oppose substitution by a generic			Not applicable	
May ask for substitution by a parallel import	X		Unless indicated by doctor, but of no practical relevance, as patients are usually not informed on products and prices	

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Can oppose substitution by a parallel import		X	In theory not with reimbursable pharmaceuticals (except remark by doctor). In practice pharmacists will try to keep good customer relationship and therefore not dispense a parallel traded pharmaceutical if the patient does not like it	
Can oppose substitution only on payment of price difference	X		In theory - patient may not oppose with reimbursable pharmaceuticals. In practice patient may ask doctor to oppose substitution with parallel import or go to another pharmacy. Pharmacists are interested in good customer relationship.	
Has to pay the difference between reimbursement price and PRP		X	Benefit in kind, only fixed fee co-payment	
Has access to full public information on prices and products		X	No easy access	
Country specifics:				

Source: ÖBIG 2006

BELGIUM

3 Belgium

3.1 Pharmaceutical System

3.1.1 Regulatory Framework and Authorities

The Belgian health care system is characterized by a compulsory health insurance system covering 99.9% of the population, which is funded from health insurance contributions and general taxation (79%), from out-of-pocket costs (18%) and from other, external sources (3%), such as a contribution of premiums paid for complementary health insurance, a yearly (licence) fee chargeable to pharmaceutical companies and a levy on the turnover of pharmaceutical companies on the Belgian market.

The most relevant regulatory bodies in the Belgian pharmaceutical system are

- The Federal Public Service (FPS) Health, Food Chain Safety and Environment - Directorate-General Medicines (SPF Santé Publique, Sécurité de la Chaîne Alimentaire et Environnement - Direction Générale Médicaments), supported by the Medicines Commission, is responsible for evaluating and surveying the safety of pharmaceuticals, and for granting marketing authorisation for pharmaceuticals
- The FPS Economy, SMEs, Self-employed and Energy - Market regulation - Division of prices and competition (SPF Economie, PME, Classes moyennes et Energie - Régulation du marché - Division prix et concurrence), which is in charge of pricing
- The National Institute for Sickness and Invalidity Insurance (Institut National d'Assurance Maladie Invalidité, INAMI), which hosts the Medicines Reimbursement Commission (Commission de Remboursement des Médicaments, CRM)
- The FPS Social security (SPF Sécurité sociale), which decides on the reimbursement of pharmceuticals

On a national level, the FPS Health, Food Chain Safety and Environment, based on advise of the medicines commission, decides on the market authorisation of pharmaceuticals[58]. The application for market authorisation must include the results of clinical tests, which prove that the pharmaceutical is safe and effective for certain indications, and is of good quality. In the Medicines Commission, the pharmaceutical industry, pharmaceutical wholesalers, pharmacists, trade unions and insurance funds are represented. In some cases (e.g. applications for market authorisation of vaccins or serums) the FDS asks the Belgian Superior Health Council (Conseil Supérieur d'Hygiène) for advice. All newly granted market authorisations and all withdrawn market authorisations are published in the Belgian law gazette (Moniteur Belge)[59].

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[58] Arrêté royal du 3 juillet 1969 relatif à l'enregistrement des médicaments

[59] http://www.ejustice.just.fgov.be/cgi/welcome.pl

The time it takes to authorise a pharmaceutical in Belgium has improved because of a re-structuring of the Registration Commission and an increase in the staff of the Pharmaceutical Inspection.

Pharmaceuticals are categorized as prescription-only or as non-prescription pharmaceuticals. In addition, a small number of pharmaceuticals are not just available when prescribed by a physician, but also in case of a written demand of the patient. Classification status depends on ingredients, indications and dosage, and is decided at the time of authorisation by the pharmaceutical division under the FPS Health, Food Chain Safety and Environment.

The pricing and reimbursement system in Belgium changed in 2002. The previous system was slow, because a price had to be accepted before the reimbursement status of the pharmaceutical could be decided. The new system aims to reduce the time taken for the decision making process from nearly 600 days to 180 days, which is in accordance with the EU Transparency Directive 89/105/EEC[60]. Under the new system, the price fixing procedure at the FPS Economy, SMEs, Self-employed and Energy runs parallel with the reimbursement application.

Applications for pricing and for reimbursement of pharmaceuticals are submitted to the Price Department (Service des Prix) of the FPS Economy, SMEs, Self-employed and Energy. The FPS Economy, SMEs, Self-employed and Energy decides on the pharmaceutical's maximum manufacturer price, using the advice of the medicines pricing commission (Commission des Prix des Spécialités Pharmaceutiques, CPSP) and the Standing Commission for Price Regulation (Comité Permanent de la Commission pour la Régulation des Prix, CPCRP).

The reimbursement application is initially examined by neutral experts for evaluation of the reimbursement conditions proposed by the manufacturer. Both the experts' report and the maximum price recommendation are forwarded to the Medicines Reimbursement Commission (CRM), which was established at the National Institute for Sickness and Invalidity Insurance (INAMI)[61].

The CRM submits its suggestions regarding the reimbursement status and reimbursement price to the FPS Social security. The final decision regarding the reimbursement status and the reimbursement price lies with the FPS Social security.

The National Institute for Sickness and Invalidity Insurance (INAMI) and the National institute for Social Insurance for the Self-Employed (Institut National d'Assurance Sociales pour Travailleurs Independents, INASTI) allocate the health insurance budget to the insurance funds, which are responsible for reimbursement.

Table 3.1 contains an overview of relevant Belgian stakeholders introduced in sections 3.1.1 and 3.1.2.

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60 Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance system, http://pharmacos.eudra.org/F2/eudralex/vol-1/new_v1/890105en.pdf#search='89/105/EECeudra'

61 10 Aout 2001. - Loi portant des mesures en matière de soins de santé (1)

Table 3.1: Belgium - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
SPF Santé publique, securite de la chaine alimentaire et environnement - Direction générale médicaments / FPS Health, food chain safety and environment - Direcorate-general Medicines	Regulatory body (Market authorisation)	Bisschoffsheimlaan 33 BE-1000 Bruxelles Belgium Tel.: +32 2 2275 544 Fax: +32 2 2275 646 Info.dgg@health.fgov.be http://health.fgov.be	Mrs. A. Lhoir Bisschoffsheimlaan 33 BE-1000 Bruxelles Belgium Tel.: +32 2 2275 544 Fax: +32 2 2275 646
SPF Economie, PME, Classes moyennes et Energie - Régulation du marché - Division prix et concurrence / FPS Economy, SMEs, Self-employed and Energy - Market regulation - Division of prices and concurrence	Regulatory body (pricing)	Ministry of Economy Koning Albert II-laan 16 BE-1000 Bruxelles Belgium Tel.: +32 2 2065 162 Fax: +32 2 2065 770 info.eco@mineco.fgov.be www.mineco.fgov.be	Mrs. M.T. Peeters Koning Albert II-laan 16 BE-1000 Bruxelles Belgium Tel.: +32 2 2065 162 Fax: +32 2 2065 770 marie-therese.peeters@mineco.fgov.be
SPF Sécurité sociale / FPS Social security	Regulatory body (reimbursement decisions)	Eurostation II Place Victor Horta 1060 Bruxelles Tel: +32 2 5286 011 http://socialsecurity.fgov.be/	Eurostation II Place Victor Horta 1060 Bruxelles Tel: +32 2 5286 011 http://socialsecurity.fgov.be/
Institut national d'assurance maladie invalidité (INAMI) / Health and Invalidity Insurance Institute	Health Insurance Institute (reimbursement advice)	INAMI Tervurenlaan 211 BE-1150 Bruxelles Belgium Tel.: +32 2 7397 111 Fax: +32 2 7397 291 communication@riziv.fgov.be www.inami.fgov.be	INAMI Tervurenlaan 211 BE-1150 Bruxelles Belgium Tel.: +32 2 7397 111 Fax: +32 2 7397 291

Institution	Task	Contact details/URL	Responsible person
Association générale de l'industrie du Médicament (Pharma.be) / Belgian Pharmaceutical Industry Association	Association of Pharmaceutical Industry	Pharma.be Marie-Louiseplein 49 BE-1000 Bruxelles Belgium Tel.: +32 2 2389 976 Fax: +32 2 2311 164 info@pharma.be www.pharma.be	Mr. L. Neels Marie-Louiseplein 49 BE-1000 Bruxelles Belgium Tel.: +32 2 2389 976 Fax: +32 2 2311 164
Nationale Vereniging van de Groothandelaars-Verdelers in farmaceutische specialiteiten (NVGV) / National Association of Wholesalers and Distributers of Pharmaceutical Specialties	Wholesaler Association	NVGV Mr. Stijn Terryn Sint-Bernardusstraat 60 BE-1060 Bruxelles Belgium Tel.: +32 2 5373 060 Fax: +32 2 5394 026	Mr. S. Terryn Sint-Bernardusstraat 60 BE-1060 Bruxelles Belgium Tel.: +32 2 5373 060 Fax: +32 2 5394 026 St@fedis.be
Association Pharmaceutique Belge (APB) / Pharmaceutical Association	Association of Pharmacists	APB Archimedesstraat 11 BE-1000 Bruxelles Belgium Tel.: +32 2 2854 200 Fax: +32 2 2854 285 Info@mail.apb.be www.apb.be	Mrs. A. Lecroart Archimedesstraat 11 BE-1000 Bruxelles Belgium Tel.: +32 2 2854 200 Fax: +32 2 2854 285
Ordre des Médecins / Doctors' Association	Medical Doctors' Association	Ordre des Médecins Jablinne de Meuxplein 34-35 BE-1030 Bruxelles Belgium Tel.: +32 2 7430 400 Fax: +32 2 7353 563 ordomedic@skynet.be	Mr. D. Holsters Jablinne de Meuxplein 34-35 BE-1030 Bruxelles Belgium Tel.: +32 2 7430 400 Fax: +32 2 7353 563 ordomedic@skynet.be
Vlaams Patienten Platform / Flemish Patient Platform	Cooperation of several patient associations	Vlaams Patiëntenplatform Groeneweg 151 3001 Heverlee Tel.: +32 16 2305 26 Fax: +32 16 2324 46 info@vlaamspatientenplatform.be www.vlaamspatientenplatform.be	Mrs. G. Reynders-Broos Vlaams Patiëntenplatform Groeneweg 151 3001 Heverlee Tel.: +32 16 2305 26 Fax: +32 16 2324 46 info@vlaamspatientenplatform.be

SPF = Service Public Fédéral, FPS = Federal Public Service

Source: ÖBIG 2006

3.1.2 Market Players

3.1.2.1 Pharmaceutical Industry

In 1966, the Belgian Pharmaceutical Industry Organisation (Association Génénerale de l'Industrie du Médicament, pharma.be) was founded within the Federation of the Chemical Industry of Belgium (Fedichem), as a specific structure for representing the pharmaceutical industry in Belgium. In 2003, 146 pharmaceutical manufacturers were united in pharma.be, which accounts for approximately 90% of pharmaceutical manufacturers situated in Belgium.

The annual turnover of the most important pharmaceutical company amounted to 8.3% of the total national sales of pharmaceuticals in 2002. In the same year, the share of the five largest pharmaceutical companies amounted to 32%, and the share of the ten largest companies amounted to 53.1% of the total pharmaceutical sales. (Pharma.be 2003)

Most Belgian pharmaceutical companies also produce self-medication (non-prescription) pharmaceuticals. In 18 pharmaceutical companies united in pharma.be, the share of self-medication pharmaceuticals in their total turnover is larger than 70%. In 60 companies, self-medication pharmaceuticals were responsible for less than 10% of the annual turnover. (Pharma.be 2003)

Around 27,000 people are employed in the pharmaceutical industry in Belgium.

Belgium's pharmaceutical industry trades extensively on an international level, generating a positive trade balance.

3.1.2.2 Distribution

The Belgian wholesale system is multi-channel. Currently, approximately 23 wholesalers distribute pharmaceuticals to the Belgian out-patient sector. In 2003, the two main wholesalers, Febelco and Multipharm, accounted for 28% and 16% of the market by value respectively. Fourteen wholesalers, including Febelco and multipharm, control more than 96% of the market in value. Most of the Belgian pharmaceutical wholesalers are united in the National Association of wholesalers and distributors of pharmaceuticals (Nationale Vereniging van Groothandelaars-Verdelers in pharmaceuticals specialiteiten, NVGV)[62].

In Belgium, pharmaceutical wholesalers are legally obliged to provide the full range of products to pharmacists, i.e. full-line wholesaling. There are no regulations regarding the stock of pharmacies.

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[62] Arrêté royal du 7 Février 2000 modifiant l'arrêté royal du 27 avril 1977 déclarant représentative une organisation professionnelle d'employeurs pour le secteur des grossistes-répartiteurs de médicaments

Pharmaceuticals in Belgium are only sold through community pharmacies[63]. In theory, physicians could receive a license which enabled them to dispense medicines, in case the distance to the nearest pharmacy was more than 5 kilometres. However, due to the relatively high pharmacy density in Belgium, in fact no physician possesses such a licence.

In October 1994, a five-year moratorium on the establishment of new pharmacies was installed[64]. The moratorium was renewed for a 10-year period in 1999. The moratorium restricts the opening of new pharmacies after the maximum number of pharmacies has been reached. In the past years hardly any new licences for pharmacy establishment were granted. The number of pharmacies allowed in a region depends on the population density:

- In rural areas (communities with up to 10,000 inhabitants) there is in general one pharmacy per 2,500 inhabitants.
- In urban areas (communities with over 10,000 inhabitants) there is in general one pharmacy per 1,000 inhabitants.

In order to assure public health, the moratorium also defines a minimum number of pharmacies. Currently over 5,200 community pharmacies are established in Belgium, which corresponds to approximately 2,000 inhabitants per pharmacy. Of all pharmacies, 75% to 80% are privately owned, whereas the others are owned by co-operatives.

There are no regulations on pharmacy ownership. Every person can own a pharmacy. However, a pharmacist must be present in the pharmacy at all times.

The distance selling and tele-shopping of pharmaceuticals are forbidden in Belgium because of the monopoly of pharmacists in the supply of pharmaceuticals.

63 Arrêté royal du 6 juin 1960 relatif à la fabrication, à la préparation et à la distribution en gros des médicaments et à leur dispensation, article 44

64 Arrêté royal du 18 octobre 1994 modifiant l'arrêté royal du 25 septembre 1974 concernant l'ouverture, le transfert et la fusion d'officines pharmaceutiques ouvertes au public

3.1.2.3 Patients

Patients do not have a formal role in the pricing and reimbursement decision of pharmaceuticals.

In case of a prescription by international non-proprietary name (INN), the pharmacists decides what pharmaceutical is dispensed. The patient has the right to express towards the pharmacist a preference for a generic or for a branded product with a lowered price. In case of OTC, the patient can decide for himself which pharmaceutical he/she buys.

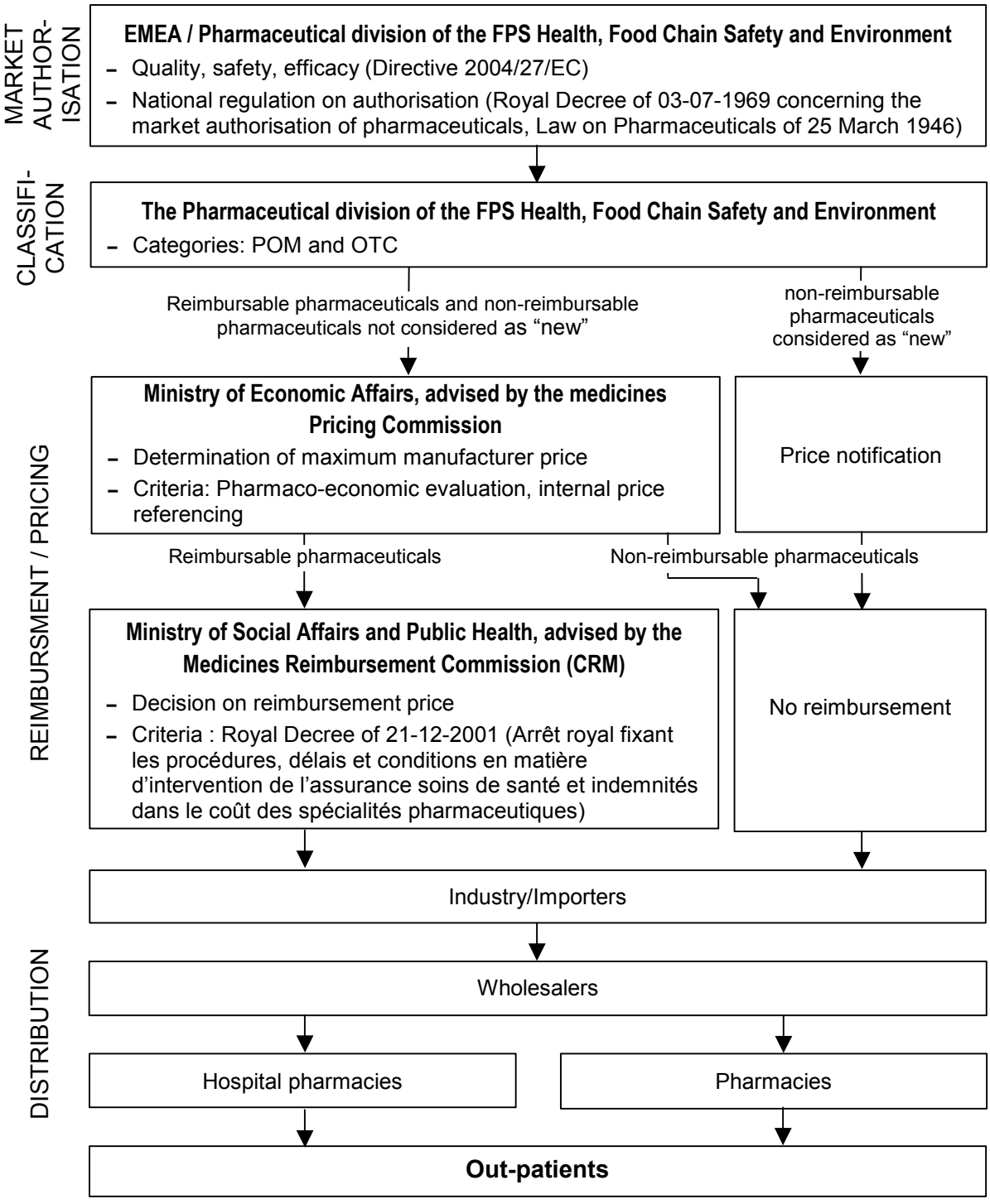
The consumption of generics is relatively low in Belgium (approximately 10%) compared to surrounding countries. This is partly due to the patients' scepticism towards generics. To promote the use of generics the Belgian government has taken several steps, such as the reduction of prices of generics. In addition, a website has been launched providing patients information on generics[65].

3.1.3 Overview of the Pharmaceutical System

Figure 3.1 gives an overview on the Belgian pharmaceutical system.

[65] http://www.goedkoopgeneesmiddel.be

Figure 3.1: Belgium - Pharmaceutical System, 2006



CRM = Commission de Remboursement des Médicaments

Source: ÖBIG 2006

3.2 Pricing

3.2.1 Scope of Price Control

In Belgium, control is exercised over the prices of all pharmaceuticals. This control can take the form of either price fixing or price notification, depending on the type of pharmaceutical[66,67,68].

In the case of pharmaceuticals seeking reimbursement, prices are fixed. The application dossier for pricing must contain the following documentation:

- A description of the product
- A copy of the market authorisation
- Company financial records for the past three years
- A proposed price and a justification for this price
- A price comparison with other EU Member States
- A market and competition research report

The maximum manufacturer prices are set and published by the FPS Economy, SMEs, Self-employed and Energy within 90 days in case of prescription-only medicines and within 60 days in case of Over-the-Counter medicines. If the deadline has expired without a decision, the price proposed by the manufacturer is accepted.

For non-reimbursed medicines, the prices of all “new” (either a new active ingredient or therapeutic indication) pharmaceuticals - whether subject to prescription or not - are essentially free, although prices must be notified to the Price Department of the FPS Economy, SMEs, Self-employed and Energy 30 days prior to implementation of the price. For non-reimbursed “new” products for which at least one presentation requires a prescription, the notification must comprise the full dossier as described for reimbursed pharmaceuticals, while notification for other non-reimbursed ‘new’ pharmaceuticals should be forwarded to the FPS Economy, SMEs, Self-employed and Energy by letter only and does not require a complete dossier. The prices of all ‘new’ reimbursed pharmaceuticals are re-evaluated after 1.5 to 3 years.

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66 22 Janvier 1945 - Loi sur la réglementation économique et les prix.

67 Arrêté ministériel du 29 Décembre 1989 relatif aux prix des médicaments remboursables

68 Arrêté ministériel du 29 Décembre 1989 relatif aux prix des médicaments non remboursables

Prices of all non-reimbursed prescription and non-prescription pharmaceuticals not considered “new” are set by the FPS Economy, SMEs, Self-employed and Energy, following the advice of the Standing Committee of the Commission for Price Regulation (Comité Permanent de la Commission pour la Régulation des Prix, CPCRP).

The pricing procedure for generics is the same as that for branded pharmaceuticals.

Table 3.2: Belgium - Pharmaceutical Pricing System, 2006

	Manufacturer level	Wholesale level	Pharmacy level
Free Pricing[1]	"New"[2] non-reimbursable pharmaceuticals	Not applied	Not applied
Statutory Pricing	All reimbursable pharmaceuticals non-reimbursable pharmaceuticals not considered "new"	All pharmaceuticals regulated via a fixed margin scheme	All pharmaceuticals regulated via a fixed margin scheme
Price Negotiations	Not applied	Not applied	Not applied
Price/volume agreements, discounts/rebates	No	Discounts to pharmacies allowed	No
Institution in charge of pricing	FPS of Economy, SMEs, Self-employed and Energy.		
Legal Basis	- 22 Janvier 1945 - Loi sur la réglementation économique et les prix. - 22 Decembre 1989 - Loi-programme, Title VI - 29 Decembre 1989 - Arrêté ministériel relatif aux prix des médicaments remboursables - 29 Decembre 1989 - Arrêté ministériel relatif aux prix des médicaments non remboursables - 20 Avril 1993 - Arrêté ministériel portant dispositions particulières en matière de prix - 12 Decembre 2000 - Arrêté ministériel fixant le prix des grands conditionnements de médicaments remboursables à partir du 15 décembre 2000 - 12 August 2005 - Arrêté ministériel modifiant l’arrêté ministériel du 29 Décembre 1989 relatif aux prix des médicaments remboursables		

1 Prices must be notified

2 i.e. either a new active ingredient or a new therapeutic indication

Source: ÖBIG 2006

3.2.1.1 Manufacturer Price

The maximum manufacturer prices of all reimbursable pharmaceuticals and of all non-reimbursable pharmaceuticals not considered as "new" are fixed by the federal Public Service for Economy, SMEs, self-employed and Energy, based on advice of the Medicines Pricing Commission (Commission des Prix des Spécialités Pharmaceutiques, CPSP). The maximum manufacturer price is expressed as a price per pack and per unit, to be applied in the out-patient and hospital sectors respectively. The maximum unit price (manufacturer price excluding VAT) for large packages of reimbursable pharmaceuticals must be at least 20% cheaper than the maximum unit price for the smallest reimbursable package.

3.2.1.2 Wholesale Price

The wholesale margins for all pharmaceuticals (reimbursable and non-reimbursable) are fixed (cf. Table 3.3).Though the margins of generics are not fixed they may not exceed the absolute value of the margin of the corresponding product.

3.2.1.3 Pharmacy Retail Price

The pharmacy margins for reimbursed and non-reimbursed pharmaceuticals are also fixed (cf. Table 3.3). As this system does not favour generic medicines because pharmacists would receive less in absolute terms when delivering a cheaper generic, pharmacists' profits on generic pharmaceuticals were set equal to their profits on the originator medicines. Like the wholesale margins, the pharmacy margins of generics are thus not fixed, but they may not exceed the absolute value of the margin of the corresponding product.

Table 3.3: Belgium - Wholesale and Pharmacy Margins, 2006

Pharmacy retail price (PRP) in € (excl. VAT)	Wholesale margin	Pharmacy margin
0.00 - 24.00	13.1% of wholesale price (15.08% of manufacturer price)	31% of PRP (51.7% of manufacturer price)
24.01 - 38.97	€ 2.18	€ 7.44
> 38.97[1]	€ 2.18 plus 0.68% of (PRP - € 24.-)	€ 7.44 plus 2.32% of (PRP - € 24.-)
> 66.76[1]	€ 2.18 plus 0.77% of (PRP - € 24.-)	€ 7.44 plus 2.61% of (PRP - € 24.-)

[1] For reimbursed pharmaceuticals only. For non-reimbursed pharmaceuticals, the maximum margin of € 2.18 for wholesalers and € 7.44 for pharmacies applies to all pharmaceuticals with a PRP above € 24.-

Source: ÖBIG 2006

The same distribution margin structure and VAT rate are applied to OTC as well as for prescription medicines. The absolute value of the pharmacy margin of a generic may be equal to the margin of the branded pharmaceutical. This implies that the margin (in %) of generics may be higher in case the price is lower.

Due to the increasing number and use of expensive innovative medicines an extra margin level, for pharmaceuticals priced above € 66.76 (cf. Table 3.3) , was implemented in 2005[69].

[69] Arrêté ministériel du 12 August 2005 modifiant l'arrêté ministériel du 29 Décembre 1989 relatif aux prix des médicaments remboursables

3.2.1.4 Value Added Tax (VAT)

The standard VAT rate is 21% and the VAT rate all pharmaceuticals is 6%.

3.2.2 Price Related Cost-containment Measures

3.2.2.1 Pharmaco-economic Evaluation

As part of the new reimbursement system, which was introduced in 2002, pharmaco-economic analysis and budgetary consequences are included in the decision making process.

For pharmaceuticals with a proven improvement in therapeutic benefit (therapeutic value class 1 (cf. 3.3.1.2)) manufacturers must provide pharmaco-economic information for decision on the reimbursement price and for re-evaluation. Official guidelines state that the manufacturer should demonstrate total costs, effectiveness, cost-benefit ratio and target population. Pharmaco-economic requirements are not mandatory for other pharmaceuticals.

A proposal for methodological guidelines for economic evaluation of pharmaceuticals was already compiled in 1995 by the Belgian Society for Pharmaco-epidemiology. Moreover, a standard report format for economic evaluations in Belgium was compiled in 2002 (Annemans 2002) which fits into the new reimbursement context, where therapeutic value and the trade-off between this value and the cost of treatments are key criteria.

3.2.2.2 Internal Price Referencing

The application dossier for pricing, which is submitted to the Price Department (Service de prix) of the Federal Public Service for Economy, SMEs, Self-employed and Energy, must contain market and competition reports, including the prices and volumes of similar products and/or therapeutic equivalents.

3.2.2.3 External Price Referencing / Cross Country Referencing

In Belgium the methodology of external price referencing is not an explicit criterion in the pricing procedure. However, when setting the prices, the prices of the same and comparable pharmaceuticals in other countries are taken into consideration. The application dossier for pricing must contain a price comparison with other EU Member States. The manufacturer chooses the prices included in the pricing dossier. Generally, 3 to 10 prices are provided including prices in France, the UK, Germany and the Netherlands.

3.2.2.4 Price Freezes / Stops

Prizes were not allowed to increase from 1996 till 1997, from 1998 to 2003, and again from 2005 till 2006[70].

When prices are not frozen, applications for price increases are submitted to the FPS Economy and must include all the documents necessary for the initial price setting, plus details of:

- The present price structure
- The volumes sold in Belgium
- A justification for a price increase and the suggested price

3.2.2.5 Price Cuts

Price revisions have been very frequent in Belgium over the past decade. In June 1996 the Belgian government introduced a 2% price cut in the manufacturer price of all reimbursed medicines. In addition, prizes for pharmaceuticals which had been included in the reimbursement list for more than 15 years were reduced by 4%. This rate was increased to 8% in 1999, 12% in 2000 and 14% in 2004. Also since 1 March 2004, an additional 2.3% (resulting in a total of 16.3%) decrease has been applied for pharmaceuticals reimbursed for 17 years[71]. As a result of this, more than 1,500 pharmaceuticals, including almost 400 generics, saw their prices cut on 1 March 2004.

Since 2005, these price reductions have become automatic when a pharmaceutical reaches its anniversary, instead of being effective on 1 January or 1 July following the anniversary. Exemptions used to be made individually for pharmaceuticals still under patent[72]. This exemption rule was abolished in 2005.

3.2.2.6 Margin Cuts

Wholesale and pharmacy margins for all pharmaceuticals are statutorily regulated (cf. 3.2.1.2 and 3.2.1.3). No margin cuts have taken place in the past years.

3.2.2.7 Discounts and Rebates

In 2000, the industry signed an agreement, which was called the “pax pharmaceutica”. Herein the industry agreed to pay back 65% of the overspend resulting from government’s under-funding of the pharmaceutical budget. This contribution is known as the claw-back system. In 2005 the percentage was increased from 65% to 72%. Generics manufacturers are exempt from the claw-back system.

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70 Arrêté ministériel du 13 Juin 2005 modifiant l’arrêté ministériel du 29 décembre 1989 relatif aux prix des médicaments remboursables

71 Arrêté ministériel du 29 Janvier 2004 modifiant l’arrêté ministériel du 21 février 2000 diminuant les prix de certains médicaments remboursables

72 Arrêté ministériel du 14 Mai 2004 modifiant l’arrêté ministériel du 21 février 2000 diminuant les prix de certains médicaments remboursables

In 2004, a separate budget and payback arrangements were introduced for statins. The claw-back level of 72% is also applicable to expenditure on statins.

It is common for wholesalers to give discounts to pharmacists. As of April 2001, pharmacists are required to demand the entire patient co-payment for reimbursable pharmaceuticals. Prior to this, they regularly offered discounts to their costumers, usually amounting to 10% of their total co-payment expenditure. The system whereby pharmacists could offer discounts to their customers on their co-payment was abolished. In order to control pharmacists' revenues, a tax was introduced in 2002 corresponding to 7.7% of patient co-payments. In 2004, pharmacists had to pay the equivalent of 4.5% of patient co-payments. The re-payment was maintained at this level in 2005, but it may be increased in order to ensure that pharmacists' margins do not exceed € 501 million.

3.2.2.8 Company Profit Controls

A tax is levied on the turnover of reimbursable pharmaceuticals (Taxe "Busquin"). The industry paid a rate of 2% on the 2003 turnover. In addition, a supplementary tax can be levied. In 2003, this supplementary tax represented 1.5% of turnover. Like the "Busquin" tax, this supplementary tax was paid to the National Institute for Sickness and Invalidity Insurance (INAMI).

In addition, since 2002, manufacturers have to pay an annual fee of € 1,487.36 for each reimbursable product presentation, unless sales of the product are below € 61,973.38 at manufacturer price (excluding VAT)[73].

3.2.2.9 Promotion Control

Regulations concerning the promotion of pharmaceuticals are laid down in a law[74]. An introduction of a tax on companies' promotional expenses has been proposed.

In 2005, a small budget of € 600,000.- was allocated by the government to cover the introduction of evidence-based advising physicians, which are neutral medical representatives to counter the promotion activities of pharmaceutical industry sales representatives.

[73] 21 décembre 2001 - Arrêté royal fixant les procédures, délais et conditions en matière d'intervention de l'assurance obligatoire soins de santé et indemnités dans le coût d es spécialités pharmaceutiques

[74] 16 décembre 2004 - Loi modifiant la réglementation relative à la lutte contre les excès de la promotion de médicaments

3.2.2.10 Parallel Trade

Before a licence for parallel trade is granted, a number of requirements need to be fulfilled. These requirements are defined in a Royal Decree[75]. The applicant for a licence for parallel trade needs to submit a dossier to the Dispatching division of the Directorate General medicines of the FPS Health, Food Chain Safety and Environment. The contents of this dossier are defined in article 4 of the Royal Decree of 19 April 2001.

As the prices of pharmaceuticals in Belgium are relatively low, the share of parallel imports is negligible, Belgium is a parallel exporter.

3.2.3 Co-Payments

Pharmacists are required to demand the entire patient co-payment for reimbursable pharmaceuticals (cf. 3.2.2.7). Traditionally patient co-payment has been high in Belgium.
The level of patient co-payment varies depending on the category of the pharmaceutical and the type of patient (cf. Table 3.4). The patient pays the fraction of the reference price that is not reimbursed as well as the full difference between the reference price and the actual price paid.
Certain persons, including widows, disabled persons, retired persons, orphans and persons over 50 years of age who have been unemployed for at least a year, are awarded a preferential reimbursement status.

If, within one calendar year, the co-payments of a family or person reach a certain threshold, then all co-payments for received health care are fully reimbursed for the rest of the calendar year. The threshold for co-payment is determined by the social status or the income. The categories are defined as described in Table 3.4.

Table 3.4: Belgium - Maximum Co-payment Categories, 2006

Category	Criteria	Maximum co-payment per year
Social	e.g. a disabled, retired, unemployed person or a person of 65 or older of age in the family	€ 450.-
Income	Family income between € 0 and € 14.878,24	€ 450.-
	Family income between € 14.878,25 and € 22.872,51	€ 650.-
	Family income between € 22.872,52 and € 30.866,80	€ 1,000.-
	Family income between € 30.866,81 and € 38.527,98	€ 1,400.-
	Family income above € 38.527,98	€ 1,800.-
Age	Persons younger than 19 years of age on 1 January	€ 650.-

Source: Institut national d'assurance maladie invalidité (INAMI)

[75] Arrête royal du 19 avril 2001 relatif a l'importation parallèle des médicaments a usage humain et la distribution parallèle des médicaments a usage humain et a usage vétérinaire.

3.2.4 Information Transparency and Marketing

Since 1974, the Belgian Center for Pharmacotherapeutic Information (Centre Belge d'Information Pharmacothérapeutique, BCFI)[76] has been providing systematic, independent information on pharmaceuticals in the form of:

- The Folia Pharmacotherapeutica, a monthly journal containing information on pharmaceuticals
- Information cards (Fiches) providing information on recently authorised active ingredients
- A yearly updated, commented list of pharmaceuticals available on the market and their prices (Répertoire Commenté des Médicaments). This commented list, which has been published by BCFI since 1977, aims to provide essential information about pharmaceutical specialties, and to help physicians in choosing the most suitable pharmaceutical
- The transparency-cards (fiches de transparence), which provide comparisons of different treatment alternatives for a number of diseases. These transparency-cards aim to help physicians and pharmacists in weighing the pros and cons of different treatment options.

With regard to information transparency, all governmental decisions, e.g. regarding new or withdrawn market authorisations of pharmaceuticals and changes in the positive list, are published in the Belgian law gazette (Moniteur Belge)[77].

The EU's provisions on pharmaceutical advertising laid down in Title VIII of the Community Code were implemented in Belgium in 1995[78] and were adapted according to new legislation of 2004. A number of provisions have been defined regarding the content and the means of advertising pharmaceuticals [78,79]. These provisions say for example that advertising is allowed for all non-prescription pharmaceuticals with market authorisation. The information given in the advertisement must be consistent with the product characteristics as they are written in the instruction leaflet, and as they were accepted when the pharmaceutical was authorised to be marketed. In addition, the advertisement must promote rational use of the pharmaceutical, by presenting it objectively and by not exaggerating its characteristics. The advertisement should not be misleading and the advertisement should contain some obligatory statements, which are indispensable for appropriate use of the pharmaceutical.

Some of the provisions defined aim specifically at advertisement towards the general public, or advertisement towards health personnel. The offering of discounts or rebates to physi-

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76 http://www.bcfi.be

77 http://www.ejustice.just.fgov.be/cgi/welcome.pl

78 Arrêté royal du 7 avril 1995 relatif à l'information et à la publicité concernant les médicaments à usage humain.

79 Arrêté royal du 20 mars 2002 modifiant l'arrêté royal du 7 avril 1995 relatif à l'information et à la publicité concernant les médicaments à usage humain

cians, pharmacists, dentists or institutions where pharmaceuticals are prescribed or administered is highly regulated[80].

Regarding the provision of information on pharmaceuticals towards patients, the members of the industry association pharma.be have subscribed to the present Code of Deontology, which was implemented on 1 January 2006[81]. This set of rules guarantees that the activities of the pharmaceutical companies in providing information on or advertising the pharmaceuticals they market takes place within a quality scientific framework that takes due account of the justified interests and expectations of the various health care players, including those of patients.

3.3 Reimbursement

Reforms to the reimbursement procedure were implemented in 2002[82] in order to bring the Belgian system into line with the EU Transparency Directive 89/105/EEC[83] and speed up the pricing and reimbursement process accordingly. An application for reimbursement must be submitted on the same day as the pricing application and both are evaluated simultaneously.

The following documents are required for reimbursement applications:

- Description of the product: active ingredient, presentation, packaging, indication and marketing authorisation details
- Reimbursement proposal: therapeutic value class, out-patient or hospital usage, reimbursement chapter (cf. 3.3.1), category (cf. Table 3.5) and price
- Justification of the reimbursement proposal: including clinical, epidemiological and - in certain cases - pharmaco-economic studies.
- Reimbursement conditions in other European Member States (optional)

While the pricing dossier is being examined by the Medicines Pricing Commission in order to establish a maximum manufacturer price, the reimbursement dossier is initially examined by neutral experts for the evaluation of the reimbursement conditions proposed by the manufacturer. Both the experts' reports (including any comments by the manufacturer) and the recommended maximum price are forwarded to the Medicines Reimbursement Commission (CRM) of the INAMI within 90 days.

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80 Loi du 16 Décembre 2004 modifiant la réglementation relative à la lutte contre les excès de la promotion de médicaments

81 Code of Deontology. Modified by the General Assembly of 14 December 2005. Association générale de l'industrie du médicament

82 Arrêté royal du 21 décembre 2001 fixant les procédures, délais et conditions en matière d'intervention de l'assurance obligatoire soins de santé et indemnités dans le coût d es spécialités pharmaceutiques

83 Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance system, http://pharmacos.eudra.org/F2/eudralex/vol-1/new_v1/890105en.pdf#search='89/105/EECeudra'

The CRM has a maximum of 60 days to submit its final suggestions regarding the reimbursement status and reimbursement price to the FPS Social security (SPF Sécurité sociale). The FPS Social security has an additional 30 days to make a decision; otherwise the reimbursement conditions initially proposed by the manufacturer will be adopted. This measure was implemented to ensure that the 180-day deadline imposed by the EU Transparency Directive 89/105/EEC[84] is respected.

3.3.1 Pharmaceutical Lists and Reimbursement Categories

Once reimbursement is approved by the Minister of Social Affairs and Public Health, pharmaceuticals are included in the list of reimbursable pharmaceuticals (liste des spécialités pharmaceutique remboursables), which is divided into chapters depending on the indications and the nature of the pharmaceutical:

- Chapter I: no additional restrictions. All pharmaceuticals in this chapter are reimbursable for all diseases.
- Chapter II: a posteriori control: To secure reimbursement, patients files have to be submitted by general practitioners, but verification is only carried out in the case of prescription anomalies. Verification is performed by the Service for Medical Evaluation and Control (Service d'évaluation et de contrôle médicaux, SECM) and by advising physicians from insurance institutions (médecin-conseil).
- Chapter IV: a priori control: Reimbursement entails the compilation of a comprehensive patient file and, after analysis of this file by an advising practitioner, authorisation for the general practitioner to prescribe the pharmaceutical for that patient. Addition of pharmaceuticals to this chapter may be the result of medical and/or budgetary factors.

The CRM provides the FPS Social security with advice regarding the chapter to which a pharmaceutical should be added.

3.3.1.1 Reimbursement Price

In addition to the reimbursement chapter (cf. 3.3.1), FPS Social security assigns a reimbursement category (cf. Table 3.5) to each pharmaceutical, according to the suggestions of the CRM. Reimbursement levels for each category are summarised in Table 3.6 [85].

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[84] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance system, http://pharmacos.eudra.org/F2/eudralex/vol-1/new_v1/890105en.pdf#search='89/105/EECeudra'

[85] Arrêté royal du 7 mai 1991 fixant l'intervention personnelle des bénéficiaires dans le coût des fournitures pharmaceutiques remboursables dans le cadre de l'assurance obligatoire soins de santé et indemnités.

Table 3.5: Belgium - Reimbursement Categories, 2006

Category	Type of pharmaceutical	Examples
A	Life saving pharmaceuticals	Cancer treatment, HIV/AIDS, diabetes
B	Important therapeutic pharmaceuticals	Antibiotics, cardiovascular disease treatment
C	Pharmaceuticals for symptomatic treatment of chronic diseases	Combined painkillers, vaccines
Cs		Antihistamines, flu vaccines
Cx		Antipasmodics, migraine treatment, oral contraceptives
D	Non-reimbursed pharmaceuticals	Sedatives and sleeping pills

Source: PPR 2005 (Pharmaceutical Pricing and Reimbursement 2005. A Concise Guide)

Table 3.6: Belgium - Reimbursement Levels, 2006

Category	Rate	Rate for preferential reimbursement[1]
A	100%	100%
B	75% (Maximum co-payment of € 10.40 for small packages and € 15.70 for large packages[2])	85% (Maximum co-payment of € 6.70 for small packages and € 10 for large packages[2])
B - ATC 4[3]	75% (Maximum co-payment of € 15.70 for small packages and € 23.50 for large packages[2])	85% (Maximum co-payment of € 10.40 for small packages and € 15.70 for large packages[2])
C	50% (Maximum co-payment of € 17.40)	50% (Maximum co-payment of € 10.40)
C - ATC 4[3]	50% (Maximum co-payment of € 26.10)	50% (Maximum co-payment of € 15.70)
Cs	40%	40%
Cx	20%	20%
D	0%	0%

[1] Preferential reimbursement is granted to invalids (depending on their revenue), orphans, pensioners, widows and widowers as well as their dependants

[2] Large packages contain a minimum of 60 units

[3] ATC 4 means that at least one reimbursable generic or therapeutic equivalent is available within the ATC class (level 4)

Source: ÖBIG

The maximum co-payments for categories B and C pharmaceuticals are updated in January each year.

The reimbursement price of therapeutically equivalent pharmaceuticals should be at least 30% below that of the reference pharmaceutical in the reference price system (cf. 3.3.2). The price of the cheaper non-branded pharmaceutical, which is thus (maximum) 70% of the price of the branded pharmaceutical, is used to calculate the maximum amount reimbursed for both the generic and the off-patent branded versions. For example, a patient opting for an off-patent branded pharmaceutical in category B, which has not cut its price to the generic (reference) price level, will only receive 75% of the generic price reimbursed. In cases where

there are no cheaper generics with the same active ingredient available, the patient will receive reimbursement over the full price of the branded pharmaceutical.

From 1 July 2006, the FPS Health will start the public tendering for manufacturers of cholesterol lowering pharmaceuticals. This will result in only the cheapest cholesterol lowering pharmaceutical being reimbursed for 75% (in case of category B). Other cholesterol lowering pharmaceuticals will receive only 50% reimbursement. The tendering of other groups of pharmaceuticals will follow after 1 July[86].

3.3.1.2 Selection Criteria

The FPS Social security, advised by the CRM, takes the following factors into account when coming to its final decision concerning the reimbursement of pharmaceuticals[87]:

- The therapeutic value, which is expressed by applying the following classification:
  - Class 1: Products with a proven improvement in therapeutic benefit compared to existing alternatives.
  - Class 2: products with no proven improvement in therapeutic benefit, which do not belong to class 3.
  - Class 3: generics
- The maximum price set by the Ministry of Economic Affairs, and the price proposed by the manufacturer (cf. 3.2.1).
- The importance of the pharmaceutical in medical practice in terms of current therapeutic and social needs.
- The budgetary implications of reimbursing the pharmaceutical
- The cost / benefit ratio

3.3.1.3 Pharmaceuticals on Positive List

In 2005, a total of 19,686 presentations pharmaceuticals for human use were authorised in Belgium. Of these, 6,093 are reimbursed[88]

3.3.1.4 Generics

The reimbursement price of generics must be at least 30% lower than that of the reference pharmaceutical in the reference price system (cf. 3.3.1.1).

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86 Albers 2006

87 Arrêt royal du 21 Décembre 2001 fixant les procédures, délais et conditions en matière d'intervention de l'assurance soins de santé et indemnités dans le coût des spécialités pharmaceutiques, article 4-5

88 Byl 2005

3.3.1.5 Non-reimbursable Pharmaceuticals

Pharmaceuticals may be excluded from reimbursement based on the criteria mentioned under 3.3.1.2. In theory, OTC medicines are not reimbursable. Only a few OTC medicines can be reimbursed if prescribed by a doctor.

3.3.1.6 Delisting and Switches

Both the manufacturer and the Minister of Social Affairs can suggest the delisting of pharmaceuticals from the reimbursement list. In addition, pharmaceuticals with a proven improvement in therapeutic benefit compared to existing alternatives (Class 1, cf. 3.3.1.2) are subject to re-evaluation of their reimbursement price and reimbursement conditions after being 1.5 to 3 years on the list of reimbursable pharmaceuticals. The documents required for this evaluation include:

- Re-evaluation report (including comparative clinical studies, epidemiological and pharmaco-economic studies)
- Manufacturer's turnover for all presentations containing the same active molecule since admission on the reimbursement list
- Reimbursement conditions in other EU Member States

Applications for POM-to-OTC switches are evaluated on a case-by-case basis. There is no specific national legislation governing switches. It is possible for a switched (from prescription-only status to OTC) product to keep reimbursement, provided that they are prescribed by a doctor.

3.3.2 Reference Price System

A reference price system was introduced in June 2001 for pharmaceuticals with generic equivalents, where the reimbursement price is based on that of the generic rather than that of the branded pharmaceutical. This means that a patient opting for an off-patent branded pharmaceutical in reimbursement category B, of which the price has not been cut to the price level of the generic (i.e. reference price) will only receive reimbursement at 75% of the generic price. The reimbursement price is set on the basis that the price of the generic is 30% below that of the branded pharmaceutical.

Until July 2005, the Belgian government applied the reference payment principle in such a strict sense, that a pharmaceutical was included in the reference price system only if a pharmaceutical which was identical in terms of active substances, dosage, pharmaceutical form and mode of action existed. Under the new system, which entered into effect in July 2005, the presence of a generic with the same active substance is a sufficient condition for a pharmaceutical to become included in the reference price system. As soon as the first generic version is commercialised, the branded pharmaceutical is included in the reference price system on the following 1 January or 1 July.

3.3.3 Pharmaceutical Budgets

In Belgium there are no pharmaceutical budgets being applied for doctors or other health care providers, meaning there is no fixed prescribing budgets in terms of money for health care professionals.

3.3.4 Other Volume Control Oriented Measures

3.3.4.1 Prescription Monitoring and other Doctors-related Measures

Since 1996, statistical information on reimbursable pharmaceuticals used in the out-patient sector has been gathered at the pharmacy level; however, this information corresponds to the pharmaceutical prescribed and not to that actually dispensed.

The aim of a monitoring programme, known as Pharmanet, which went fully operational in 2004, is to provide the INAMI with information on medical practice. General practitioners are informed of their prescription habits, and on how they perform compared with other general practitioners during specific public health campaigns. These campaigns for example cover antibiotics or medication for high blood pressure. This can lead to agreements between doctors and insurers; e.g. to guarantee that practitioners, who are below certain prescription levels for antibiotics or for high blood pressure medication, receive a bonus.

Physicians are subject to a priori and a posteriori approval controls for the reimbursement of pharmaceuticals subject to conditional reimbursement (Chapter IV and Chapter II, cf. 3.3.1).

In addition, as of 1 April 2006, doctors are required to prescribe a set minimum, depending on their medical specialty, of lower priced pharmaceuticals. The volume quotas, expressed in Defined Daily Doses (DDD), affect reimbursable out-patient pharmaceuticals dispensed by retail pharmacies, but not pharmacists' magistral preparations. For the general practitioners, the minimum prescribing rate for lower priced pharmaceuticals is 27% of all prescriptions expressed in DDD. The following are considered as cheaper alternatives:

- INN prescriptions
- Generics prescribed by brand name
- Prescriptions by brand name for original products priced at the reference price level

The electronic prescription monitoring system Pharmanet collects data allowing the assessment of individual doctor's prescribing practices. Doctors' prescribing habits will be monitored every six months. If a doctor fails to attain the national minimum without sufficient justification, his/her prescriptions will be monitored for a further six months. If no improvement is recorded by the end of this period, the doctor will be liable for a fine of € 1,000.- to € 5,000.-. Numbers published by Pharma.be showed that in 2005 the share of 'cheaper pharmaceuticals' of all prescribed pharmaceuticals was already 31.7% (in DDD), whereas in 2004 this share amounted to only 18.2%.

A monthly pharmaceutical bulletin and a yearly pharmaceutical formulary which is edited by an independent scientific body (Centre Belge d'Information Pharmacothérapeutique, CBIP) is issued to prescribers and pharmacists. Within the formulary, the lower priced pharmaceuticals are marked and basic price comparisons of pharmaceuticals are provided.

3.3.4.2 Generics and Parallel Trade

A law permitting generic substitution was passed in 1993[89] but no further administrative acts have been passed in the meantime to actually implement the legislation. This means that in practice substitution is not allowed unless the pharmacist has the express permission of the prescriber to do so, and in very exceptional cases (e.g. during the weekend).

Prescription by international non-proprietary name (INN) was introduced on 1 October 2005. Previously, although INN prescriptions had not been explicitly prohibited, no reimbursement could be granted for pharmaceuticals prescribed by INN. The new legislation does not oblige doctors to prescribe by INN, pharmacy dispensing regulations for INN prescriptions are as follows:

- Dispense a presentation containing the active ingredient at the dosage and pack size prescribed. If the pack size is not stated, pharmacists must supply the smallest pack. If the pack size prescribed does not exist, or is not reimbursed, the pharmacist will dispense a pack size as close as possible to that prescribed, but with fewer units.
- Dispense either a generic (or a parallel imported pharmaceutical) or a branded pharmaceutical if several presentations are available, provided the price of the branded product has been cut to the reference level. If the pharmacist has a choice of several products, he/she must dispense the presentation most appropriate for the patient in terms of expenditure as well as therapeutic effect. Where some products require no prescription control (Chapter I) but others require a posteriori control (Chapter II), the pharmacist will dispense pharmaceuticals under Chapter I.
- Dispense the branded product when it is the only version marketed.

The introduction of reference pricing has stimulated the use of generics, which used to be very limited before 2001. As a consequence, the market share of generics increased to 10% by the beginning of 2004.

[89] Loi du 6 août 1993 portant des dispositions sociales et diverses

3.4 Overview of the Reimbursement Market in Belgium

Tasks / Duties	Yes	No	Comment	Legal bases
Public Authorities				
Decide on prescription status	X		FPS Health, Food Chain Safety and Environment	Arrêté royal du 3 juillet 1969 relatif à l'enregistrement des médicaments
Decide on manufacturer price	X		Maximum price of prescription-only pharmaceuticals seeking reimbursement is set by the FPS Economy, SMEs, Self-employed and Energy	29 Decembre 1989 - Arrêté ministériel relatif aux prix des médicaments remboursables 29 Decembre 1989 - Arrêté ministériel relatif aux prix des médicaments non remboursables
Agree on manufacturer price or reimbursement price		X		
Fix wholesale margin	X		Regulated via regressive mark-up scheme	
Fix pharmacy retail price	X		Regulated via regressive mark-up scheme	
Decide on reimbursement status	X		FPS Social security	Arrêté royal du 21 décembre 2001 fixant les procédures, délais et conditions en matière d'intervention de l'assurance obligatoire soins de santé et indemnités dans le coût d es spécialités pharmaceutiques
Decide on reimbursement price	X		FPS Social security	
Use Pharmaco-economic guidelines	X			
Use Internal reference pricing	X			
Use External reference pricing		X	Prices in other countries are only „taken into consideration"	
Price freezes	X		1996, 1998 - 2003, 2005	
Margin cuts				
Discounts and Rebates	X		Industry claw-back system, tax on co-payments	
Company profit control	X		Taxe "Busquin"	
Country specific:	X			
Pharmaceutical Industry				

Tasks / Duties	Yes	No	Comment	Legal bases
Sets manufacturer price freely		X		
Notifies manufacturer price	X		For non-reimbursable pharmaceuticals considered as "new" (= new active ingredient + new therapeutic indication)	
Negotiates manufacturer price		X		
Is free to set price below fixed manufacturer price	X			
Decides on application for reimbursement	X			
Negotiates reimbursement price		X		
Free to keep manufacturer price above reimbursement price	X		Very uncommon, only within the framework of reference reimbursement	
Free to grant rebates / discounts to wholesalers	X			
Free to grant rebates / discounts to pharmacies	X		No rebates in kind	
Can engage in marketing towards doctors	X			
Can engage in public advertising	X		Only for OTC	
Can provide information toward patients	X			
Applies for switches and de-listing	X			
Country specific:	Industry has agreed to pay back 65% of the overspend resulting from government's under-funding of the pharmaceutical budget			
Distribution Chain				
Wholesaler				
Margins are fixed by statute	X		Regulated via regressive mark-up scheme	

Tasks / Duties	Yes	No	Comment	Legal bases
Margins are subject to statutory discounts / rebates		X		
Free to grant discounts / rebates to pharmacies	X			
Pharmacists				
Margins are fixed by statute	X		Regulated via regressive mark-up scheme	
Free to set retail price		X		
Obliged to inform patient on cheaper product		X		
Obliged to substitute by a generic		X		
Allowed to substitute by a generic		X	Only with permission of prescriber	
Obliged to substitute by a parallel import		X		
Allowed to substitute by a parallel import		X		
Therapeutic / analogous substitution is allowed		X		
Are subject to statutory discounts / rebates	X		Tax corresponding to 4.5% of patient co-payments	
Claw back system exists		X		
May grant rebates to customers		X		
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			
Are obliged to inform on co-payment / deductibles		X		

Tasks / Duties	Yes	No	Comment	Legal bases
Prescription habits are monitored	X			
Are subject to prescription guidelines	X			
Budgets are controlled		X		
Allowed to prescribe INN	X			
Obliged to prescribe INN		X		
Can oppose generic substitution			Not applicable	
Can oppose therapeutic substitution			Not applicable	
Can oppose substitution by parallel import			Not applicable	
Country specific:				
Patients				
Can shop for cheapest price of the product		X		
Pay a flat rate per prescription/pack		X		
Pay a certain percentage per prescription / pack or a deductible	X		With a maximum for some Reimbursement Categories	
Annual minimum co-payment		X		
Annual maximum co-payment	X			
May ask for substitution by a generic			Not applicable	
May oppose substitution by a generic			Not applicable	
May ask for substitution by a parallel import			Not applicable	
Can oppose substitution by a parallel import			Not applicable	

Tasks / Duties	Yes	No	Comment	Legal bases
Can oppose substitution only on payment of price difference			Not applicable	
Has to pay the difference between reimbursement and retail price	X			
Has access to full public information on prices and products	X			
Country specifics:				

Source: ÖBIG 006

CYPRUS

4 Cyprus

4.1 Pharmaceutical System

4.1.1 Regulatory Framework and Authorities

The health care system in Cyprus is a public system, de facto a National Health Care Service, even though it has never been officially stated. Besides the public system, there is a significant private sector. Those two sectors exist next to each other but are not complementary.

The key authorities in the pharmaceutical system in Cyprus (public and private) are:

- the Ministry of Health (MoH), which is responsible for purchasing pharmaceuticals (public sector), for the decision on reimbursement (public system) and on prices (public and private system)[90].
- the Department of Pharmaceutical Services of the MoH is in charge of issuing market authorisation and the classification of pharmaceuticals (public and private system). The market authorisation procedure was harmonised to EU legislation in 2001[91].

In the *private system* pharmaceuticals are either locally produced or imported, with imported pharmaceuticals being the majority. Pharmaceuticals have to be authorised by the Department of Pharmaceutical Services of the MoH. They are dispensed in private pharmacies. Patients have to pay the full price for pharmaceuticals.

Under the *public system*, the MoH purchases pharmaceuticals via tendering. In the tender process decisions are made on the basis of the cost of therapy, safety, quality, efficacy and especially the price. Non-registered pharmaceuticals are also distributed by the public system. The MoH provides a comprehensive range of health care services free or at reduced rates to eligible population, which accounts for around 80% of the population. However, there are still a lot of people opting for private health services, since they expect a quicker access to diagnosis and treatment (cf.4.3.1).

In the course of preparing for the accession to the European Union in May 2004, significant reforms to all areas of the health care market were and are still undergoing in order to be in line with the European laws and directives.

One of the core issues of the health care reforms is the full implementation of the General Health System (GHS) by the year 2008. The general principals of the GHS are the following[92]:

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90 Law of Medicines of Human Use, Article 91

91 Law No. 70(I)2001

- Universal coverage of the population, free access at the point of use for all residents.
- Financing from contributions by employers, employees, pensioners and the government.
- Free choice of doctors and hospitals between the public and the private sectors - where general practitioners act as gatekeepers to specialised services.
- Management by a Legal Entity of Public Law (Health Insurance Organisation, HIO), managed by representatives of the government.
- Maintenance of high quality standards through monitoring of all health providers.
- There will be free access to health care for uninsured, and persons with limited resources as well as for chronically ill persons with disabilities and large families.

Table 4.1 contains an overview of the relevant stakeholders introduced in section 4.1.1.

Table 4.1: Cyprus - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Ministry of Health (MoH)	Ministry of Health (legal Framework), in charge of classification, reimbursement, and pricing	MoH 1475 Lefkosia, Cyprus Tel.: +357 2240 7100 Fax: +357 2240 7149 ministryof-health@cytanet.com.cy www.moh.gov.cy/moh/moh.nsf/index_en/index_en?OpenDocument	Mr. Andreas Gavrielides Minister 1475 Lefkosia, Cyprus Tel.: +357 2240 7100 Fax: +357 2240 7149 ministryofhealth@cytanet.com.cy
Department of Pharmaceutical Services of the MoH	Market authorisation and classification of pharmaceuticals (public and private system), purchase of pharmaceuticals (public system)	MoH 1475 Lefkosia, Cyprus Tel.: +357 2240 7101 107 Fax: +357 2240 7149 ministryof-health@cytanet.com.cy rocphc1@cytanet.com.cy or ditcc@cytanet.com.cy	Mr. Athos Tsinontides Clinical Pharmacist PharmD 1475 Lefkosia, Cyprus Tel.: +357 2240 7101 Fax: +357 2240 7149 atsinontides@phs.Moh.gov.cy

[92] National Action Plan for Social Inclusion, http://europa.eu.int/comm/employment_social/social_inclusion/docs/nap_incl_2004_cy_en.pdf

Institution	Task	Contact details/URL	Responsible person
Cyprus Association of Pharmaceutical Companies (CAPC)	Association of Pharmaceutical Industry	CAPC P.O. Box 21455 1509 Nicosia, Cyprus Tel.: +357 2288 9800 Fax: +357 2266 8630 chamber@ccci.org.cy www.capc.org.cy	Mr. Sotos M. Jacovides President. P.O. Box 21593 1511 Nicosia, Cyprus Tel.: +357 2275 7188 Fax: +357 2275 0604 Msj_info@spidernet.com.cy
Cyprus Pharmaceutical Association (CPA)	Association of Pharmaceutical Industry	CPA P.O.BOX. 20611 Nicosia, Cyprus Tel.: +357 2751 801 Fax: +357 2755 710 phaassoc@logos.cy.net www.cpa.org.cy	CPA P.O.BOX. 20611 Nicosia, Cyprus Tel.: +357 275 1801 Fax: +357 275 5710 phaassoc@logos.cy.net www.cpa.org.cy
Pancyprian Pharmaceutical Association	Pharmacy's Association	Pancyprian Pharmaceutical Association 37B Digenis Akritas Aven P.O. Box 7073 1055 Nicosia, Cyprus Tel.: + 357 22 407 105 Fax: + 357 22 776 260 paracelsus@cytanet.com.cy	Mr. Nicos Nouris 37B Digenis Akritas Aven P.O. Box 7073 1055 Nicosia, Cyprus Tel.: + 357 22 407 105 Fax: + 357 22 776 260
Cyprus Consumers Association (CCA)	Patients' Association	CCA 5 Acropolis Ave., (Flat 21) 2000 Strovolos P.O.Box 24874 1304 Nicosia, Cyprus Tel.: +357 2251 6112 Fax: +357 2251 6118 cyconsas@spidernet.net or cca@spidernet.net www.cyprusconsumers.org.cy/	CCA 5 Acropolis Ave., (Flat 21) 2000 Strovolos P.O.Box 24874 1304 Nicosia, Cyprus Tel.: +357 2251 6112 Fax: +357 2251 6118 cyconsas@spidernet.net or cca@spidernet.net www.cyprusconsumers.org.cy/

Source: ÖBIG 2006

4.1.2 Market Players

4.1.2.1 Pharmaceutical Industry

In Cyprus, the pharmaceutical industry sector is split into companies that import and distribute their own pharmaceuticals, as well as wholesalers who store and distribute pharmaceuticals. Additionally there are 60 importers, who act at the same time as wholesalers. Among these leading importers/wholesalers are MS Jacovides/MSJ, Marathon Trading and Geo Pavlides & Araouzos.

There are 5 locally producing manufacturers (exclusively generics) and 50 international pharmaceutical companies, which are represented in the Association of Pharmaceutical Companies, CAPC[93]. These pharmaceutical companies are mainly subsidiaries of international pharmaceutical companies, who do not import by themselves but through distributors.

4.1.2.2 Distribution

In 2002, the total health expenditure for the permanent residents represented 5.8% of the GDP, whereas 2.85% were public expenditure and the rest were private expenditure[94].

In general, pharmacies are the only health establishments authorised to dispense POM and OTC to the general public. There are two exceptions: aspirin may also be sold outside of pharmacies i.e. supermarkets, and in a few cases doctors are allowed to dispense pharmaceuticals.

In Cyprus, there are around 440 pharmacies in the private sector. There are no geographical or demographical criteria for opening a new pharmacy. Generally pharmacies are rather small with one pharmacist working in the pharmacy. The pharmacist has to be present when pharmaceuticals are dispensed. Pharmacy chains are only allowed if 51% of the ownership are in the hands of a pharmacist. Until now there is only one pharmacy chain in Cyprus.

Additionally hospitals can also dispense pharmaceuticals to eligible patients under the public system. There is no pharmacy mark-up on pharmaceuticals distributed through this channel.

4.1.2.3 Patients

Patients play a minor role in the choice of pharmaceuticals. Furthermore patients are not informed on pharmaceuticals and on their prices.

In many cases patients opt to pay for health care services and pharmaceuticals out of their own pockets, since there is a greater choice of services and pharmaceuticals in the private system.

At present, patients can freely choose their doctors; there is no gatekeeping system. Besides patients can consult private doctors in any specialisation at their own expense. In the private sector, there are no regulations for the remuneration of doctors, whereas in the public system doctors are paid on a fee-for service basis.

Patients have the choice to make use of public health care in about 300 health centres, 11 out-patient departments and 4 district hospitals. Additionally, they can also utilize around 100 hospitals in the private system. In 2003, 33% of patients visited out-patient departments in

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93 www.capc.org.cy

94 National Action Plan for Social Inclusion, http://europa.eu.int/comm/employment_social/social_inclusion/docs/nap_incl_2004_cy_en.pdf

public hospitals, while 67% visited private health care facilities. In contrast, public hospitals accounted for 79% of hospitalisation days[95].

Table 4.2 summarises the above mentioned actors in the pharmaceuticals distribution.

Table 4.2: Cyprus - Overview of the Pharmaceutical Distribution, 2005

Actors of the pharmaceutical distribution	2005
Pharmaceutical industry	~ 55[1]
Wholesalers	60
Pharmacies	440
Other dispensary	40
Inhabitant per pharmacy	1,660
Inhabitant per dispensary (pharmacies and hospital pharmacies)	1,522

[1] 5 locally producing manufacturers (generic manufacturer) and around 50 subsidiaries of international pharmaceutical companies

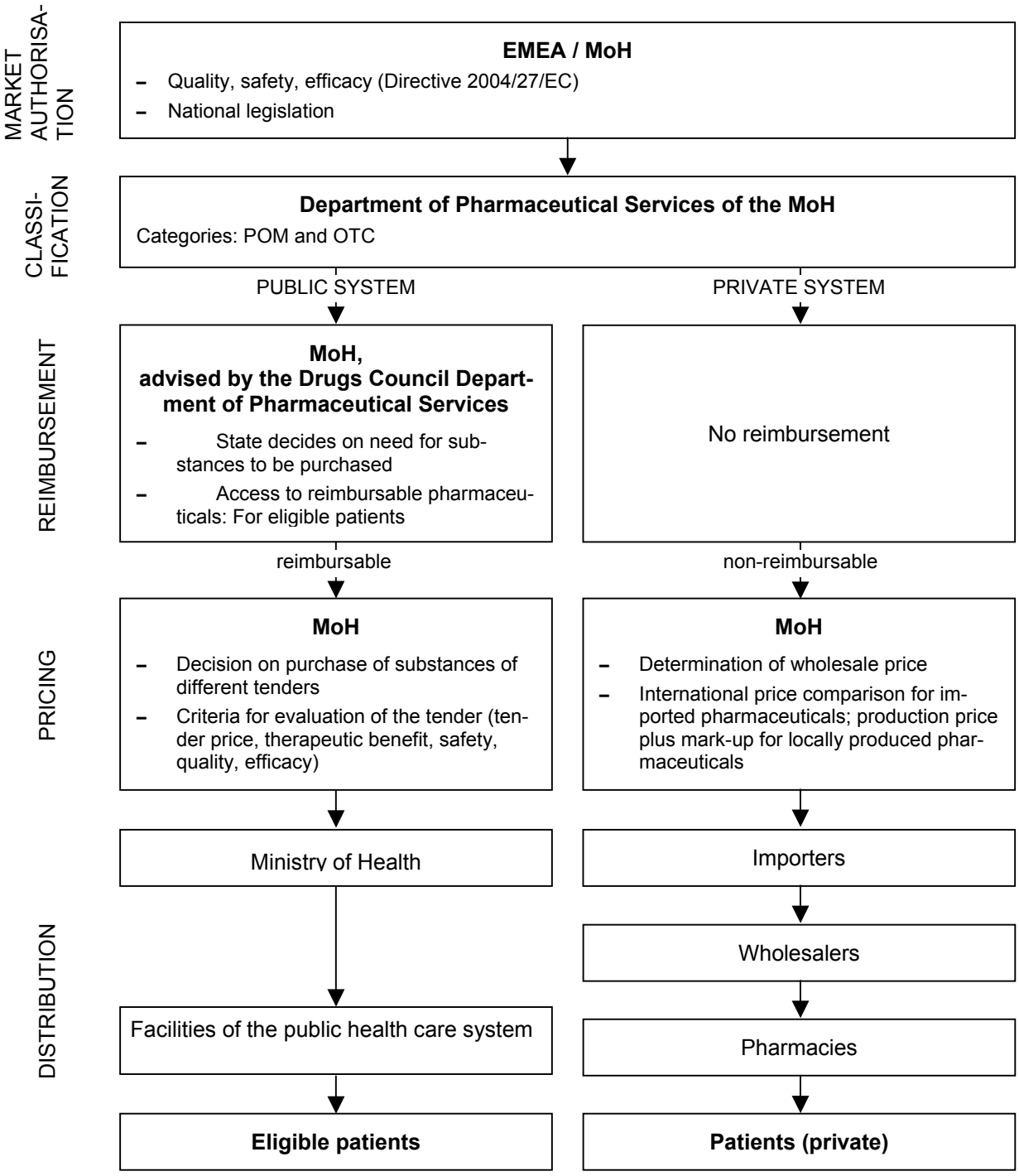
[2] 40 hospitals: act as public pharmacies to eligible patients

Source. Ministry of Health, Department of Pharmaceutical Services; data gathering by ÖBIG

Figure 4.1 on the next page shows an overview of the pharmaceutical system in Cyprus

[95] According to a study by the London School of Economics commissioned by the Ministry of Health in Cyprus

Figure 4.1: Cyprus - Pharmaceutical System, 2006



POM = Prescription-only Medicines, OTC = Over-the-Counter

Source: ÖBIG 2006

4.2 Pricing

4.2.1 Scope of Price Control

In Cyprus, there are two different pricing systems, depending on whether the pharmaceutical is distributed in the private system or under the government controlled system[96].

In the *private system* a new pricing procedure came into force in March 2005. The prices at the wholesale level are statutorily set by the MoH on the basis of the advice of the Price Committee[97] within the Department of Pharmaceutical Services (cf. 4.2.1.2).

In the *public system* pharmaceuticals are purchased through tendering operated by the Department of Pharmaceutical Services of the MoH. The criteria that are considered in the tender processes are the cost of the therapy and its safety, quality and efficacy, although price considerations generally take priority. It takes around three months to complete the tendering process and award a contract. The contract is then valid for 12 to 24 months, depending on the pharmaceutical.

Through the tender process the MoH can take advantage of economics of scale by buying products in bulk. Consequently prices are generally lower than the maximum prices set by the Price Committee in the private system.

Table 4.3 provides a concise overview of the pricing system in Cyprus (only private system).

96 MOH Circular: 12/01/05 New Pricing Policy (MOH ref PH.S.21.6.03)

97 Members are from the government, the Ministry of Finance, the Ministry of Commerce and Industry, and associations representing pharmacists, importers, patients and industry

Table 4.3: Cyprus - Pharmaceutical Pricing System in the Private Sector, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	*Imported* pharmaceuticals	Not applied	Not applied
Statutory Pricing	*Locally* produced pharmaceuticals on the basis of production costs	- *Imported* pharmaceuticals on the basis of international price comparison - *Locally* produced pharmaceuticals are regulated via a maximum mark-up of 20%	*Locally* produced pharmaceuticals are regulated via a maximum mark-up of 33%
Price Negotiations	*Imported* pharmaceuticals between importer and wholesaler	Not applied	Not applied
Price/volume agreements, discounts/rebates	No	No	No
Institution in charge of pricing	- MoH		
Legal Basis	- MOH Circular: 12/01/05 New Pricing Policy (MOH ref PH.S.21.6.03) - Law of Medicines of Human Use, Article 91 (2)		

Source: ÖBIG 2006

4.2.1.1 Manufacturer Price

In the old pricing system (before March 2005) the prices of all pharmaceuticals (locally produced and imported) were statutorily set at the manufacturer level in the private system.

For *locally* manufactured pharmaceuticals the manufacturer price was set and still is set on the basis of the production cost.

For *imported* pharmaceuticals a further 6% was then added to cover cost, insurance and freight (CIF) charges as well as a maximum margin of 25% to 33% for wholesale and pharmacy. For products imported from Greece, 12% was added to the manufacturer price to cover the cost of free medical samples distributed to doctors.

Since March 2005 Cyprus has a new pricing procedure, in which the old pricing procedure for *locally* manufactured pharmaceuticals (mainly generics) is still applied: the manufacturer price is set on the basis of the production cost.

The manufacturer prices for *imported* pharmaceuticals are freely negotiated between the pharmaceutical company/importer and the wholesaler. The authorities do not know the manufacturer prices of imported pharmaceuticals.

4.2.1.2 Wholesale Price

The wholesale price of *imported* pharmaceuticals is statutorily set on the basis of an international price comparison with 4 countries, and a 3% mark-up is added to cover the transport and import expenses.

In order to bring the level of prices of pharmaceuticals in Cyprus close to the average of Europe, one country with high prices, two countries with intermediate prices and one country with low prices of pharmaceuticals have been chosen for the "basket" of countries[98].

The following countries represent the countries of reference. In the case of pharmaceuticals that do not circulate in these countries, the alternative countries of reference will be taken into consideration[99]:

- Sweden (alternative countries: Denmark and Germany)
- Austria and France (alternative countries: Italy and Belgium)
- Greece (alternative countries: Spain and Portugal)

The maximum wholesale price is calculated on the average of the manufacturer price in the reference countries. As already mentioned before, a 3% mark-up is added to cover the transport and import expenses. The wholesale price of pharmaceuticals in the countries of reference or in the alternative countries of reference are calculated based on their pharmacy retail price by the pharmacists after deducting the pharmacist's margin and the VAT if applicable. The prices of the countries of reference are converted in Cyprus pounds, according to the average annual foreign exchange rates.

There are no statutory regulations for wholesale mark-ups for *imported* pharmaceuticals. The price span can be freely negotiated between the wholesalers and the pharmaceutical industry/importer. According to the MoH the average wholesale margin amounts to 14.35% based on the wholesale price.

The maximum wholesale price for *locally* produced pharmaceuticals is the production cost plus a mark-up of 20%[100]. Additionally the general regulation for generics is applied, that the maximum wholesale price for generics may not exceed 80% of the wholesale prices of original products (cf. 4.3.1.3).

4.2.1.3 Pharmacy Retail Price

The maximum mark-up for pharmacies is 33% of the pharmacy purchase price, corresponding to a maximum margin of 25% of the pharmacy retail price.

For 920 pharmaceuticals a higher mark-up of 38% corresponding to a margin of 27.5% is applied. This is due to the fact, that in the course of the changes in the pricing procedure the

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98 MOH Circular: 12/01/05 New Pricing Policy (MOH ref PH.S.21.6.03)

99 MOH Circular: 12/01/05 New Pricing Policy (MOH ref PH.S.21.6.03)

100 Law of Medicines of Human Use, Article 91 (2)

prices were generally decreased, the government therefore admits a 5% higher mark-up for these 920 pharmaceuticals.

In general margins are only applied for pharmaceuticals in the private system. In the public system the pharmaceuticals are purchased via public tendering and are dispensed only in facilities of the public health care system.

4.2.1.4 Value Added Tax (VAT)

There is no VAT on pharmaceuticals in Cyprus, and there are no plans to implement a VAT rate any time soon.

4.2.2 Price Related Cost-containment Measures

4.2.2.1 Pharmaco-economic Evaluation

Pharmaco-economic considerations are only slowly being integrated in the pricing procedure (cf. 4.2.1). Furthermore pharmaco-economic evidence plays an important role in justifying the inclusion of a product on the positive list. Pharmaceutical companies must demonstrate the cost-effectiveness of a product and that it has significant medical benefit over existing treatments at a similar price level (cf. 4.2.1.1).

4.2.2.2 Public Procurement

In the public system, the MoH operated by the Department of Pharmaceutical Services purchases pharmaceuticals through public tendering. Public tendering is undertaken according to the ATC classification. The cost of the therapy and its safety, quality and efficacy are the relevant criteria to be considered in the tendering processes, although price considerations generally take priority. It takes around three months to complete the tendering process and award a contract. The contract is then valid for 12 to 24 months, depending on the pharmaceutical (c.f. 4.2.1).

4.2.2.3 External Price Referencing / Cross Country Referencing

As it has already been mentioned the wholesale prices for *imported* pharmaceuticals are compared to reference countries. The exact procedure is explained in section 4.2.1.2.

4.2.2.4 Price Freezes / Stops

In the course of the implementation of the new pricing procedure in 2005 (cf. 4.2.1.1) around 60% of the prices of pharmaceuticals went down. Due to the changes in the pricing procedure around 40% of the pharmaceutical prices would have potentially been raised, therefore the MoH introduced price freezes for these pharmaceuticals, so that their prices would be at the same level as before the reforms in 2005[101].

[101] MoH, Department of Pharmaceutical Services, personal communication, March 2006

4.2.2.5 Margin Cuts

In Cyprus the pricing system changed twice in the last two years. In 2003 there have been margin cuts, and two years later the pricing system underwent major reforms (cf. 4.2.1.1).

4.2.2.6 Discounts and Rebates

In Cyprus there is no mandatory/statutory system of discounts or rebates applied to pharmaceutical industry, wholesalers or pharmacies[102].

4.2.2.7 Company Profit Controls

In Cyprus there are no company profit controls[103].

4.2.2.8 Parallel Trade

Parallel trade currently plays a very limited role in Cyprus, therefore there are no specific regulations in place for parallel imported pharmaceuticals.

4.2.3 Co-Payments

The level of co-payment is again depending on if the pharmaceutical is dispensed in the private or in the public system.

- *Public system*: around 80% of the population is eligible to receive prescriptions free of charge. These patients receive pharmaceuticals free of charge (group A) or are required to pay 50% of the tendered price of the pharmaceutical (group B). Group A consist of politicians, retired civil servants and their dependants, students, people that receive social welfare and people with very low income. Group B includes people with low income.
- *Private system*: patients have to pay the full price for the pharmaceuticals. Patients who are not eligible for the public health care services have to pay the full price out-of pocket. Since there is a greater choice of pharmaceuticals in the private pharmacies, many patients eligible for free prescription still opt to pay the full price for their pharmaceuticals in private pharmacies.

4.2.4 Information Transparency

In Cyprus prices of pharmaceuticals are relatively easy accessible by the public, since they are published on the webpage of CAPC[104]. This price list is valid for one year and up-dated regularly throughout the year.

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102 MoH, Department of Pharmaceutical Services, personal communication, March 2006

103 MoH, Department of Pharmaceutical Services, personal communication, March 2006

104 http://www.capc.org.cy/enhome.html

4.3 Reimbursement

In Cyprus, there is no reimbursement under the private system. Only under the public system eligible patients can purchase pharmaceuticals either free or at a reduced rate of 50% depending on their level of income (cf. 4.3.1).

4.3.1 Pharmaceutical Lists and Reimbursement Categories

In Cyprus there is a **positive list,** the so called national formulary. The national formulary lists pharmaceuticals reimbursed under the public system at 100% or 50%, depending on the income level of the patient (cf. 4.2.3). It mainly includes generics; original pharmaceuticals are only considered when there are no generics available or there are specific reasons for including an original pharmaceutical.

Only doctors working under the public system may apply for inclusion of pharmaceuticals and active ingredients to the national formulary. There is no additional inclusion of active ingredients to the national formulary. The application needs to state a justification for the inclusion of the pharmaceutical, along with the proof of the cost-effectiveness of the pharmaceutical The Drugs Council, which is part of the Pharmaceutical Services Department[105] decide on whether a pharmaceutical should be included on the national formulary and whether any restrictions should be placed on the specialisation of prescribing doctors.

The national formulary is regularly up-dated in the case of pharmaceuticals not being available anymore or of the availability of cheaper pharmaceuticals. So pharmaceuticals are either added or removed from the national formulary.

4.3.1.1 Reimbursement Price

The reimbursable pharmaceuticals in the national formulary are either fully reimbursed or at a reduced rate of 50%. The level of reimbursement depends on the income level of the eligible patients (cf. 4.2.3).

4.3.1.2 Pharmaceuticals on Positive List

The positive list (public system) includes 700 active ingredients, whereas the different dosages are not counted. These pharmaceuticals are mainly generics, due to their cost-effectiveness.

In the private system, there are around 2,200 pharmaceuticals (counted in regard to different pharmaceuticals forms and dosages). These pharmaceuticals are POM and OTC. All pharmaceuticals in the private system are non-reimbursable; even if patients have prescriptions

[105] includes representatives from medicine and pharmacy

they have to pay the full price for the pharmaceutical. The private system provides original products as well as generics.

4.3.1.3 Generics

Prices of generics are set through the tendering process in the public system. In the private system the maximum wholesale price for generics may not exceed 80% of the wholesale prices of original products (cf. 4.2.1.1).

4.3.1.4 Non-reimbursable Pharmaceuticals

Under the private system all pharmaceuticals are non-reimbursable. Patients have to pay the full price for the pharmaceuticals.

4.3.1.5 Appeal Procedure

The legislation in Cyprus[106] on the appeal procedure is in line with the EU Transparency Directive[107], meaning that the MoH decides within 90 days (180 days in the case of an application to have a product's status changed) from the date it receives the recommendations of the Drugs Council Department of Pharmaceutical Services.

4.3.1.6 Delisting and Switches

Pharmaceuticals are added or removed from the national formulary when a new pharmaceutical becomes available at a lower price. Apart from this, there is no system in place to switch pharmaceuticals from prescription to OTC status. There are plans to implement such a system, although they are at an early stage.

4.3.2 Reference Price System

In Cyprus no reference price system is applied (cf. 4.2.2.3).

4.3.3 Pharmaceutical Budgets

Doctors treating patients eligible under the public system are limited to prescribing pharmaceuticals listed on the national formulary. Private doctors are allowed to prescribe without limitations, since patients have to pay the full price of the pharmaceutical. There are no financial limitations on the prescribing habits of doctors.

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106 Law of Medicines of Human Use, Article 91

107 EU Transparency Directive 89/105/EEC, http://dg3.eudra.org/F2/eudralex/vol-1/DIR_1989_105/DIR_1989_105_EN.pdf

4.3.4 Other Volume Control Oriented Measures

4.3.4.1 Prescription Monitoring and Other Doctors-related Measures

In Cyprus there are no other volume control oriented measures.

4.3.4.2 Generics

In 2005, there are 700 active ingredients in the public sector, which are mainly generics. Generic substitution is not allowed and there are no specific schemes in operation to encourage the use of generics.

4.4 Overview of the Reimbursement Market in Cyprus

In order to give a broader picture of the pharmaceutical system in Cyprus, this overview displays not only the public sector but also the private sector.

Tasks / Duties	Yes	No	Comment	Legal bases
Public authorities				
Decide on prescription status	X		MoH, Department of Pharmaceutical Services	Law No. 70(I)2001
Decide on manufacturer price	X		*Private sector:* For locally produced pharmaceuticals on the basis of production costs *Public sector:* Public tendering	
Agree on manufacturer price		X		
Fix wholesale margin	X		*Private sector:* locally produced pharmaceuticals are regulated via a maximum mark-up of 20% *Public sector:* Public tendering	MOH Circular: 12/01/05 New Pricing Policy (MOH ref PH.S.21.6.03) Law of Medicines of Human Use, Article 91 (2)
Fix pharmacy retail price	X		*Private sector:* locally produced pharmaceuticals are regulated via a maximum mark-up of 33% *Public sector:* Public tendering	MOH Circular: 12/01/05 New Pricing Policy (MOH ref PH.S.21.6.03) Law of Medicines of Human Use, Article 91 (2)

Tasks / Duties	Yes	No	Comment	Legal bases
Decide on reimbursement status	X		*Private sector:* No reimbursement *Public sector:* MoH advised by the Drugs Council Department of Pharmaceutical Services	Law of Medicines of Human Use, Article 91
Agrees on reimbursement price		X		
Decide on reimbursement price	X		*Private sector:* No reimbursement *Public sector:* MoH advised by the Drugs Council Department of Pharmaceutical Services	Law of Medicines of Human Use, Article 91
Use Pharmaco-economic guidelines		X	Pharmaco-economic evidence play an important role for the inclusion on the positive list	
Use Internal reference pricing		X		
Use External reference pricing	X		*Private sector:* For imported pharmaceuticals *Public sector:* Public tendering	
Price freezes		X		
Margin cuts	X		In 2003 and in 2005	
Discounts and Rebates		X		
Company profit control		X		
Country specific:				
Pharmaceutical Industry				
Sets manufacturer price freely	X		*Private sector:* For imported pharmaceuticals *Public sector:* Public tendering	
Notifies manufacturer price		X		
Negotiates manufacturer price		X	Not applicable	
Is free to set price below fixed manufacturer price	X			

Tasks / Duties	Yes	No	Comment	Legal bases
Decides on application for reimbursement		X	*Private sector:* No reimbursement *Public sector:* Reimbursement at 100% or at 50%	
Negotiates reimbursement price		X	Not applicable	
Free to keep manufacturer price above reimbursement price		X	Not applicable	
Free to grant rebates / discounts to wholesalers	X			
Free to grant rebates / discounts to pharmacies	X			
Can engage in marketing towards doctors	X			
Can engage in public advertising	X			
Can provide information toward patients	X			
Applies for switches and de-listing			Non available	
Promotional control		X		
Country specific:				
Distribution chain				
Wholesaler				
Margins are fixed by statute	X		*Private sector:* locally produced pharmaceuticals are regulated via a maximum mark-up of 20% *Public sector:* Public tendering	MOH Circular: 12/01/05 New Pricing Policy (MOH ref PH.S.21.6.03) Law of Medicines of Human Use, Article 91 (2)
Margins are subject to statutory discounts / rebates		X		
Free to grant discounts / rebates to pharmacies	X			
Pharmacists				

Tasks / Duties	Yes	No	Comment	Legal bases
Margins are fixed by statute	X		*Private sector:* locally produced pharmaceuticals are regulated via a maximum mark-up of 33% *Public sector:* Public tendering	MOH Circular: 12/01/05 New Pricing Policy (MOH ref PH.S.21.6.03) Law of Medicines of Human Use, Article 91 (2)
Free to set retail price		X		
Obliged to inform patient on cheaper product		X		
Obliged to substitute by a generic		X	Not applicable	
Allowed to substitute by a generic		X	Not applicable	
Obliged to substitute by a parallel import		X	Not applicable	
Allowed to substitute by a parallel import		X	Not applicable	
Therapeutic / analogous substitution is allowed		X	Not applicable	
Are subject to statutory discounts / rebates		X	Not applicable	
Claw back system exists		X	Not applicable	
May grant rebates to customers	X			
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			
Are obliged to inform on co-payment / deductibles	X		*Private sector:* Patient has to pay the full price *Public sector:* 100% or 50% reimbursement	
Prescription habits are monitored		X	Not applicable	

Tasks / Duties	Yes	No	Comment	Legal bases
Are subject to prescription guidelines		X	Not applicable	
Budgets are controlled		X	Not applicable	
Allowed to prescribe INN	X			
Obliged to prescribe INN		X		
Can oppose generic substitution			Not applicable	
Can oppose therapeutic substitution			Not applicable	
Can oppose substitution by parallel import			Not applicable	
Country specific:				
Patients				
Can shop for cheapest price of the product		X	Not applicable	
Pay a flat rate per prescription / pack		X	*Private sector:* Patient has to pay the full price *Public sector:* 100% or 50% reimbursement	
Pay a certain percentage per prescription / pack or a deductible		X	*Private sector:* Patient has to pay the full price *Public sector:* 100% or 50% reimbursement	
Annual minimum co-payment		X	*Private sector:* Patient has to pay the full price *Public sector:* 100% or 50% reimbursement	
Annual maximum co-payment		X	*Private sector:* Patient has to pay the full price *Public sector:* 100% or 50% reimbursement	
May ask for substitution by a generic		X	Not applicable	

Tasks / Duties	Yes	No	Comment	Legal bases
May oppose substitution by a generic		X	Not applicable	
May ask for substitution by a parallel import		X	Not applicable	
Can oppose substitution by a parallel import		X	Not applicable	
Can oppose substitution only on payment of price difference		X	Not applicable	
Has to pay the difference between reimbursement price and retail price		X	Not applicable	
Has access to full public information on prices and products	X		The positive list is published on the website of the CAPC	http://www.capc.org.cy/enhome.html
Country specifics:				

Source: ÖBIG 2006

CZECH REPUBLIC

5 Czech Republic

5.1 Pharmaceutical System

5.1.1 Regulatory Framework and Authorities

In 1993 the Czech Republic and Slovakia separated and became independent states. In the course of these changes, the Czech Republic went from a Soviet-style, centralised health care system (Semashko model) to a liberalised, pluralistic based on mandatory insurance and a public/private mix for the provision of health care. In 1991, new laws were approved, especially the General Health Insurance Law[108] and the Law on the General Health Insurance Fund[109].

Based on these health care laws, there are nowadays the following most relevant actors in the pharmaceutical system:

- the Ministry of Health (Ministerstvo zdravotnictvi, MZ) - supported by the Categorisation Committee - being responsible for the decision on the extent of reimbursement of pharmaceuticals[110],
- the Ministry of Finance (Ministerstvo financí, MF), setting the maximum manufacturer price as well as the mark-ups for wholesalers and pharmacies[111],
- the nine sickness funds, especially the General Health Insurance (Všeobecná zdravotni pojišťovna, VsZP), responsible for the reimbursement of pharmaceuticals[112], and
- the State Institute for Drug Control (Státní Ústav pro Kontrolu Léčiv, SUKL), being in charge of the authorisation and classification according to the prescription status and distribution of pharmaceuticals, as well as for switches (changes from prescription status to OTC)[113].

The Categorisation Committee, which is an external advisory body of the MZ plays a significant role in the decision on reimbursement. It is comprised of representatives of the MZ, the health insurance entities, and of members of medical and patient associations (cf. 5.3).

As mentioned before, the Czech Republic underwent a lot of reforms in the course of the transition. The system changed from monopolisation to decentralisation and privatisation.

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108 Act No. 550/91 Coll.

109 Act No. 551/91 Coll.

110 Act on Medicines No. 79/1997 Coll. (Chapter 2, Article 7) http://www3.who.int/idhl/531CR02004.pdf

111 Act No. 526/90 Coll.

112 Health Insurance Act No. 48/1997 Coll. http://www3.who.int/idhl/531CR02003.pdf

113 Act on Medicines No. 79/1997 Coll. (Chapter 2, Article 9) http://www3.who.int/idhl/531CR02004.pdf and Decree No. 288/2004 Coll.

One major change was the introduction of a mandatory health insurance. Today there are 9 sickness funds (compared to 27 sickness funds in 1994). As already mentioned, VsZP is the predominant one, covering 70% of the population, whereas the others are group specific or company specific insurances (for members of the military service, bank employees, workers of mines, employees of the car-manufacturer SKODA, and others). The sickness funds are funded through health insurance contributions which for children, elderly and unemployed persons are covered by the state.

Table 5.1 contains an overview of relevant stakeholders in the Czech Republic

Table 5.1: Czech Republic - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Ministerstvo zdravotnictvi (MZ) / Ministry of Health	Ministry of Health, Decision on Reimbursement	MZ Palackého nám. 4 CZ-128 01 Praha 2 Czech Republic Tel.: +420 22 4971 111 Fax: +420 22 4972 111 mzcr@mzcr.cz www.mzcr.cz/	Ms. Pynelopi Valsamisova Palackého nám. 4 CZ-128 01 Praha 2 Czech Republic Tel.: +420 22 4972 709 Pynelopi.valsamisova@mzcr.cz
Ministerstvo finance (MF) / Ministry of Finance	Ministry of Finance, Decision on Manufacturer price	MF Letenská 15 CZ-118 10 Prague 1 Czech Republic Tel.: +420 25 7041 111 Fax: +420 25 7042 788 Podatelna@mfcr.cz www.mfcr.cz/cps/rde/xchg	Mr. Bohuslav Sobotka Letenská 15 118 10 Prague 1 Czech Republic Tel.: +420 25 704 1111 Fax: +420 25 704 2788
Státní Ústav pro Kontrolu Léčiv (SUKL) / State Institute for Drug Control	Medicines Agency (Registration, classification, etc.)	SUKL Srobarova 48 CZ-100 41 Praha 10 Czech Republic Tel.: +420 27 2185 111 Fax: +420 27 1732 377 sukl@sukl.cz www.sukl.cz	Mr. Ludvik Stika Srobarova 48 CZ-100 41 Praha 10 Czech Republic Tel.: +420 27 2185 835 Fax: +420 27 2739 995 milan.smid@sukl.cz
Všeobecná zdravotni pojišťovna (VsZP) / General Health Insurance	General Health Insurance, Reimbursement	VsZP Orlická 4/2020 CZ-130 00 Praha 3 Czech Republic Tel.: +420 22 2175 info@vzp.cz www.vzp.cz	Mr. Karel Nemecek Orlická 4/2020 CZ-130 00 Praha 3 Czech Republic Tel.: +420 22 2175 1111 Fax: +420 22 1107 160

Institution	Task	Contact details/URL	Responsible person
Mezinárodní asociace farmaceutických společností (MAFS) / Associa-tion of International Research Based Pharmaceutical Industry	Association of International Research Based Phar-maceutical Industry	MAFS IBC pobřežní 3 CZ-186 00 Praha 8 Czech Republic Tel.: +420 22 4832 551 Fax: +420 22 4832 554 katerina.nedvedova@mafs.cz www.mafs.cz/cz/index.php	Mr. Pavol Mazan Executive Director Na porici 12 CZ-110 00 Praha 1 Czech Republic Tel.: +420 22 4875 754 Fax: +420 22 4875 755 mafs@tnet.cz
Ceská Lékarnická Komora / Chamber of Pharmacists	Pharmacy's Association	Pharmacy's Association Antala Staska, 80 CZ-140 46 Praha 4 Czech Republic Tel.: +420 26 1006 5029 Fax: +420 26 1260 366 komora@lekarnici.cz www.lekarnici.cz/	Mr. Lubomir Chudoba President or Ms. Jana Mrázková Antala Staska, 80 CZ-140 46 Praha 4 Czech Republic Tel.: +420 26 1006 507 Fax: +420 26 1260 366 chudoba@lekarnici.cz mrazkova@lekarnici.cz
Associace Velko-distributoru Léciv (AVEL) / Association of wholesalers	Wholesaler's Association	AVEL Pelikánova 7 CZ-162 00 Praha 6 Czech Republic Tel.: +420 27 4778 329 Fax: +420 27 4778 324 www.avel.cz	Mr. Pavel Suchy Pelikánova 7 CZ-162 00 Praha 6 Czech Republic Tel.: +420 27 4778 329 Fax: +420 27 4778 324 pavel.suchy@mbox.dkm.cz
Svaz pacientu CR / Patient's Asso-ciation	Patient's Association	Patient's Association Sokolská 32 CZ-120 00 Praha 2 Czech Republic Tel.: +420 22 4266 666 svaz.pacientu@pacienti.cz or pacienti@pacienti www.pacienti.cz	Mr. Lubos Olejar President Sokolská 32 CZ-120 00 Praha 2 Czech Republic Tel.: T-Mobile: 603 720 158 lubos.olejar@pacienti.cz or olejar@pacienti.cz
Casopis lékaru ceských (CLS) / Medical Associa-tion	Medical Association	CLS Lékarský dum, Sokolská 31 CZ-120 26 Praha 2 Czech Republic Tel.: +420 22 4266 2014 Fax: +420 22 4266 212 cls@cls.cz www.cls.cz	Mr. Jaroslav Blahos Lékarský dum, Sokolská 31 CZ-120 26 Praha 2 Czech Republic Tel.: +402 22 4915 195 Fax: +402 22 4216 836 cls@cls.cz

Institution	Task	Contact details/URL	Responsible person
Ceska Asociace Farmcetuckych Firem (CAFF) / Association of Pharmaceutical Industry	Association of Pharmaceutical Industry	CAFF Vinohradská 184 CZ-130 52 Praha 3 Czech Republic Tel.: +420 26 7132 3512 Fax: +420 26 7132 358 caff@aff.cz http://caff.tradecentrum.cz	Mr. Lumir Krocek Vinohradská 184 CZ-130 52 Praha 3 Czech Republic Mobil: +420 724 028 852 Fax: +420 26 7132 358 Lumir.krocek@aff.cz
Ceská Lekarská Komora / The Czech Medical Chamber	Medical Doctor's Association	Lékarská 2 150 00 Praha 5 Czech Republic Tel.: +420 25 7217 226 recepce@clkcr.cz www.lkcr.cz/	Mr. David Rath President Lékarská 2 150 00 Praha 5 Czech Republic Tel.: +420 25 7217 226 recepce@clkcr.cz www.lkcr.cz/

Source: ÖBIG 2006

5.1.2 Market Players

5.1.2.1 Pharmaceutical Industry

Before the political transition in the Czech Republic all the pharmaceutical producing companies (mainly generic producing companies) were publicly owned. In the 1990s the privatisation and decentralisation were further enhanced. This resulted in the settlement of international pharmaceutical companies in the Czech Republic. In 1993, the International Research Based Pharmaceutical Industry founded an Association (Mezinárodní asociace farmaceutických společností, MAFS) in order to negotiate with the sate administration their interests. Today it has around 34 members. Since 2001 the Czech Pharmaceutical Industry operates the Association of the Pharmaceutical Industry (Česká asociace farmaceutických firem, ČAFF) with around 30. All in all there are over 250 manufacturers in the Czech Republic.

5.1.2.2 Distribution

The pharmaceutical wholesale in the Czech Republic is organised in a multi-channel system in which around 160 pharmaceutical companies with a wholesale licence operate. In fact 5 of them dominate the market.

In 2005, the regulation on the dispensing of pharmaceuticals was changed, so that self-dispensing doctors are now allowed to operate. This resulted in a reduction of pharmacies, especially of community pharmacies, from around 2,200 to 1,850 pharmacies dispensing pharmaceuticals to the patients (1 pharmacy per 5,520 inhabitants). Pharmacy chains are

allowed, whereas the dispensing of pharmaceuticals over the internet is not allowed. A limited range of OTC pharmaceuticals are allowed to be sold outside the pharmacy.

In 2003, a total of 14,000 pharmaceuticals were registered in the Czech Republic (counting different pharmaceutical forms and dosages, but excluding different pack sizes). Of these 8,000 were prescription-only medicines. However only 2,000 pharmaceuticals were on the market.

In the Czech Republic market authorisation is harmonised to EU legislation[114]. Based on the EU Directives, SUKL publishes guidelines (called REGs) on registration on their website[115]. SUKL classifies pharmaceuticals into the following three categories[116]:

- prescription-only pharmaceuticals (POM),
- pharmacy-only OTC products
- OTC products dispensable outside of pharmacies.

5.1.2.3 Patients

The interests of patients are represented in the Patient's Association[117]. The Patient's Association is not involved in the decision making process of pharmaceutical pricing and reimbursement. It offers extensive information on the patients' rights and concerns.

Primary care is provided by general practitioners (GP) within a family physician system. Patients register with GPs who have a contract to their health insurance and receive treatment free of charge. In general GPs act as gatekeepers to specialist services. Secondary care is provided by specialists in out-patient practices, the still exciting polyclinics and out-patient departments, while community, regionally and centrally run hospitals offer tertiary care. The main problem of public hospitals is funding due to limited resources, which is expected to have improved through the introduction of the remuneration on the basis of DRG.

114 Community Directive 2001/83/EC

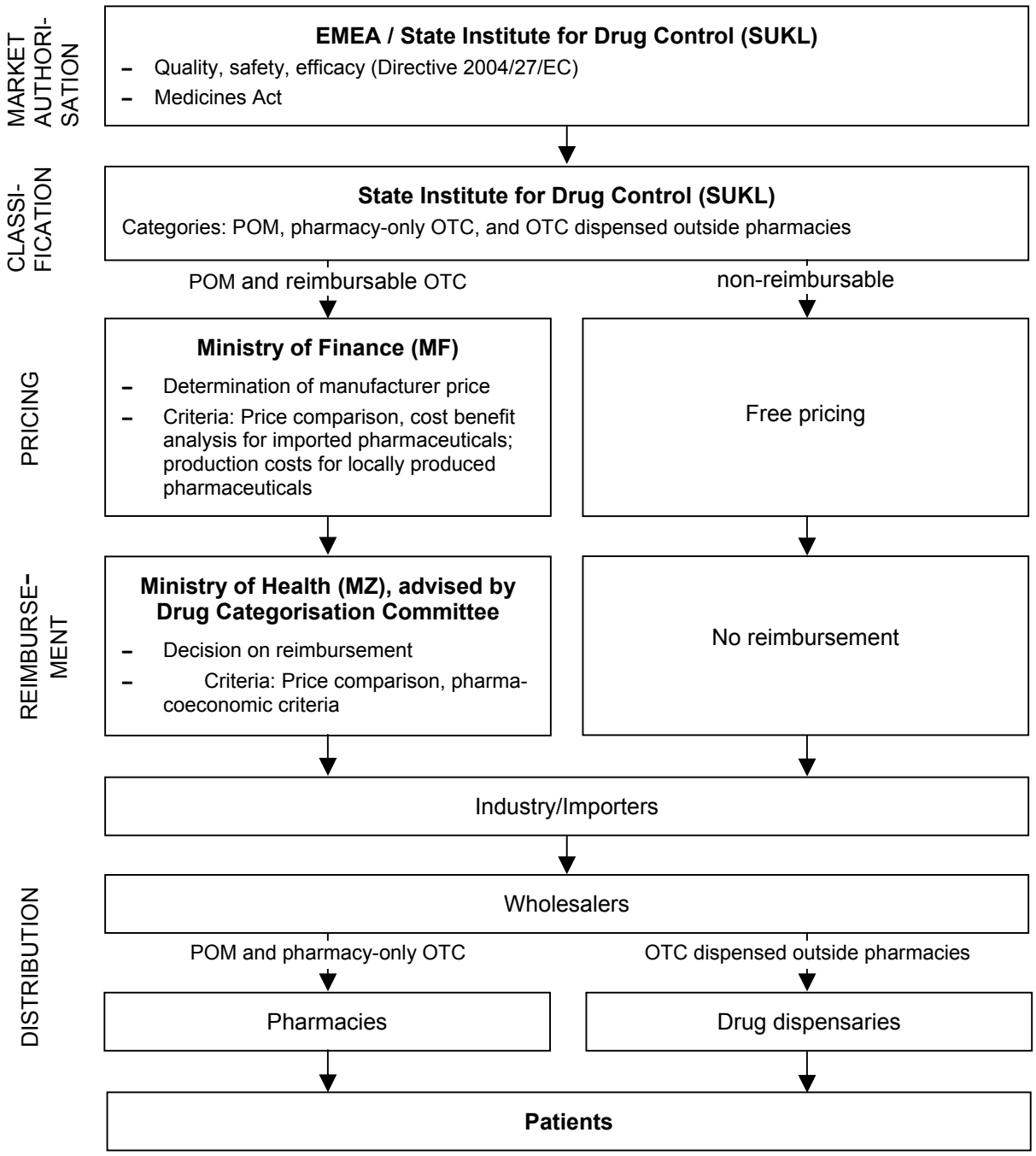
115 www.sukl.cz

116 Act on Medicines No. 79/1997 Coll. And REG 11 http://www3.who.int/idhl/531CR02004.pdf

117 www.pacienti.cz

5.1.3 Overview of the Pharmaceutical System

Figure 5.1: Czech Republic - Pharmaceutical System, 2006



POM = Prescription-only medicines, OTC = Over-the-Counter pharmaceutical

Source: ÖBIG 2006

5.2 Pricing

5.2.1 Scope of Price Control

There is free pricing for non-reimbursable OTC, while other pharmaceuticals are subject to State price regulation. The MF sets the maximum manufacturer price as well as a combined mark-up for wholesalers and pharmacies. There are no price negotiations applied. In reality the MF accepts the price the pharmaceutical companies have applied for.

The maximum prices are set and published by the MF within 90 days according to the EU Transparency Directive[118]. The lists of maximum prices are revised annually. The pharmaceutical companies can then apply for reimbursement at the MZ (cf. 5.3).

The price published by the MF is a maximum price; in fact pharmaceutical companies set their manufacturer prices at 70 to 80% of the maximum price. The prices of generics are usually set at 55% of the original pharmaceutical.

Table 5.2 provides a concise overview of the Czech pricing system.

Table 5.2: Czech Republic - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Non-reimbursable OTC pharmaceuticals	Not applied	Not applied
Statutory Pricing	Reimbursable pharmaceuticals, mostly POM	All pharmaceuticals regulated via a combined mark-up for wholesalers and pharmacies	all pharmaceuticals regulated via combined mark-up for wholesalers and pharmacies
Price Negotiations	Not applied[1]	Not applied	Not applied
Price/volume agreements, discounts/rebates	No[2]	No	No
Institution in charge of pricing	Ministry of Finance		
Legal Basis	Act No. 526/90 Coll.		

[1] Except for "allowed" profit mark-ups for locally manufactured pharmaceuticals

[2] There are rebates common, but not officially stated

Source: ÖBIG 2005

[118] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance system, http://pharmacos.eudra.org/F2/eudralex/vol-1/new_v1/890105en.pdf#search='89/105/EECeudra'

5.2.1.1 Manufacturer Price

As already mentioned, the MF sets the maximum manufacturer price. There are different criteria for pricing locally manufactured or imported pharmaceuticals.

- For locally manufactured pharmaceuticals, pharmaceutical companies have to base their price application upon the production costs. This should prove the ”justified” profitability of the pharmaceutical. Generally the appointed price is up to 10% higher than the production costs.
- In the case of imported pharmaceuticals the pharmaceutical companies need to include a list of the prices charged at manufacturer level (for that pharmaceutical) in other countries to their price application (= external/cross country referencing). It is neither specified by law nor via any official agreement which countries should be chosen. In 2005 Hungary, Spain, and three other countries in which the pharmaceutical is first on the market are mentioned by the MF as an example. However, Czech authorities may also ask companies to provide prices from other European countries.

5.2.1.2 Wholesale Price

In the Czech Republic a *combined* maximum mark-up for wholesalers and pharmacies, i.e. for the full distribution segment is applied. This system is unique among EU Member States.

The “maximum total wholesale and pharmacy mark-up” was set by the MF at 32% in 1999 and was decreased in January 2006 to 29%. The mark-up is added on the manufacturer price and is valid for all pharmaceuticals (also for generics, non-reimbursable and OTC products). There is some flexibility over how the maximum mark-up is split between the two distribution actors, with the wholesaler usually taking 5 to 7% and the pharmacist 22 to 24%[119]. There are no official agreements on how the mark-ups are split.

In fact, in general the maximum mark-up is not fully used, which leads to different prices for the same pharmaceuticals (especially in the OTC segment) in pharmacies. So patients have the possibility to shop for the cheapest pharmaceutical (cf. 5.4).

5.2.1.3 Pharmacy Retail Price

As it has been mentioned before, there is a common wholesale and pharmacy mark-up (cf. 5.2.1.2).

5.2.1.4 Value Added Tax (VAT)

The standard VAT rate is 19%, and the VAT on pharmaceuticals is 5%. The VAT is levied on the level of wholesale; since April 2004 pharmacies are also obliged to pay VAT.

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[119] Association of Pharmacists, written information, January 2006

5.2.2 Price Related Cost-containment Measures

5.2.2.1 Pharmaco-economic Evaluation

In the Czech Republic, neither economic nor scientific guidelines are laid down. Manufacturers state that they would appreciate clearer rules on which pharmaco-economic studies are appropriate. However, manufacturers are not obliged to present pharmaco-economic studies as there is no official evaluation procedure (cf. 5.3).

5.2.2.2 Internal Price Referencing

Internal price referencing is the major method to determine the reimbursement price of a pharmaceutical in the Czech Republic. There is a mix of therapeutic referencing (i.e. comparisons of similar pharmaceuticals on ATC 4 level) and comparison on ATC 5 level (= active ingredient) applied.

The procedure is explained in detail in the section on the reference price system (cf. 5.3.2).

5.2.2.3 External Price Referencing / Cross-country Referencing

As it is explained in more detail in section 5.2.1.1, the MF is only comparing prices of imported pharmaceuticals on the manufacturer level. External price referencing is also applied in the reimbursement process (cf. 5.3).

5.2.2.4 Price Freezes / Stops

In the last five years there were no statutory price freezes/stops in the Czech Republic.

5.2.2.5 Margin Cuts

In 2005 wholesale and pharmacy margins on pharmaceuticals were statutorily decreased from 32% to 29%. There were further margin cuts in 1996 from 38% to 35% and in 1999 from 35% to 32%.

5.2.2.6 Discounts and Rebates

There is no mandatory/statutory system of discounts or rebates applied to pharmaceutical industry, wholesalers or pharmacies in the Czech Republic. However, the VsZP negotiates on discounts on pharmaceuticals prices with individual manufacturers to lower or eliminate co-payment for patients. These so-called “agreed prices” are valid for all pharmacies in the Czech Republic, although the participation of companies is voluntary. Additionally, individual community pharmacies also negotiate discounts with individual pharmaceutical companies.

5.2.2.7 Company Profit Controls

In the Czech Republic, there is a cost-plus system applied for locally manufactured pharmaceuticals. Therefore company profit controls are only functional for local manufacturers. This means that the State accepts the manufacturing price of the pharmaceutical, i.e. its concrete production costs (to be proven by the pharmaceutical company), and allows for a profit margin. The acceptable profit margin is negotiated for each individual product.

5.2.2.8 Parallel Trade

Parallel trade currently plays no role, therefore there are no specific regulations in place for parallel imported pharmaceuticals. In any case, the Czech Republic is more an export than an import country.

5.2.3 Co-Payments

There are no fixed co-payment rates in the Czech Republic[120]. As of 1 March 2006, there is a regulation for the calculation of the co-payment rates[121]. Patients have to pay the difference between the reimbursement price and the pharmacy retail price. Prescribing doctors are required to inform patients whether the prescribed pharmaceutical is fully, partially or non-reimbursable. Doctors are informed on the reimbursement category by the sickness funds. The actual co-payment depends on the pharmacy retail price, which can vary between pharmacies.

In the last few years there have been discussions on the quality of and the ability to finance the health care system. In the course of these discussions, the introduction of a prescription fee has been mentioned.

5.2.4 Information Transparency and Marketing

In the Czech Republic, prices of pharmaceuticals are relatively easy to access, since the VsZP publishes the positive list on their website[122]. Besides the prices, the list also contains information on the ATC code, brand name, pharmaceutical forms, dosage and pack size and information on the manufacturer.

In general, patients are not publicly informed on the level of co-payment. It is the responsibility of the doctor to inform the patients on the level of co-payment (cf. 5.2.3).

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120 http://www.mzcr.cz/data/c1804/lib/VYHL_SBIRKA_211205.doc

121 http://monitor.isa/479211192/1442992T060329111450.txt.binXMysM0dapplication/vnd.ms-excelXsysM0dhttp://www.zdn.cz/dokumenty/ruzne/doplatek1.xls

122 www.vzp.cz

SUKL publishes guidelines[123] on the labelling of pharmaceuticals and on package leaflets which are fully compatible with the EU's patient information provisions. These guidelines include a list of excipients that should be declared on the label.

The Czech legislation[124] has not yet implemented all requirements of the EU's provisions on pharmaceutical advertising[125]. It includes special provisions applying to advertising for pharmaceuticals in all media including audio-visual presentations and printed information.

It is not allowed to advertise the following pharmaceuticals to the public:

- Not authorised in the Czech Republic
- Supplied only on medical prescription
- Containing narcotic, psychotropic and other addictive substances

Furthermore it is forbidden to indicate prices in advertisements.

5.3 Reimbursement

The reimbursement of the pharmaceuticals in the Czech Republic is based on a reference price system, which was introduced in 1995[126], meaning that the decision on the reference price is taken first and then on the level of reimbursement. Pharmaceutical companies may only apply for reimbursement after the MF has set the maximum manufacturer price (cf. 5.2.1.1).

Total pharmaceutical expenditure amounted to about € 1,450 million in 2003, thereof 76.8% of the expenses were covered by public funds. Compared to the year 2000 pharmaceutical expenditure rose by 34.4%.[127]

For the reimbursement procedure[128] the manufacturer has to submit to the MZ an application containing a proposal for reimbursement in CZK/DDD, along with the proposed prescription and indication restrictions. The application also needs to include information on the composition of the pharmaceutical, dosage information as well as pricing data (the maximum manufacturer price as determined by the MF and the pharmacy retail and pharmacy purchase price in relevant countries such as Poland, Hungary, Greece and Portugal).

123 SUKL REG 57, published in February 2001

124 Law on the regulation of Advertising No. 40/1995 and Advertising Law 138/2002 Coll.

125 Directive 2001/83/EEC

126 Health Insurance Act No. 48/1997 Coll., http://www3.who.int/idhl/531CR02003.pdf

127 OECD Health Database 2005

128 Regulation No. 4/2001

In case of a pharmaceutical, of which a pharmaco-therapeutic benefit is expected, pharmaco-economic studies (e.g. alternative costs for the health insurance for treatment) are desired, but are not mandatory (cf. 5.2.2.1).

The MZ then checks the application to ensure that it meets the necessary requirements. It is then sent to the Categorisation Committee, which is comprised of representatives of the MZ, the health insurance entities, and of members of medical and patient associations. The Categorisation Committee revises the applications in respect of economical and clinical aspects, and then transfers their recommendations to the MZ, which then finally takes the decision on the reimbursement price. Usually the MZ follows the recommendations of the Categorisation Committee and accepts the recommended prices. The approved reimbursement prices are published twice a year by the MZ in a Ministerial decree.[129] On the basis of this decision, the VsZP publishes a list of all reimbursable pharmaceuticals, the Czech *positive list*[130]. These pharmaceuticals are reimbursed "automatically" if prescribed by a contract doctor by VsZF, the most important Czech sickness fund. There is no negative list.

The other sickness funds also rely more or less on this VsZF reimbursement list, but deviations are possible.

However, there are no published reimbursement procedure rules available, so the reimbursement process is - compared to other EU Member States - still rather in-transparent.

5.3.1 Pharmaceutical Lists and Reimbursement Categories

Besides inclusion of pharmaceuticals in the *positive list* (cf. 5.3), the MZ is responsible for setting the level at which the sickness funds reimburse pharmaceuticals. It is also required to establish the reimbursement conditions for pharmaceuticals, such as the speciality of the doctors permitted to prescribe a pharmaceutical and any indication restrictions.

In general there are four reimbursement categories:

- H: reimbursement only in hospital settings (or in the case of referrals of general practitioners)
- L: reimbursement only if prescribed by a specialist
- P: reimbursement only for certain therapeutic indication
- I: full reimbursement

Apart from one exception (anti-allergic pharmaceuticals that have a fixed reimbursement price[131]), there are no fixed reimbursement rates for pharmaceuticals or patient groups; reimbursement is closely linked to the reference price system. The reimbursement rates also dif-

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129 Act on Medicines No. 79/1997 Coll. and REG 11 http://www3.who.int/idhl/531CR02004.pdf

130 www.vzp.cz

131 Fixed by the Social Health Insurance

fer between the sickness funds. They vary from full reimbursement (on basis of the reference price, cf. 5.3.2) of generics to no reimbursement[132].

Pharmaceutical companies can only apply for reimbursement, when the maximum manufacturer price of their pharmaceutical is set by the MF. Then the reimbursement price is set by the MZ on recommendation of the Categorisation Committee based on the decision on the reference price (cf. 5.3.2).

5.3.1.1 Pharmaceuticals on Positive List[133]

In 2003, there were around 14,000 pharmaceuticals authorised in the Czech Republic (counted incl. different pharmaceutical forms, dosage, and pack size). But there is only a minor part on the market: only every seventh pharmaceutical is marketed. 4 out of 5 pharmaceuticals, that apply for reimbursement, are granted reimbursement. The criteria to include a pharmaceutical into the positive list are: a price comparison and pharmaco-economic criteria (cf. 5.3). If a pharmaceutical does not fulfil these criteria, then it is not included into the positive list. There is no negative list in the Czech Republic.

The MZ publishes (twice a year) the list of reimbursable pharmaceuticals in a Ministerial decree. Furthermore, the VsZP publishes a list of all reimbursable pharmaceuticals[134].

Table 5.3: Czech Republic - Pharmaceuticals, 2003

Pharmaceuticals	2003
Authorised	~ 14,000
On the market	~ 2,000
Prescription-only	~ 8,000
Reimbursable	82%[1]

[1] 82% of the pharmaceuticals are reimbursable, 52% are fully reimbursable (Data 2002)

Source: ÖBIG 2005

5.3.1.2 Generics

Reimbursement prices of generics are usually set at 55% of the manufacturer price of the original pharmaceutical (= on-patent brand) (cf. 5.2.1). The same distribution margin system is applied as for other pharmaceuticals, cf. 5.2.1.2 and 5.2.1.3.

132 http://www.mvcr.cz/sbirka/1997/sb019-97.pdf

133 http://www.mvcr.cz/sbirka/1997/sb019-97.pdf

134 www.vzp.cz

5.3.1.3 Non-reimbursable Pharmaceuticals

Most of the non-reimbursable pharmaceuticals are OTC products. Patients may purchase them at their own expense. There is no exemption, e.g. for old-age pensioners or children from this rule.

5.3.1.4 Appeal Procedure

The pharmaceutical company has 10 days from receiving the decision from the Categorisation Committee to appeal against it. In this case the pharmaceutical company can seek assistance from MAFS. However the number of cases that MAFS can defend are limited.

5.3.1.5 Delisting

SUKL has established a set of requirements for switching pharmaceuticals from prescription to OTC status[135]. These requirements also clarify what conditions manufacturers have to fulfil in order to obtain non-prescription status for their pharmaceutical. These requirements are based on EU guidelines.

There is a general tendency towards an increase in switching and towards exclusion of OTC products from reimbursement.

5.3.2 Reference Price System

In 1995, a reference price was introduced in the Czech Republic.

In order to set maximum reimbursement prices, pharmaceuticals were statutorily (= by law)[136] clustered into 521 pharmaco-therapeutic groups based on the ATC-classification of the WHO: ATC 5 level (same active ingredient) or ATC 4 level (therapeutically similar pharmaceuticals).

According to the Health Insurance Act, at least one pharmaceutical in each of these 521 groups listed in the annex to the Health Insurance Act is guaranteed full reimbursement. In general, the reimbursement price for pharmaceuticals in each group is set at the level of the cheapest available pharmaceutical in the group using the defined daily dose (DDD) system, i.e. taking into account the way of administration of the pharmaceutical (oral, topical, …), its pharmaceutical form (tablets or oral solution) and its dosage/strength.

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135 REG 41 Classification of medicinal products - guidance for application of medicinal product as non-prescriptional one and Decree on Registration No. 473/2000 Coll., amended by Decree No. 302/2003 Coll. www.sukl.cz/en08/en0802.htm

136 Health Insurance Act No. 48/1997 Coll. http://www3.who.int/idhl/531CR02003.pdf

The “drug decree”[137] defines the level of reimbursement of those substances which are covered by law. The decree was updated regularly, every 3 months until 1999, and every 6 months from 1 January 2000. The updating changes are based on the recommendations from the Categorisation Committee.

For the other pharmaceuticals, patients are obliged to pay the difference between the reference price and the pharmacy retail price. The annex has not been updated since it was originally drawn up in 1997, it therefore sets only the minimum reimbursement requirements as there are many more ATC groups than those listed.

As already mentioned, the reference price system is a key element of the reimbursement of pharmaceuticals. The decision on the reference price is taken first and then on reimbursement level. In general, the cheapest out of a defined group of pharmaceuticals (in most cases a generic, often a locally manufactured one) is fully reimbursed. All other pharmaceuticals are partly or fully paid for by patients: sickness funds only reimburse up to the price of the generic equivalent, i.e. the reference price.

5.3.3 Pharmaceutical Budgets

In the Czech Republic, there are prescribing budgets for GPs set by the health insurance. These budgets are based on average costs per speciality and region. There are penalties for doctors who exceed their budget; the payments allocated by the health insurance will be cut. Exceptions are only made for doctors who can justify the overspending. In practice, prescribing budgets tend not to be enforced, since the insurance companies want to avoid that patients are being refused treatment due to high expenditure. This is especially the case since there has been strong competition between the insurance companies.

5.3.4 Other Volume Control Oriented Measures

5.3.4.1 Prescription Monitoring and Other Doctors-related Measures

Besides having pharmaceutical budgets there is another way of controlling pharmaceutical expenditure in the Czech Republic. In general, there are restrictions for certain specialists on the prescribing of particular pharmaceuticals[138], which is set during the reimbursement process. For example, newer and more expensive pharmaceuticals are often restricted to prescription by specialists.

137 Decree No. 57/1997

138 www.sukl.cz

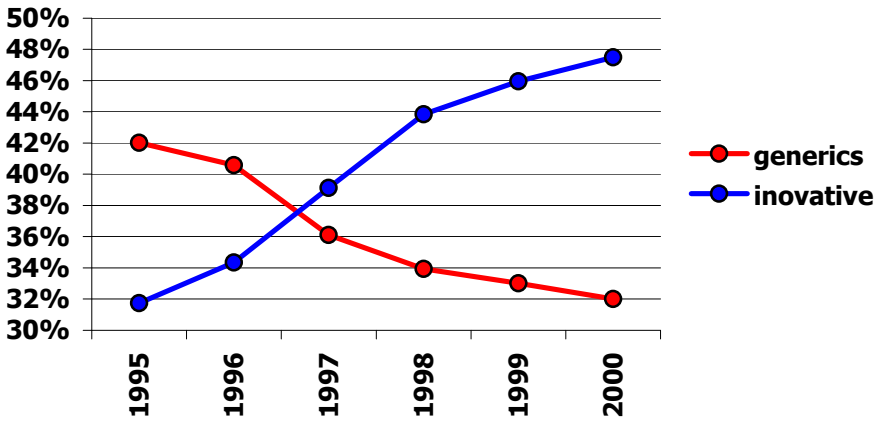
5.3.4.2 Generics

The share of generic pharmaceuticals in the Czech Republic is medium size (in 2000 around 32% of the market in terms of value). There has been a long tradition of generic manufacturing companies in the Czech Republic. The size of the generic market is also due to the introduction of the reference price system, which encourages the use of low cost, fully reimbursed generic pharmaceuticals.

Doctors need to inform patients on the reimbursement status of all prescribed pharmaceuticals which leads to cost awareness among patients. Doctors can only use trade names on the prescriptions.

Generic substitution is - unless the doctors does not explicitly forbid it - allowed. It is restricted to pharmacies. At the moment a drug decree is under reconstruction in the Parliament on the introduction of obligatory generic substitution[139].

Figure 5.2: Czech Republic - Generics and Innovative Medicine in Value, 1995 - 2000



Source: Švilhovec 2003, MAFS, data gathering by ÖBIG

[139] Association of Pharmacists, personal communication, March 2006

5.4 Overview of the Reimbursement Market in the Czech Republic

Tasks / Duties	Yes	No	Comment	Legal bases
Public authorities				
Decide on prescription status	X		SUKL	Act on Medicines No. 79/1997 Coll. (Chapter 2, Article 9) http://www3.who.int/idhl/531CR02004.pdf and Decree No. 288/2004 Coll.
Decide on manufacturer price	X		As a maximum price, company is free to set price below	Act No. 526/90 Coll.
Agree on manufacturer price		X	N.app.	
Fix wholesale margin	X		Combined maximum wholesale and pharmacy mark-up of 29%	
Fix pharmacy retail price	X			
Decide on reimbursement status	X		MZ supported by the Categorisation Committee	Act on Medicines No. 79/1997 Coll. (Chapter 2, Article 7) http://www3.who.int/idhl/531CR02004.pdf
Agrees on reimbursement price		X	N.app.	
Decide on reimbursement price	X		MZ supported by the Categorisation Committee	Act on Medicines No. 79/1997 Coll. (Chapter 2, Article 7) http://www3.who.int/idhl/531CR02004.pdf
Use Pharmaco-economic guidelines		X	No clear guidelines	
Use Internal reference pricing	X		Reimbursement decision	
Use External reference pricing	X		Pricing decision for imported pharmaceuticals on the manufacturer level, as well as for the reimbursement process	
Price freezes		X	N.app.	
Margin cuts	X		In 1996, 1999, 2006	
Discounts and Rebates	X		N.app.	
Company profit control	X		Cost-plus system for locally manufactured pharmaceuticals	
Country specific:				
Pharmaceutical Industry				

Tasks / Duties	Yes	No	Comment	Legal bases
Sets manufacturer price freely	X		Only for non-reimbursable OTC	
Notifies manufacturer price		X	N.app.	
Negotiates manufacturer price		X	N.app.	
Is free to set price below fixed manufacturer price	X			
Decides on application for re-imbursement	X			
Negotiates reimbursement price		X	N.app.	
Free to keep manu-facturer price above reimbursement price		X	N.app.	
Free to grant rebates / discounts to wholesalers	X		On a voluntary basis	
Free to grant rebates / discounts to pharmacies	X		On a voluntary basis	
Can engage in marketing towards doctors	X		Not all requirements of the code of conduct implemented	
Can engage in public advertising	X		With certain restrictions	
Can provide information toward patients	X			
Applies for switches and de-listing	X			
Promotional control		X	N.a.	
Country specific:				
Distribution chain				
Wholesaler				
Margins are fixed by statute	X		Based on a maximum manu-facturer price / combined with pharmacy mark-up 29%	
Margins are subject to statutory dis-counts / rebates		X	N.app.	

Tasks / Duties	Yes	No	Comment	Legal bases
Free to grant discounts / rebates to pharmacies	X		On a voluntary basis	
Pharmacists				
Margins are fixed by statute			Based on a maximum manufacturer price / combined with pharmacy mark-up 29%	
Free to set retail price		X	N.app.	
Obliged to inform patient on cheaper product		X	On a voluntary basis	
Obliged to substitute by a generic		X	On a voluntary basis	
Allowed to substitute by a generic	X			
Obliged to substitute by a parallel import		X	N.app.	
Allowed to substitute by a parallel import		X	N.app.	
Therapeutic / analogous substitution is allowed	X			
Are subject to statutory discounts / rebates		X	N.app.	
Claw back system exists		X	N.app.	
May grant rebates to customers	X		On a voluntary basis	
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			
Are obliged to inform on co-payment / deductibles	X			
Prescription habits are monitored	X		Only contract doctors	

Tasks / Duties	Yes	No	Comment	Legal bases
Are subject to prescription guidelines	X		Guidelines of the Medical Association indicative	
Budgets are controlled	X		Not enforced in reality	
Allowed to prescribe INN		X	Only trade name	
Obliged to prescribe INN		X	Only trade name	
Can oppose generic substitution		X	N.app.	
Can oppose therapeutic substitution		X	N.app.	
Can oppose substitution by parallel import		X	N.app.	
Country specific:				
Patients				
Can shop for cheapest price of the product	X			
Pay a flat rate per prescription / pack		X	No fix co-payment rates	http://monitor.isa/479211192/14429 92T060329111450.txt.binXMysM0d application/vnd.ms-excelX-sysM0dhttp://www.zdn.cz/dokument y/ruzne/doplatek1.xls
Pay a certain percentage per prescription / pack or a deductible		X	N.app.	
Annual minimum co-payment		X	N.app.	
Annual maximum co-payment		X	N.app.	
May ask for substitution by a generic		X	N.a.	
May oppose substitution by a generic		X	N.a.	
May ask for substitution by a parallel import		X	N.app.	
Can oppose substitution by a parallel import		X	N.app.	
Can oppose substitution only on payment of price difference		X	N.a.	

Tasks / Duties	Yes	No	Comment	Legal bases
Has to pay the difference between reimbursement price and retail price	X		Difference between reference and pharmacy retail price	
Has access to full public information on prices and products	X			www.vzp.cz
Country specifics:				

N. app. = Not applicable, N. a. = Not available

Source: ÖBIG 2006

DENMARK

6 Denmark

6.1 Pharmaceutical System

6.1.1 Regulatory Framework and Authorities

The Danish National Health Service Scheme (den offentlige sygesikring)[140] is based on the fact that nearly all health services are provided by public authorities and financed by the state, i.e. through taxes. The basic legal framework for provision of health care services in Denmark is from 1 January 2007 the Health Act (Sundhedsloven), latest amended by 24 June 2005.[141]

By 1 January 2007 a major administrative reform including a stronger decentralisation of responsibilities will take place. 98 new municipalities and five new regions, will be responsible for the organisation of health care. The regions will be in charge of reimbursement of pharmaceuticals and thereby replacing the currently responsible National Health Service.[142]

The state will generally undertakes these tasks where delegation to the municipalities and regions would be inappropriate. The Ministry of the Interior and Health (Indenrigs- og Sundhedsministeriet, IM) will also provide the legal framework after 1 January 2007.

All inhabitants in Denmark are covered by den offentlige sygesikring, that includes treatment by doctors/physicians, specialists, dentists, and physiotherapists etc., as well as pharmaceutical treatment. Citizens are free to choose between two insurance groups:

- Group 1 members are attached to one general practitioner and need a reference from this GP in order to visit a specialist. Both visits to GPs and to specialists are free of charge for the patient. This group comprises 98 percent of the population.
- Group 2 members are free to choose any GP and may visit a specialist without reference from a GP. The public health insurance only covers part of the costs.

There is no difference between the two groups with regard to the reimbursement of pharmaceuticals.

The Danish pharmaceutical system is primarily regulated in the following three laws:

- The Danish Medicines Act (Lægemiddelloven) from 17 December 2005 is the legal basis for market authorisation, licensing, etc. The law implements the three latest EU Directives

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140 Lov om offentlig sygesikring (National Health Security Act) No. 311 of 9 June 1971, latest amended by LF No. 1431 of 22 December 2004

141 Sundhedsloven (Health Act) No. 546 of 24 June 2005 as amended by Lov No. 1395 of 21 December 2005

142 IM 2006a (basing on Health Act No. 546 of 24 June 2005)

2004/24/EC, 2004/27/EC and 2004/28/EC on, for instance the improvement of free movement of human, veterinary and herbal pharmaceuticals and expanding the powers of the European Medicines Agency (EMEA).[143]

- The current reimbursement system, that is valid since 1 April 2005, is regulated in the National Health Service Act (Sygesikringsloven).[144]
- The Pharmacy Act (Apotekerloven) that regulates the classification and distribution of pharmaceuticals.[145]

The most relevant player in the pharmaceutical system is the Danish Medicines Agency (Lægemiddelstyrelsen, DMA)[146], [147], that

- is in charge of market authorisation and licensing of pharmaceuticals as well as for the registration of medical devices and natural products,[148]
- is responsible for market surveillance and vigilance,
- decides on reimbursement eligibility of pharmaceuticals and
- is involved in the pharmaco-economics (consumption analysis, monitoring of prices, etc.).

The independent Reimbursement Committee (Medicintilskudsnævnet) advises the DMA in questions about reimbursement of pharmaceuticals. The Medicintilskudsnævnet may consist of a maximum of seven people, of whom two have to be general practitioners (GP), one a clinical pharmacologist, two specialists on internal medicine and one representative from the National Health Insurance Scheme. Members are appointed by the IM after recommendation by the Negotiation Committee of Public Health Security.[149]

In addition to this exist the Institute for Rational Pharmacotherapy (Institut for Rationel Farmakoterapi, IRF. The aim of the IRF is to promote the most rational use of current and future medicinal products with respect to both pharmacological and economics aspects. The IRF was founded in 1999 as a partly independent institute under the DMA.[150]

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143 Lov om lægemidler (Medicines Act) as amended by Lov No. 1180 of 12 December 2005; http://www.retsinfo.dk/_LINK_0/0&ACCN/A20050118030

144 Lov om offentlig sygesikring (National Health Service Act), No. 311 of 9 June 1971, latest amended by LF No. 1431 of 22 December 2004; Art. 7 (1), (2) and (3)

145 Lov om apoteksvirksomhed (Pharmacy Act) No. 279 of 6 June 1984, as amended by LBK No. 657 of 28 July 1995 and by BEK No. 1207 of 12 December 2005; http://147.29.40.91/_SHOWF_A522523397/1481&A19950065729REGL&0005&000001

146 Sundhedsloven (Health Act) No. 516 of 24 June 2005 as amended by Lov No. 1395 of 21 December 2005; Art. 155; http://www.retsinfo.dk/_LINK_0/0&ACCN/A20050054630

147 http://www.dkma.dk/db/filarkiv/5987/About%20the%20Danish%20Medicines%20Agency.pdf

148 Vaccines and sera are licensed and controlled by the National Serum Institute (Statens Serum Institut, SSI), http://www.ssi.dk/sw379.asp

149 Currently the Reimbursement Committee consists of 6 members, that are appointed until 30 June 2009, cf. http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=2095

150 http://www.irf.dk

Table 6.1: Denmark - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Indenrigs- og Sundhedsministeriet (IM) / Ministry of the Interior and Health	Ministry of Health (legal framework)	Slotsholmsgade 10-12 DK-1216 Copenhagen K Denmark Tel.: +45 7226 9000 Fax: +45 7226 9001 www.im.dk	Mr. Lars Løkke Rasmussen Minister Slotsholmsgade 10-12 DK-1216 Copenhagen K Denmark Tel.: +45 7226 9000 Fax: +45 7226 9001 im@im.dk
Lægemiddelstyrelsen / Danish Medicines Agency (DMA) advised by Medicintilskudsnævnet / Reimbursement Committee	Medicines Agency (registration, vigilance, reimbursment decisions, etc.)	Axel Heides Gade 1 DK-2300 Copenhagen S Denmark Tel.: +45 4488 9595 Fax: +45 4488 9599 jl@dkma.dk www.dkma.dk (Jytte Lyngvig)	Chief Executive Officer Jytte Lyngvig Axel Heides Gade 1 DK-2300 Copenhagen S Denmark Tel.: +45 4488 9595 et@dkma.dk (Elisabeth Thomsen)
Institut for Rationel Farmakoterapi (IRF) / Institute for Rational Pharmacotherapy	Institution in charge of appraisals and rational use of medicines, guidance to DMA	IRF Laegemiddelstyrelsen Axel Heides Gade 1 DK-2300 Copenhagen S Denmark Tel.: +45 4488 9121 www.irf.dk/en/forside.htm	Mr. Jens Peter Kampmann Axel Heides Gade 1 DK-2300 Copenhagen S Denmark Tel: +45 4488 9120 Fax: +45 4488 9122 jpk@dkma.dk
Sundhedsstyrelsen (SST) / National Board of Health, Danish Centre for Evaluation and HTA (DACEHTA)	Institution in field of pharmacoeconomics	SST P.O. Box 1881 DK-2300 Copenhagen S Denmark Tel.: +45 7222 740 Fax: +45 7222 7411 www.sst.dk	Mr. Finn Børlum Director Prof. Kristensen Islands Brygge 67 DK-2300 Copenhagen S Denmark Tel: +45 7222 7548 fbk@sst.dk
Lægemiddelindustriforeningen (LIF) / The Danish Association of the Pharmaceutical Industry	Association of Pharmaceutical Industry	LIF Postboks 829 DK-2100 Copenhagen Ø Denmark Tel.: +45 3927 6060 Fax: +45 3927 6070 info@lifdk.dk http://www.lifdk.dk	Ms. Ida Sofie Jensen Adm. Dir. Strødamvej 50A DK-2100 Copenhagen Ø Denmark Tel.: +45 3927 6060 Fax: +45 3927 6070 ij@lifdk.dk

Institution	Task	Contact details/URL	Responsible person
Industriforeningen for Generiske Lægemidler (IGL) / The Danish Generic Medicines Industry Association	Association of Generic Medicine Industry	GL Nikolaj Plads 23 DK-1067 Copenhagen K Tlf.: + 45 70 20 02 51 info@igldk.dk http://www.igldk.dk	Mr. Hans Henrik Raith Nikolaj Plads 23 DK-1067 Copenhagen K Tlf.: + 45 70 20 02 51 info@igldk.dk
Parallelimportø-foreningen af Lægemidler (PFL) / Association of Parallel Importers	Association of Parallel Import-ers	PFL Industriparken 23-25 DK-2750 Ballerup Denmark Tel.: +45 4466 3200 Fax: +45 4466 3201	Mr. Hans Bøgh-Sørensen Industriparken 23-25 DK-2750 Ballerup Denmark Tel.: +45 4466 3200 ebp@paranova.dk
MEGROS Foren-ingen af medecin-grossister / Association of Pharmaceutical Wholesalers	Wholesaler Association	MEGROS Amagertorv 11 DK-1160 Copenhaben K Denmark Tel.: +45 3645 4536 Fax: +45 3314 1933	Mr. Sven Pedersen Amagertorv 11 DK-1160 Copenhagen K Denmark Tel.: +45 3645 4536 Spe@nomeco.dk
Danmarks Apote-kerforening / Danish Pharma-ceutical Associa-tion	Association of Pharmacists	Danmarks Apotekerforening Bredgade 54, Postboks 2181 DK-1017 Copenhagen K Denmark Tel.: +45 3376 7600 Fax: +45 3376 7699 apotekerforenin-gen@apotekerforeningen.dk	President Mr. Niels Kristensen Bredgade 54, Postboks 2181 DK-1017 Copenhagen K Denmark Tel.: +45 3376 7600 nk@apotekerforeningen.dk http://www.apotekerforeninge n.dk
Den Almindelige Danske Læge forening (DADL) / Danish Medical Association	Medical Doctors' Association	DADL Trondhjemsgade 9 DK-2100 Copenhagen Ø Denmark Tel.: +45 3544 8500 Fax: +45 3544 8503 dadl@dadl.dk http://www.dadl.dk	Director Ms. Bente Hyldahl Fogh Trondhjemsgade 9 DK-2100 Copenhagen Ø Denmark Tel.: +45 3544 8221 bhf@dadl.dk
Forbrugerradet (FR) / Danish Consumer Council	Patients' Representative	FR Postboks 218 DK-1017 Copenhagen K Denmark Tel.: +45 7741 7756 fbr@fbr.dk http://www.fbr.dk/english	Mr Rasmus Kjeldahl Director Fiolstræde 178 DK-1017 Copenhagen K Denmark Tel.: +45 7741 7719 fbr@fbr.dk

Source: ÖBIG 2006

6.1.2 Market Players

6.1.2.1 Pharmaceutical Industry

The pharmaceutical industry is a rather significant sector in the Danish economy: In the year 2003 pharmaceutical production amounted to € 5,985 million, thereof € 4,634 million (77%) went into export.[151] In 2005 189 manufacturers supplied pharmaceuticals in Denmark (ten were parallel importers) and the export rate was almost 90%.[152]

Danish original manufacturers and other research-oriented pharmaceutical companies are organised in the Danish Association of the Pharmaceutical Industry (Lægemiddelindustriforeningen, LIF). During the last 15 years LIF has played a role in the pricing policy as it concluded several voluntary price agreements including price freezes with Danish authorities.[153]

Generic manufacturers and parallel importers are not members of LIF. The later rather have their own organisations. The Danish Generic Medicines Industry Association (Industriforeningen for Generiske Lægemidler, IGL) is a trade association founded in 2002. The association which are all engaged in the sale and marketing of generic medicines for the Danish market. Some of the companies also manufacture generic medicines.[154]

The parallel importers are members of the Association of Parallel Importers (Parallelimportøforeningen af Lægemidler, PFL). Parallel trade plays a significant role in Denmark (cf. 6.2.2.8).

The leading manufacturers in Denmark are Pfizer, Nycomed and AstraZeneca. In 2005 the parallel importer Orifarm had - after Pfizer - the second larges sales among all pharmaceutical companies.[155]

6.1.2.2 Distribution

Although in Denmark, in contrary to its Nordic neighbours, a multi-channel distribution system is in place, there are three wholesalers (Max Jenne, Nomeco and KV Tjellsen) operating on the market.[156] Hospitals are mainly delivered by the centralised public purchasing agency AMGROS.

The number of pharmacies is controlled by DMA.[157] The establishment of pharmacy chains is not possible as a pharmacist may only own a maximum of 4 pharmacies (until 1 October

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151 EFPIA 2005

152 LIF 2006b

153 LIF 2006b

154 http://www.igldk.dk

155 LIF 2006b

156 http://www.girp.org/main5wholelist.htm

157 Lov om apoteksvirksomhed (Pharmacy Act), amended by LBK No. 657 of 28 July 1995; Chapter 4

2001 only one), including branch pharmacies and so-called pharmacy shops (Apoteksudsalg).[158] Apoteksudslag are allowed to sell all types of Over-the counter (OTC) pharmaceuticals (Håndkøbslægemidler).

A major change in the distribution system occurred on 1 October 2001 when the pharmacy obligation for some OTC was terminated. Consequently, many former Pharmacy-only OTC (now called Ha) were switched into OTC for general sale (Freekøb, HF) and into OTC for limited sale (Handkøb, HX), cf. section 6.1.3. In January 2003 the range of HF and HX was considerably extended and now includes 175 pharmaceuticals.[159]

Also from October 2001 on, supermarkets and other licensed stores like gas stations (Godkendte salgsstede) were allowed to sell HF pharmaceuticals under certain conditions (e.g. no self-service). In 2003 slightly more than 10% of all OTC were sold outside a pharmacy.[160]

In 2006 there are 271 pharmacies, 51 branch pharmacies, about 140 pharmacy shops, 710 OTC shops affiliated to one of the pharmacies and approximately 1,300 Godkendte salgssteder on the market.[161] In average one POM-dispensary serves 15,000 inhabitants.

Denmark was, together with Netherlands, one of the first EU Member State to allow internet sale of OTC pharmaceuticals. In the mean time several internet pharmacies, like Dit Apotek[162] have been established. Mail order of pharmaceuticals is consequently also allowed.

6.1.2.3 Patients

Danish patients obtain information on their medication by the prescribing doctor in the first place and by the dispensing pharmacists in second place. Furthermore the DMA offers extensive information on the prices of pharmaceuticals, their content including benefits and potential risks via a internet platform "Medicinpriser".[163]

As patients with few exceptions (cf. 6.2.3) always have to pay a variable co-payment for pharmaceuticals, information on the current co-payment balance of every person in Denmark is also available.[164]

Concerning generic substitution (cf. 6.3.1.4) patients may oppose substitution but then have- in addition to the "normal" co-payment - to pay the difference to the reimbursement price. However, if a doctor decides to forbid substitution of a branded pharmaceutical the patient may not ask for substitution in the pharmacy by him/herself but then also has to pay the price

158 ÖBIG 2003

159 Danmark Apotekerforeningen 2006b

160 AESGP 2005

161 IM 2006a and b

162 e.g. http://www.dit-apotek.dk

163 http://www.medicinpriser.dk

164 http://www.medicinprofilen.dk

difference out-of-pocket.[165] But if the patient can not tolerate a cheaper (generic) product, the doctor can apply the DMA for an increased reimbursement for the more expensive (often branded) medicinal product (cf. 6.3.1.3 for details).

In general the patient need not shop around for cheap pharmaceuticals as the prices of reimbursable products are the same throughout the country. Only for HF and HX (see above and 6.1.3) price differences of 5 to 10% are observed between pharmacies, pharmacy resp. OTC shops and Godkendte salgssteder..[166]

6.1.3 Overview of the Pharmaceutical System

In Denmark, pharmaceuticals are classified by DMA in several groups:[167]

- Prescription-only pharmaceuticals (POM), which must be sold in pharmacies and are mostly included in general reimbursement;
- Håndkøbslægemidler, i.e. non-prescription pharmaceuticals (Over-the Counter, OTC), whereby three subcategories (plus a category for veterinary products) exist[168]:
  - Pharmacy-only OTC (HA), which must be dispensed in pharmacies.
  - OTC for limited sale (Handkøb, HX) - mild pain killers and antiviral creams -, which may be sold in gas stations and supermarkets in limited amounts and are non-reimbursable.
  - OTC for general sale (Freekøb, HF) - like nicotine replacement products -, which may be also sold in gas stations or supermarkets and are non-reimbursable.

Some OTC-medicines have been granted reimbursement for specific defined diseases. Reimbursement requires that the medicinal product is dispensed after prescription in a pharmacy.

When deciding, whether an OTC may be sold outside a pharmacy DMA considers:

- if the products can be used by the consumers without the opportunity of advice offered at the pharmacy and
- the risk that the pharmaceutical can be abused or used incorrectly.[169]

In addition DMA categorises all marketed pharmaceuticals by their ATC (Anatomic Therapeutic Chemical) Code and groups those with the same ATC 5 level (i.e. the same active ingredient). Pharmaceuticals in the same group are considered to be interchangeable, meaning they may substitute each other, see section 6.3.1.4 for generic substitution.

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165 DMA 2006a

166 DMA 2006b

167 Lov om lægemidler (Medicines Act) as amended by Lov No. 1180 of 12 December 2005; Chapter 6

168 List of all HF, HX and HA

169 DMA 2006b

It is the target of DMA to establish as large substitution groups as possible. At the establishment of the first regimen of generic substitution in 1991 all pharmaceuticals (including nowadays HF and HX) were evaluated in terms of the bioequivalence and grouped into substitution groups.[170] The list of substitutable pharmaceuticals is up-dated on a regular basis and available in the internet.[171] However, the pharmacist is not obliged to substitute HF and HA.

In 2004, total pharmaceutical sales amounted to DKK 15,466 million / € 2,075.6 million[172] (in terms of Gross Pharmacy Retail Prices), whereof 75% were attributable to out-patient care. All together 7,393 pharmaceuticals (counted by packs) were on the market in 2004, thereof 4,083 were qualified for reimbursement (including 390 OTC).[173]

Figure 6.1 on the next page shows the life cycle of a pharmaceutical in Denmark. The term free pricing means that the price of a given non-reimbursable OTC may vary between the various pharmacies, pharmacy shops, supermarkets etc.

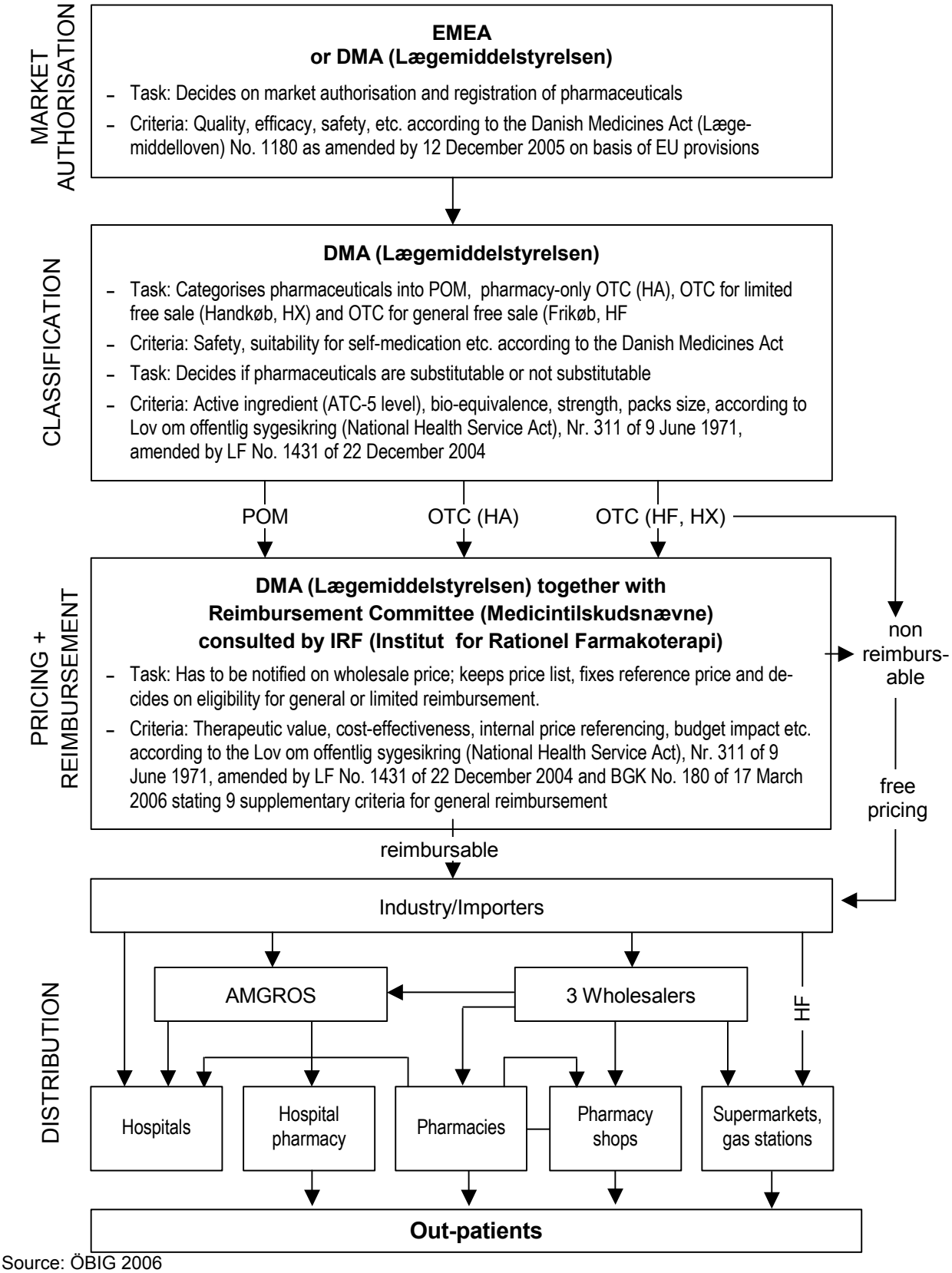
170 DMA 2006e

171 http://www.laegemiddelstyrelsen.dk/db/filarkiv/5872/GeneriskSubstitution_Laegemidler_Drug_Niveau.xls

172 Please note that exchange rate used for all further calculations was: € 1 = DKK 7,4518 (Annual rate 2005 as published by the Austrian National Bank on basis of European Central Bank, cf. http://www.oenb.at/de/stat_melders/datenangebot/zinssaetze/wechselkurse/wechselkurse.jsp

173 DMA 2005b

Figure 6.1: Denmark - Pharmaceutical System, 2006



Source: ÖBIG 2006

6.2 Pricing

6.2.1 Scope of Price Control

There is, technically speaking, free pricing for all pharmaceuticals on manufacturer and wholesale price level. However, prices of reimbursable off-patent pharmaceuticals and generics are indirectly influenced through the reimbursement price. Pharmaceuticals companies wishing to include their products in the reimbursement system have to apply for reimbursement at DMA (cf. 6.3.1 for details).

Table 6.2: Denmark - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Free pricing for all products set by the manufacturer/ importer, cf. below. Public procurement for all pharmaceuticals *used* in hospitals (not only HOM but also for others)		Non-reimbursable products, mostly OTC[1]
Statutory Pricing	Not applied, but price of reimbursable pharmaceuticals (POM and OTC) may be indirectly influenced via the reimbursement system		Reimbursable pharmaceuticals (POM and OTC) via a regressive mark-up scheme[2]
Price Negotiations	Manufacturers and wholesalers negotiate their share of the wholesale price.		Not applied
Discounts / rebates	Yes, cost related discounts	Yes, cost related discounts	Yes, 1,72% in 2005 to the National Health Service
Public Procurement	- Mainly relevant for products used in hospitals (performed by AMGROS) - Not relevant in out-patient sector, except for vaccinations and certain blood products		
Institution in charge of pricing	- Hospital Purchasing Agency AMGROS - IM for pharmacy mark-up scheme - (DMA on behalf of IM for reimbursement price)		
Legal Basis	- Lov om offentlig sygesikring (National Health Security Act) No. 311 of 9 June 1971, latest amended by LF No. 1431 of 22 December 2004 - BEK om ændring af bekendtgørelse om beregning af forbrugerpriser på apoteksforbeholdte lægemidler samt ikke apoteksforbeholdte håndkøbslægemidler m.v. (Executive Order BEK No. 237) of 24 March 2006, Art. 1174		

DMA = Lægemiddelstyrelsen, HOM = Hospital-only Medicines, IM = Indenrigs- og Sundhedsministeriet, OTC = Over-the Counter

1 The pricing of OTC pharmaceuticals which are not limited to distribution from pharmacies is free and subject to local competition.

2 The mark-up is negotiated with the IM every 2 years and is calculated from the wholesale price.

Source: ÖBIG 2006

174 http://147.29.40.90/_SHOWF_A704859012/1318&B20060023705REGL&0001&000010

HF and HX are priced freely in the sense that the their prices can change according to local competition contrary to the prices of all other medicinal products which have to be the same in all pharmacies.[175] The pharmacy retail price is currently regulated by a statutory mark-up scheme, which is due to change by 1 April 2007 (cf. 6.2.1.3).

6.2.1.1 Manufacturer Price

As already mentioned, pharmaceutical companies may freely set the price for pharmaceuticals when placing them on the market. They are only obliged to inform DMA on the wholesale price of the product, which then includes it into the Danish pricelist (Medicinpriser),[176] that is published on the internet.[177]

Pharmaceutical companies may change their price every forth-night, provided that the price increase or reduction is at minimum DKK 1.- / € 0.3 by notifying DMA, which up-dates its pricelist. This notified price is binding until officially changed by the pharmaceutical company, as neither DMA nor another public authority has the power to change prices.[178] As companies are not obliged to notify DMA on the prices of HF and HX, these are not included in the Medicinpriser.

Still, the prices of reimbursable pharmaceuticals are indirectly influenced via the reimbursement system, that is explained in great detail in section 6.3.1.

The prices of medicines used in a hospital setting are not regulated by statute. The majority of hospitals (80%) obtains the necessary medicines through AMGROS. AMGROS buys pharmaceuticals mainly via public procurement, i.e. inviting companies to tender and thus achieves significant discounts (cf. 6.2.2.6).[179, 180]

6.2.1.2 Wholesale Price

Since 2001 the wholesale margin is no longer regulated by law, but is negotiated individually between wholesalers and pharmaceutical companies.[181] Wholesalers are allowed to grant discounts to pharmacies and are very likely to receive rebates from manufacturers.

In 2005 the average wholesale margin in terms of the gross Pharmacy Retail Price was 4%.[182]

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175 DMA 2006e

176 Bekendtgørelse om underretning om priser på lægemidler og leveringsforhold (Executive Order on Notification of prices of medicinal products and supply capacity), No. 206 of 22 March 2005, Art. 3 and 4; http://147.29.40.90/_SHOWF_A503022001/1821&B20050020605REGL&0004&000006

177 http://www.medicinpriser.dk

178 Lov om lægemidler (Medicines Act) No. 1180 of 12 December 2005 , Art. 77

179 PPR 2005

180 ÖBIG 2003

181 IM 2005

182 LIF 2006b

6.2.1.3 Pharmacy Retail Price

Danish pharmacy retail prices are regulated by Executive Order (BEK) of the IM. The price is composed of the notified wholesale price (cf. 6.2.1.1) plus a fixed amount and a mark-up in percentage multiplied by a variable factor, the so-called conscription percentage (Udskrivningsprocenten).

According to BEK No. 237 the current regressive pharmacy mark-up scheme is composed as shown in Table 6.3. The conscription percentage is variable and changed in average twice a year, the recent factor of 55% being applied since 18 July 2005.

Currently the conscription percentage is at a quite low level (the highest percentage ever was 77.9% between 1.11.1999 und 24.7.2000) and according to Danmarks Apotekerforening it is not likely to be raised again soon, rather the opposite.[183]

In addition to the profit mark-up the pharmacy receives a flat rate refund, the so-called prescription fee, for every dispensed POM (and OTC medicines dispensed according to prescription).[184] This fee was increased by 10 April 2006 to DKK 9.25 / € 1.24 (incl. VAT) and is included in the Gross Pharmacy Retail price (PRP).[185]

Table 6.3: Denmark - Pharmacy Mark-up Scheme, 2006

PPP from ... to ... in DKK / €	Pharmacy mark-up (1.4.2006 - 31.3.2007)
<= DKK 30.00 / € 4.03	0.550 x (0.293 x PPP + DKK 14.78 / € 1.98)
DKK 30.00 / € 4.03 < PPP <= DKK 60.00 / € 8.05	0.550 x (0.226 x PPP + DKK 16.78 / € 2.25)
PPP > DKK 60.00 / € 8.05	0.550 x (0.16 x PPP + DKK 20.78 / € 2.79)

PPP = Pharmacy purchasing price

Source: Bekendtgørelse om ændring af bekendtgørelse om beregning af forbrugerpriser på apoteksforbeholdte lægemidler samt ikke apoteksforbeholdte håndkøbslægemidler m.v. (Executive Order BEK No. 237) of 24 March 2006, Art. 1

The current pharmacy remuneration system is only a transitional one, as Apotekerforeningen and IM have agreed in the beginning of the year 2005 to simplify the system. Besides the mark-up scheme and the prescription fee, a complicated claw-back system (basing on the turnover of the pharmacies and rebates granted to them by wholesalers) together with statutory discounts to the National Health Service (1.72% in 2005 and 0.8% in 2004)[186] is in place.

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183 Randlov 2006

184 Danmarks Apotekerforeningen 2006b

185 Bekendtgørelse om ændring af bekendtgørelse om beregning af forbrugerpriser på apoteksforbeholdte lægemidler samt ikke apoteksforbeholdte håndkøbslægemidler m.v. (Executive Order BEK No. 237) of 24 March 2006, Art. 2, http://147.29.40.90/_SHOWF_B796790507/1361&B20060023705REGL&0001&000010

186 Danmark Apotekerforeningen 2006a, DMA 2006e

The system was re-adjusted so that the pharmacies will have an approximate similar profit on all pharmaceuticals. A desired "side-effect" of the adjusted system is that it favours the sale of cheaper pharmaceuticals, thus encouraging the pharmacist to comply with the obligatory generic substitution system that was introduced in April 2005 together with the new reimbursement system (6.3.1).[187]

From 1 April 2007 pharmacies will be remunerated with a flat rate mark-up of 8.5% on the Pharmacy Purchasing Price, to which DKK 13.35 / € 1.79 will be added.[188] The fixed prescription fee will also remain and will amount to DKK 10.- / € 1.34 (incl. VAT).

The margins of pharmaceuticals used exclusively in hospitals are regulated separately, furthermore the pharmacy mark-up scheme is not binding for godkendte salgssteder (cf. 6.1.2.2).

6.2.1.4 Value Added Tax (VAT)

The VAT rate for pharmaceuticals is the same as the standard rate, which is 25%. Thus, the VAT rate is the highest among all EU Member States.

6.2.2 Price Related Cost-containment Measures

6.2.2.1 Pharmaco-economic Evaluation

Pharmaceutical companies are not obliged to present a pharmaco-economic evaluation of their pharmaceutical to DMA when applying for general reimbursement status. Since an amendment to the National Health Service Act (Sygesikringsloven) in 1997 DMA welcomes the provision of such reports, as cost-effectiveness is one of the criteria for inclusion in general reimbursement (cf. 6.2.2.1). Quality guidelines on preparation of pharmaco-economic evaluations were published by DMA in 1998, 2001 and 2004.

According to DMA representatives, pharmaco-economic evaluations still are of minor relevance[189] as the quality of those pharmaco-economic evaluations submitted to DMA in many cases have been insufficient, and the evaluations cannot as a consequence be part of the basis for decision.

In addition, IRF also performs its own pharmaco-economic evaluations. Current assessments include anti-epileptic pharmaceuticals and asthma therapy.[190]

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187 DMA 2006e

188 Randlov 2005

189 DMA 2006a

190 http://www.irf.dk/en/reviews

6.2.2.2 Internal Price Referencing

Internal price referencing is the major method to determine the reimbursement price of a pharmaceutical in Denmark. It was introduced in the year 1993.[191] The reimbursement price of a pharmaceutical nowadays[192] is always the price of the cheapest pharmaceutical in one substitution/reimbursement group.

Currently there are app. 600 groups established, some of them only containing one product, the original branded one.[193]

Which pharmaceutical is included into which substitution/reimbursement group is determined by DMA.[194] The criteria taken into account are:[195]

- ATC-group (whereby only ATC-5 level is considered)
- Formulation and bioequivalence
- Pharmaceutical form (capsules, tablets, lozenges etc. are comparable but not tablets and inhalation products) and dispensing details e.g. type of medical device
- package size.[196]

6.2.2.3 External Price Referencing / Cross Country Referencing

International price comparisons were, until 1 April 2005 - when a change in the reimbursement system was introduced - a major feature of the Danish reimbursement policy.

Until that time the notified wholesale prices could not exceed the average European price of a country basket including 13 EEA countries (Austria, Belgium, Finland, France, Germany, Iceland, Ireland, Italy, Liechtenstein, the Netherlands, Norway, Sweden and the UK), if companies wanted the respective product to qualify for reimbursement.[197] This was due to a promise made by Lif and applied only to pharmaceuticals marketed by companies that were members of Lif.[198]

Nowadays external price referencing still plays a role, e.g. for evaluation purposes (~ controlling the reimbursement price within a group of substitutable pharmaceuticals, cf. 6.3.1.4), but

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191 DMA 2006e

192 In the beginning the reference price (=reimbursement price for pharmaceuticals included in the reference price system, i.e. off-patent pharmaceuticals and generics) was the average of the 2 cheapest products of the group, in 2000 it became the lowest average European price and in 2005 it became the lowest price of the group. But basically the system is the same as in the beginning.

193 PPR 5/2005

194 Lov om lægemidler (Medicines Act) as amended by Lov No. 1180 of 12 December 2005; http://www.retsinfo.dk/_LINK_0/0&ACCN/A20050118030

195 DMA 2006c

196 Executive Order on Prescriptions BEK No. 1221 of 7 December 2005

197 PPR 5/2005

198 DMA 2006e

to a much minor extent than before. Still the same country basket (see above) and procedures (e.g. comparison of wholesale rather than manufacturer price, comparing only almost the same pack sizes etc.).

6.2.2.4 Price Freezes/Stops

Price freezes basing on voluntary agreements between LIF and the authorities were a dominating feature of the pharmaceutical pricing policy between 1995 and 2005. In 1997 there was also a statutory price freeze imposed on all reimbursable pharmaceuticals.[199]

The latest price freeze agreement was terminated earlier than planned with the introduction of the new reimbursement system in April 2005. A major feature of this agreement was, that LIF had guaranteed to keep the prices of reimbursable pharmaceuticals below an European average price (cf. 6.2.2.3).

Since that time there is no price freeze agreement in place.

6.2.2.5 Margin Cuts

Within the current refunding system for pharmacists, the variable factor of the pharmacy mark-up, the so-called conscription percentage, is regularly (mostly twice a year) adapted by Executive Order to reach the agreed annual maximum profit for pharmacies (cf. 6.2.1.3 and 6.2.2.6 for details).[200]

The conscription percentage was reduced latest on 10 April 2006 from 59.4% to 55.0%.[201]

6.2.2.6 Discounts and Rebates

Since 2001, after a change of the Pharmacy Act, wholesalers are allowed to grant discounts to pharmacies, which resulted in discounts of e.g. 0.95% in 2001.[202] However, only cost-related discounts are possible, as discounts in kind remain forbidden and the pharmacist has to pass 50% of all obtained discounts on to customers.[203]

Pharmacies have to grant a statutory discount to the National Health Service, which amounted to 0.8% in 2005. Furthermore there is an overall ceiling for the earnings of all pharmacies negotiated every two years between IM and Danmark Apotekerforening (e.g. DKK 2.1 billion / € 281.8 million in 2003). In case of excess profits the conscription percentage (cf. 6.2.1.3) is adjusted by Executive Order and in some cases the National Health Service recoups some of the excess profits ("claw-back"). In 2005, for example, a pharmacy had

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199 Lov om midlertidigt prisstop for lægemidler m.v. (Price Stop Act) No. 224 25 March 1997

200 Danmark Apotekerforeningen 2006a and 2006b

201 Bekendtgørelse om ændring af bekendtgørelse om beregning af forbrugerpriser på apoteksforbeholdte lægemidler samt ikke apoteksforbeholdte håndkøbslægemidler m.v. (Executive Order BEK No. 237) of 24 March 2006, Art. 1

202 ÖBIG 2003

203 AESGP 2005

to pay back in average DKK 200,000.- / € 26.840.- [204] and the conscription percentage was reduced to 61.0% and in autumn 2005 to 59.4%.[205] This discount will be terminated when the current transitional remuneration system for pharmacies will be replaced by the new system on 1 April 2007 (cf. 6.2.1.3).[206]

Pharmacists may not sell below the published price from "Medicinpriser", i.e. they may not give discounts to their customers.[207]

Furthermore AMGROS tries to negotiate discounts when purchasing medicines for hospitals directly from manufacturers (cf. 6.2.1.1).

6.2.2.7 Company Profit Controls

There are no direct company profit controls in place in Denmark. However, the profits of companies are indirectly influenced by the applied reference price system (cf. 6.3.2).

6.2.2.8 Parallel Trade

Parallel imports are, together with generics a key factor of the obligatory generic substitution scheme.

There are no specific pricing rules in place for parallel imported products as there is - as already stated - in general free pricing in Denmark. However, parallel imports underlie the same conditions of reimbursement like other products, i.e. DMA includes them into a substitution group basing on its ATC-5 level. Sometimes a substitution group only consists of the branded original product and the parallel imported one (cf. 6.3.1.4). In 2004 573 parallel imported products were on the market.[208]

6.2.3 Co-Payments

In Denmark proportional, so-called need-depending, co-payments are in place for reimbursable pharmaceuticals. This means, that patients are obliged to pay a defined share of the reimbursement price (cf. 6.3.1.1) depending on their out-of-pocket expenditure for reimbursable pharmaceuticals within a 12-month period.[209]

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204 Danmark Apotekerforeningen 2006b

205 Bekendtgørelse om ændring af bekendtgørelse om beregning af forbrugerpriser på apoteksforbeholdte lægemidler samt ikke apoteksforbeholdte håndkøbslægemidler m.v. (Executive Order BEK No. 122) of 28 February 2005, Art. 1

206 Danmark Apotekerforeningen 2006a

207 DMA 2006a

208 DMA 2005b

209 IM 2005

Before the patient is eligible for reimbursement he or she has to pay the full cost of his/her reimbursable medication up to a threshold of DKK 480.- / € 64.4 per 12-month period. After this, the reimbursement rate rises gradually, as Table 6.4 demonstrates.

Table 6.4: Denmark - Reimbursement Rates and Patient Co-payment Rates, 2006

Annual expenses for patients in terms of reimbursement price in DKK/ €[1]	**Co-payment rate in %**	**Reimbursement rate in %**
Adults		
DKK 0-480 / € 0-64.41	100%	0%
DKK 480-1,165 / € 64.41-156.34	50%	50%
DKK 1,165-2,730 / € 156.34-366.35	25%	75%
> DKK 2,730 / € 366.35	15%	85%
Children up to 18 years		
DKK 0 - 1,165 / € 156.34	50%	50%
DKK 1,165-2,730 / € 156.34-366.35	25%	75%
> DKK 2,730 / 366.35	15%	85%
Chronically ill[2]		
DKK 0-18,105 (adults) or 19,705 (<18 yrs) / € 0-2,625.8 (adults) or 2,858.4 (<18 yrs)	Co-payment rates and reimbursement rates as stated above	
> DKK 18,105 or 19,705 / € 2,625.8 or 2,858.4	0%	100%
Terminally ill[3]		
DKK / € 0	0%	100%

1 before subtraction of reimbursement rate

2 A chronically ill patient in this context is defined as a patient who has a large consumption of prescribed medicine and accordingly large costs.

3 Includes all consumed pharmaceuticals (also not reimbursable pharmaceuticals prescribed by a doctor.

Source: Sundhedsloven (Health Act) No. 546 of 24 June 2005 as amended by Lov No. 1395 of 21 December 2005; Chapter 42, Art. 146, 147 and 148 on basis of Lov om offentlig sygesikring (National Health Service Act), No. 311 of 9 June 1971, latest amended by LF No. 1431 of 22 December 2004; Art. 7 (1), (2) and (3)

The basic Danish reimbursement system is for every Danish citizen independent of economic or social situation. The social laws have social clauses for co-payments. Handicapped people, pensioners or very poor persons may always apply for social assistance by their respective counties.[210]

210 Sundhedsloven (Health Act) No. 546 of 24 June 2005 as amended

Still, the reimbursement system foresees several exceptions for chronically or terminally ill patients:[211]

- On written application of the prescribing doctor to DMA chronically ill patients with a "large, permanent and professionally documented need" may be exempt from further co-payments if their full out-of-pocket expenses have reached a ceiling of DKK 3,520.- / € 472.37 within a 12-month period (this equals total annual pharmaceutical expenses of DKK 19,567 / € 2,625.8 for adults and of DKK 21,300 / € 2,858.4 for children under 18 years.[212])
- On written application of the prescribing doctor to DMA terminally ill patients (i.e. mainly those who are taken care of at their respective homes) may be exempt from any further co-payments of all sort of co-payments and receive any medication, including OTC, non-reimbursable products and the most expensive pharmaceuticals in a substitution group free of charge as long as they are prescribed by a doctor. This is independent of the current status of their co-payment balance.

In addition to above mentioned co-payments, patients have to pay the difference between the reimbursement price and the gross pharmacy retail price if he/she refuses substitution of the pharmaceutical by a cheaper, often generic one (cf. 6.3.1.4 for generic substitution). These co-payments - as well as out-of-pocket payments for OTC - are not regarded for the calculation of the 12-month co-payment ceiling of DKK 3,520.- / € 472.37 for chronically ill patients.[212, 213]

6.2.4 Information Transparency and Marketing

Advertising of pharmaceuticals in regulated in the Medicines Act[214], that is fully compliant with EU Directive 2001/83/EC.[215] and in Executive Order on Advertising of Medicinal Products No 793 of 10 September 2001. As of 16 June 2003 the ban on TV advertising on OTC was lifted, meaning that from this time on advertising to the public for OTC is allowed in all media. Public advertising is controlled by DMA and by a voluntary code of conduct of LIF[216] as well as the ”Nævnet for Medicinsk Informationsmateriale” (the juridic and ethic control committee of the pharmaeutical industry).

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211 Sundhedsloven (Health Act) No. 546 of 24 June 2005 as amended by Lov No. 1395 of 21 December 2005; Chapter 42, Art. 147 and 148

212 IM 2005

213 DMA 2006a

214 Lov om lægemidler (Medicines Act) as amended by Lov No. 1180 of 12 December 2005; chapter 7

215 http://europa.eu.int/comm/enterprise/pharmaceuticals/eudralex/vol-1/dir_2001_83/dir_2001_83_de.pdf

216 AESGP 2005

It is stated by law[217], that patients may control their pharmaceutical consumption and out-of-pocket expenditure for reimbursable pharmaceuticals (i.e. their "personal medicine profile" (Personlige Elektroniske Medicinprofil) via the internet.[218] To obtain access patients have a digital signature. The main purpose of the electronic profile was to inform prescribing/treating doctors of which other medications the patient is having in order to avoid double medications, interactions etc.[219]

This internet platform, the "Medicinpriser"[220] data base of DMA and information leaflets are the main source of information for patients, together with information from pharmacists on pharmaceuticals, including the cheapest available pharmaceutical. Furthermore a number of websites e.g. IRF's[221] website for consumers are available.[219]

6.3 Reimbursement

The current Danish reimbursement system is applied since 1 April 2005 and is characterised by the following aspects, that are explained in more detail in the following sections:

- the existence of a positive list including pharmaceuticals eligible for **general** reimbursement,
- **individual** special reimbursement on request,
- variable reimbursement rates depending
  - on the consumption of the patient within a 12-month period,
  - adults/children under 18 yrs and
  - disease status (chronically or terminally ill) with co-payments,

  calculated on basis of a reimbursement price calculated by DMA ,
- OTC only reimbursed for patients with defined illnesses or for pensioners and
- obligatory generic substitution.[222]

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217 Sundhedsloven (Health Act) No. 546 of 24 June 2005 as amended by Lov No. 1395 of 21 December 2005; Chapter 42, Art. 157

218 http://www.medicinprofilen.dk

219 DMA 2006e

220 http://www.medicinpriser.dk

221 http://www.irf.dk

222 IM 2005

6.3.1 Pharmaceutical Lists and Reimbursement Categories

6.3.1.1 Reimbursement Price

Although in Denmark a sort reference price system (cf. 6.3.2) is applied for reimbursable pharmaceuticals, the use of the term "reference price" was removed from legislation in the year 2000 and was replaced with the term "reimbursement price" (tilskudspris).[223]

This reimbursement price is the basis for the calculation of the reimbursement and the co-payment rates as shown in Table 6.4 in section 6.3.2.

The reimbursement basis is the gross pharmacy retail price of the cheapest available bio-equivalent product among those with the same ATC-5 code, the same formulation and a similar pack size (cf. 6.3.1.4 for details).[224] Such identical pharmaceuticals are clustered in so-called reimbursement/substitution groups.

In case of on-patent pharmaceuticals, where there is no parallel import on the market, the reimbursement price is the notified price to DMA (i.e. the price in “Medicinpriser”).

6.3.1.2 Selection Criteria

Normally, general reimbursement is granted by DMA (on recommendation by the Reimbursement Committee (cf. 6.1.1):

- if the pharmaceutical has a safe and valuable therapeutic effect on a well-defined indication and
- if the price of the product is reasonable in relation to the therapeutic value.[225]

After the decision the pharmaceutical is included in the Danish positive list.

Eligibility for general reimbursement may be denied to companies seeking reimbursement status for the products, if[226]

- there is a considerable risk of off-label use (i.e. that the pharmaceutical will be used beyond the authorised indication like it is often the case for *bisphosphonates*),
- the implementation of treatment with the pharmaceutical requires a special medical examination and diagnostic procedure, e.g. products for *Alzheimer’s dementia*,

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223 Martikainen/Rajaniemi 2002

224 Lov om offentlig sygesikring, LBK No. 509 of 1 July 1998 as amended by Act. No. 1431 of 22 December 2004

225 Lov om offentlig sygesikring (National Health Service Act), No. 311 of 9 June 1971, latest amended by LF No. 1431 of 22 December 2004; Art. 7a

226 DMA 2006a

- the pharmaceutical is exclusively or primarily used for purpose for which it is not reasonable to expect reimbursement from the National Health Service, e. g. *nicotine replacement products,*
- the effect of the pharmaceutical is not clinically documented, e.g. *herbal medicine*
- there is a risk that the pharmaceutical is used as a first line therapy, regardless that the DMA is of a different opinion, e.g. *anti-obesity products,*
- it is not clarified if or when the pharmaceutical should be used as first line agent, e.g. *some new anti-rheumatic products*
- there is a certain risk that the pharmaceutical may be abused, e.g. *sleeping medicine,*
- the pharmaceutical is primarily used in hospital treatment, e.g. *anti-cancer products* or
- the pharmaceutical is not suitable - due to a special pharmaceutical form the medicinal product - to be administered by patients themselves, e.g. *injection and infusion fluids.*

In the year 2005 (2004), for instance, the Reimbursement Committee granted 10 (7) of the 19 (13) new pharmaceuticals for which companies applied for general reimbursement. The others were rejected for various reasons e.g. rejected because the price deemed to be too high (4 cases in 2005 and 1 in 2004 or in 2 cases 2005 because it was unclear if the product qualified for first line agent.

However, patients may be granted reimbursement for non reimbursable products on individual basis (if doctor applies for his/her patient) (cf. 6.3.1.3).

6.3.1.3 General and Individual reimbursement

Pharmaceuticals being granted **general reimbursement** status by DMA are reimbursed by the National Health Service depending on the patient need, i.e. the consumption of reimbursable medicines in a 12-month period, which is measured by his/her annual co-payment expenses.

Basically there are four reimbursement levels - 0%, 50%, 75% and 85% - applied. For chronically or terminally ill patients 100% reimbursement is possible. The reimbursement and the respective co-payment rates valid in the year 2006 are shown in Table 6.4 in section 6.2.3.

However, it is also possible that pharmaceuticals are granted general reimbursement status, only on certain conditions, i.e. when prescribed for special diseases (POM and selected OTC) and when prescribed to pensioners.

If a pharmaceutical is not included in the positive list, reimbursement is still possible on **individual basis.** In such cases the prescribing doctor has to send a request for individual reimbursement to DMA on behalf of the patient, using forms prepared by DMA.

The doctor has to include the reason why individual reimbursement for this specific product is necessary, e.g. if the medication is of special importance to the patient, if it has shown effect,

if other relevant treatment has proven to be insufficient etc. The income of the patient or his/her annual co-payment balance play no role for the decision. In case of a denial the doctor nevertheless may apply again.

In 2005 the main reasons for applications for individual reimbursement were (number of approvals):[227]

- Approvals for a specific product, e.g. because of therapeutic needs, cf. above (111,000)
- Approvals for raised reimbursement (2,700), cf. 6.3.1.4
- Approvals for chronically ill patients, i.e. with large consumption (10,000)
- Approvals for terminally ill patients (9,000)

To simplify the procedure for patients and doctors DMA has published a list of guiding criteria which normally have to be met for individual approval for selected pharmaceuticals on its website.[228] Electronic application is planned for autumn 2006.[229]

DMA re-assesses its reimbursement decisions on an irregular basis, e.g. because of evidence-based treatment recommendations, significant price increases, high number of granted individual approvals for one product, etc. The re-assessment procedure is regulated by an Enactment of DMA[230] and will be performed by ATC groups. The first full ATC group to be re-evaluted is Group C (with the subgroups C03 (diuretics), C04 (peripheral vasodilators), C05 (vasoprotectives), C08 (calcium channel blockers), C09 (agents acting on the renin-angiotensin system) and C10 (serum lipid reducing agents), whose assessment started in spring 2006. The reimbursement status for all medicinal products will be reassessed over a 5 years period.[231]

6.3.1.4 Generics and parallel traded products

General reimbursement of generics follows the same rules as other pharmaceuticals, but there is no formal reimbursement decision (i.e. no meeting of the Reimbursement Committee) necessary. The generic or the parallel imported equivalent of a pharmaceutical already included in the positive list is automatically granted reimbursement status, as long as its price is below the price of the original (branded) product.[231]

Voluntary generic substitution of pharmaceuticals is allowed in Denmark since November 1991 (so-called "G"-Scheme)[232] and became mandatory in 1997.

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227 DMA 2006a

228 http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=1571

229 DMA 2006e

230 DMA Guidelines on procedure for reassessment of the reimbursement status of medicinal products" of 8 June 2005; http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=6306

231 DMA 2006e

232 IM 2003

As the reimbursement price (6.3.1.1) - from which the reimbursement and co-payment rates are calculated - always equals the lowest price of a product in one reimbursement/substitution group. Generic substitution has become one of the most important pillars of the Danish reimbursement system.

Mandatory generic substitution means that the pharmacist must always dispense the cheapest available product - generic or parallel import - of the same package. Substitution of a certain pack size by another pack size is only possible, if it is within a range of 10-25% (depending on the type of product) divergence in the size of package from the smallest package to the largest package in the group.[233]

The institution deciding whether a pharmaceutical qualifies for substitution or not is the DMA. It groups pharmaceuticals into a substitution/reimbursement group according to their ATC-group (whereby only ATC-5 level is considered), their formulation and bioequivalence, whereas the single packages within one substitution group are clustered according to package size and dispensing details.[234]

Though there is obligatory substitution, both, doctors and patients, may deny it:

- Doctors may oppose substitution by clearly marking the prescription with "ej S" without giving a reason for the refusal. In this case the reimbursement rate is calculated from the reimbursement price (i.e. the cheapest product in a substitution group) and the patient is obliged - – on top of the normal co-payment - to pay the difference between the reimbursed expenses and the actual pharmacy retail price out-of-pocket. This additional payment is not taken into account for the calculation of the 12-month co-payment ceiling for chronically ill patients (cf. 6.2.3).
- Patients may also oppose substitution without giving a reason, but then they are also obliged to pay the difference between the reimbursed expenses and the actual pharmacy retail price out-of-pocket (unless the price difference is considered as irrelevant). This additional payment is not taken into account for the calculation of the 12-month co-payment ceiling for chronically ill patients.
- If the doctor refuses substitution for good medical reasons - for example because the patient cannot use the cheaper products because of allergy - the doctor can apply DMA for raised reimbursement (cf. 1.3.1.3) for the expensive product. If the application is approved the reimbursement will be calculated from the price of the product and not from the lower reimbursement price.

A price difference between the cheapest and the prescribed pharmaceutical is considered as irrelevant if it is between certain limits - DKK 5.- to 20.- / € 0.67 to 2.68 - depending on the pharmacy retail price of the product.[235] In these cases it is not mandatory for the pharmacy to substitute.

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233 DMA 2006c

234 Executive Order on Prescriptions BEK No. 1221 of 7 December 2005

235 DMA 2006c

Since 2004 more than 50% of all prescriptions filled in a pharmacy were generics or parallel imported pharmaceuticals. Thus, Denmark is one of the EU Member States with the highest generic market share.[236] Parallel export, in contrary, is of no significance.

6.3.1.5 Non-reimbursable Pharmaceuticals

There is no negative list in Denmark, but eligibility for general reimbursement may be denied to companies seeking reimbursement status for the products as extensively explained in section 6.3.1.2.

In case pharmaceuticals are denied general reimbursement status they still might be eligible for individual reimbursement as explained in section 6.3.1.3.

Nonetheless, OTC are only reimbursable - provided that they are included in a list of eligible OTC for reimbursement drawn up by DMA[237] - in case they are:

- prescribed by a doctor for one of the specified indications included in a list of illnesses eligible for reimbursement like Aspirin (or rather generic ASA) for example secondary prevention of ischaemic heart disease.

or

- prescribed for pensioners with a special health allowance (helbredstillægskort) from their municipality.[238]

6.3.1.6 Appeal Procedure

Companies that have been denied reimbursement status for their products may apply for a re-evaluation at DMA. They can also appeal to the Ministry of the Interior and Health but only regarding matters relating to procedure.[239]

6.3.1.7 Switches

No particular guidelines / procedures for switches of POM to OTC are in place. The attitude of DMA towards switches is, in general, affirmative.[240]

The latest major switches concerned the abolition of the pharmacy obligation for some OTC, that happened in two steps (October 2001 and January 2003), cf. section 6.1.3 for details. A full list is available on the website of DMA.[241]

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236 LIF 2006b

237 http://www.dkma.dk/db/filarkiv/5601/liste_sygdomsklausul.pdf

238 IM 2005

239 DMA 2006e

240 AESGP 2005

241 http://www.medicinpriser.dk/frihandel.cfm

6.3.2 Reference Price System

Although the term "reference price" was by statute replaced by the term reimbursement price (tilskudpris) in the year 2001, a reference price system is in fact in place. The original reference price system was already introduced in the year 1993.[242]

The reimbursement price is for all pharmaceuticals in one substitution/reimbursement group nowadays the lowest available Danish price, which is retrieved through internal price referencing (cf. 6.2.2.2 for former calculation methods). Which product falls into which substitution/reimbursement group is determined by DMA on basis of ATC-5 level, bioequivalence, medical equivalence, formulation and also pack size (cf. 6.1.3 and 6.3.1.4).

The reimbursement rate and the respective patient co-payment rate, which both depend on the annual consumption and the status of the patient (cf. 6.2.3), are calculated on basis of the reimbursement price as the following Table 6.5 illustrates.

Table 6.5: Denmark - Example of Reimbursement Groups and for Reimbursement Category 50%, valid since 1 April 2005

Pharmaceutical	Price (PRP)[1]	Reimbursement Price (tilskud pris)	Amount reimbursed	Patient co-payment
Alfa	200	200	100	100
Beta	300	200	100	200
Gamma	600	200	100	500

[1] Gross Pharmacy Retail Price

Source: IM 2005

A pre-requisite for a functioning reference price system is obligatory generic substitution, which was established in April 2005 (cf. 6.3.1.4). This means, that the pharmacist always have to dispense the cheapest available pharmaceutical within one substitution/reimbursement group. However, if the price difference between the prescribed pharmaceutical and the reimbursement price is irrelevant (meaning that it between certain limits - DKK 5.- to 20.- / € 0.67 to 2.68 - depending on the pharmacy retail price of the product) the pharmacist may dispense the prescribed one.[243]

As in all reference price systems patients have to pay the difference between the reimbursement price and the gross pharmacy retail price if he/she refuses substitution of the pharmaceutical by the cheaper, often generic, pharmaceutical.

This could lead to the situation that - in case the cheapest pharmaceutical is out of stock - the pharmacist may dispense the second cheapest pharmaceutical (but without making the

242 ÖBIG 2001

243 DMA 2006c

patient pay the difference to the reference price). To guarantee the sufficient availability of (cheap) pharmaceuticals DMA has ruled, that together with price applications a declaration of availability has to be submitted.[244]

6.3.3 Pharmaceutical Budgets

Pharmaceutical budget currently play no role in the Danish pharmaceutical system. However, with the transfer of responsibility for reimbursement of pharmaceuticals for the National Health Insurance to the regions from 1 January 2007 on (cf. 6.1) it is foreseen, that the regions will receive a budget to cover their expenses by the state.

6.3.4 Other Volume Control Oriented Measures

6.3.4.1 Prescription Monitoring and Other Doctors-related Measures

IRF prepares a national list of recommended "first line" therapy substances to serve doctors as - not mandatory - guideline for prescribing doctors.[245] This recommendation list doesn't contain prices of pharmaceuticals. However the regions are - in expectation of the shift of responsibility for pharmaceutical expenditure from central to regional level from 1 January 2007 on - preparing more detailed prescribing guidelines, also taking cost-effectiveness into account.[246]

Prescribing behaviour of doctors is monitored by DMA via an internet-based system called "Ordiprax".[247] Ordiprax was developed by IRF and allowing GPs and specialists to compare their prescribing habits with those of colleagues in their region.[248]

However, as there are neither prescribing budgets nor sanctions for the refusal of generic substitution applicable for doctors the Ordiprax system is more an inspirational tool than a control mechanism.

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244 PPR 5/2005

245 Tilson / Barry 2005

246 DMA 2006a

247 http://www.ordiprax.dk

248 DMA 2006d

6.4 Overview of the Reimbursement Market in Denmark

Tasks / Duties	Yes	No	Comments	Legal bases
Public Authorities (Ministry, Medicines Agency together with Reimbursement Committee)				
Decide on prescription status	X			Lov om lægemidler (Medicines Act) No. 1180 of 12 December 2005
Decide on manufacturer price		X	There is, technically speaking, free pricing for all pharmaceuticals on manufacturer and wholesale price level. However, prices of reimbursable off-patent pharmaceuticals and generics are indirectly influenced through the reimbursement price. Pharmaceuticals companies wishing to include their products in the reimbursement system have to apply for reimbursement at DMA. Before introduction of the new system in 2005 price freezes basing on voluntary agreements between LIF and the authorities were a dominating feature of the pharmaceutical pricing policy from 1995 on.	Lov om lægemidler (Medicines Act) No. 1180 of 12 December 2005 , Art. 77
Agree on manufacturer price		X		
Fix wholesale margin		X		
Fix pharmacy retail price	X		Via regressive mark-up scheme	Bekendtgørelse om ændring af bekendtgørelse om beregning af forbrugerpriser på apoteksforbeholdte lægemidler samt ikke apoteksforbeholdte håndkøbslægemidler m.v. (Executive Order BEK No. 237) of 24 March 2006, Art. 1
Decide on reimbursement status	X			Lov om offentlig sygesikring (National Health Service Act), No. 311 of 9 June 1971, latest amended by LF No. 1431 of 22 December 2004; Art. 7
Agrees on reimbursement price			Not applicable	
Decide on reimbursement price	X		Lowest available price in a group of pharmaceuticals, grouped by ATC 5 level. In some groups there might be only 1 product.	
Use Pharmaco-economic guidelines	X		Yes, but not mandatory	

Tasks / Duties	Yes	No	Comments	Legal bases
Use Internal reference pricing	X		On ATC 5 level for determining reimbursement price of substitutable products	
Use External reference pricing	X		Only on informal basis, but used to be obligatory until 1 April 2005	
Price freezes	X		Used to be a very popular mechanism to contain the price of pharmaceuticals; voluntary (2001-2005) and statutory (1997) price freezes were applied. The latest price freeze agreement between LIF and DMA was abolished when the new reimbursement system took place in April 2005	Lov om midlertidigt prisstop for lægemidler m.v. (Price Stop Act) No. 224 25 March 1997
Margin cuts	X		The variable factor "conscription percentage" of the pharmacy mark-up is regularly adapted (app. twice a year); the last five changes being reductions.	Bekendtgørelse om ændring af bekendtgørelse om beregning af forbrugerpriser på apoteksforbeholdte lægemidler samt ikke apoteksforbeholdte håndkøbslægemidler m.v. (Executive Order), BEK No. 122 of 28 February 2005, Art. 1
Discounts and Rebates	X		Statutory discounts of pharmacies to National Health Service	Lov om offentlig sygesikring (National Health Service Act), No. 311 of 9 June 1971 as amended
Company profit control			Not applicable	
Country specific:	In fact there is a reference price system in place, however it is stated by law, that the term to be used is "reimbursement price" (tilskud pris) DMA also decides in which substitution/reimbursement group a pharmaceutical is included.			
Pharmaceutical Industry				
Sets manufacturer price freely	X		Manufacturers may change their price every two weeks, provided - the price change is min. DKK 1.- / € 0.3 and - it is notified to DMA	Lov om lægemidler (Medicines Act) No. 1180 of 12 December 2005, Art. 77
Notifies manufacturer price	X			
Negotiates manufacturer price	X		Manufacturers and wholesalers negotiate their share of the price	
Decides on application for reimbursement	X			Lov om offentlig sygesikring (National Health Service Act), No. 311 of 9 June 1971, latest amended by LF No. 1431 of 22 December 2004; Art. 7
Negotiates reimbursement price			Not applicable	

Tasks / Duties	Yes	No	Comments	Legal bases
Free to keep manufacturer price above reimbursement price	X		But this could leave to the loss of reimbursement status	Lov om lægemidler (Medicines Act) No. 1180 of 12 December 2005 , Art. 77
Free to grant rebates / discounts to wholesalers	X			
Free to grant rebates / discounts to pharmacies			Not available	
Can engage in marketing towards doctors	X		In line with code of conduct	
Can engage in public advertising	X		Only for OTC	Lov om lægemidler (Medicines Act) as amended by Lov No. 1180 of 12 December 2005; http://www.retsinfo.dk/_LINK_0/0&ACCN/A20050118030
Can provide information toward patients	X		Only for OTC	Lov om lægemidler (Medicines Act) as amended by Lov No. 1180 of 12 December 2005; http://www.retsinfo.dk/_LINK_0/0&ACCN/A20050118030
Applies for switches and de-listing	X			Lov om lægemidler (Medicines Act) as amended by Lov No. 1180 of 12 December 2005; http://www.retsinfo.dk/_LINK_0/0&ACCN/A20050118030
Promotional control		X		
Country specific:				
Wholesaler				
Margins are fixed by statute		X	Negotiates his/her share on wholesale price with manufacturers	
Margins are subject to statutory discounts / rebates		X	Not applicable	
Free to grant discounts / rebates to pharmacies	X		Only in cash	
Pharmacists				
Margins are fixed by statute	X		Based on wholesaler maximum price;	Bekendtgørelse om ændring af bekendtgørelse om

Tasks / Duties	Yes	No	Comments	Legal bases
Free to set retail price		X	System of pharmacy remuneration is currently in a transitional phase, a new system will be introduced by 1 April 2007.	beregning af forbrugerpriser på apoteksforbeholdte lægemidler samt ikke apoteksforbeholdte håndkøbslægemidler m.v. (Executive Order BEK No. 237) of 24 March 2006, Art. 1
Obliged to inform patient on cheaper product		X		Sundhedsloven (Health Act) No. 546 of 24 June 2005 as amended by Lov No. 1395 of 21 December 2005
Obliged to substitute by a generic	X		If pharmaceutical is cheaper (except doctor has interdicted it) or price difference is irrelevant	
Allowed to substitute by a generic	X			
Obliged to substitute by a parallel import	X		If pharmaceutical is cheaper (except doctor has interdicted it) or price difference is irrelevant	
Allowed to substitute by a parallel import	X			
Therapeutic / analogous substitution is allowed		X		
Are subject to statutory discounts / rebates	X		Yes, 1,72% in 2005 to the National Health Service	
Claw back system exists	X			Lov om offentlig sygesikring (National Health Service Act), No. 311 of 9 June 1971 as amended
May grant rebates to customers	X		50% of all discounts obtained from wholesalers have to passed on to customers	
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			Lov om lægemidler (Medicines Act) as amended by Lov No. 1180 of 12 December 2005
Are obliged to inform on co-payment		X		
Prescription habits are monitored	X		Through Ordiprax system	
Are subject to prescription guidelines		X		
Budgets are controlled		X		
Allowed to prescribe INN	X			

Tasks / Duties	Yes	No	Comments	Legal bases
Obliged to prescribe INN		X		
Can oppose generic substitution	X		But have to give medical reasons	Sundhedsloven (Health Act) No. 546 of 24 June 2005 as amended by Lov No. 1395 of 21 December 2005
Can oppose therapeutic substitution			Not applicable	
Can oppose substitution by parallel import	X		But have to give medical reasons (which are very unlike to be accepted by DMA)	Sundhedsloven (Health Act) No. 546 of 24 June 2005 as amended by Lov No. 1395 of 21 December 2005
Country specific:				
Patients				
Can shop for cheapest price of the product	X			
Pay a flat rate per prescription / pack		X		
Pay a certain percentage per prescription / pack or a deductible	X			Sundhedsloven (Health Act) No. 546 of 24 June 2005 as amended by Lov No. 1395 of 21 December 2005; Chapter 42, Art. 146, 147 and 148 on basis of Lov om offentlig sygesikring (National Health Service Act), No. 311 of 9 June 1971, latest amended by LF No. 1431 of 22 December 2004; Art. 7
Annual minimum co-payment		X	DKK 480.-/ € 64.4 for a period of 12 months	
Annual maximum co-payment	X		Only for chronically or terminally ill patients, all other patients always have to pay a patient co-payment share	
May ask for substitution by a generic	X			Sundhedsloven (Health Act) No. 546 of 24 June 2005 as amended by Lov No. 1395 of 21 December 2005
May oppose substitution by a generic	X		But then has to pay difference to reimbursement price out-of-pocket	
May ask for substitution by a parallel import	X			
Can oppose substitution by a parallel import	X		But then has to pay difference to reimbursement price out-of-pocket	
Can oppose substitution only on payment of price difference	x			
Has to pay the difference between reimbursement price and retail price	X			

Tasks / Duties	Yes	No	Comments	Legal bases
Has access to full public information on prices and products	X		Patients have possibility to check their co-payment balance through their personal medicine profile	http://www.medicinprofilen.dk
Country specifics:				

Source: ÖBIG 2006

ESTONIA

7 Estonia

7.1 Pharmaceutical System

7.1.1 Regulatory Framework and Authorities

In Estonia, around 95% of the 1.4 million inhabitants are covered by statutory health insurance. 77% of the health expenditure are funded through public funds (general taxation and health insurance contributions, which account for 13% of an employee's salary), and the remaining 23% are privately funded. Only a small part of the population (around 3%) is covered by private health insurance.

The most relevant players in the Estonian pharmaceutical system are

- the Ministry of Social Affairs (Sotsiaalministeerium, SM) which is responsible for the strategic planning in terms of pharmaceuticals. It is also in charge of pricing and reimbursement decisions
- the State Agency of Medicines (Ravimiamet, SAM) under the SM which is responsible for issuing market authorisations as well as classification and vigilance. SAM also acts as advisory body to the SM in the reimbursement process
- the Estonian Health Insurance Fund[249] (Haigekassa, EHIF) which is responsible for the reimbursement of pharmaceuticals

The procedure of granting market authorisation of pharmaceuticals in Estonia is in line with the EU regulations. Pharmaceutical companies need to include in their application for market authorisation a proof of quality, safety and efficacy of the pharmaceutical[250]. If all requirements for a market authorisation are fulfilled, SAM issues the market authorisation followed by the classification of pharmaceuticals according to their prescription status into POM and OTC.

In January 2005, there were 2,768 pharmaceuticals (incl. all pharmaceutical forms and strengths) authorised[251] on the Estonian pharmaceutical market. These contain 859 different active ingredients.

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249 Health Insurance Act, 2002, http://www.legaltext.ee/failid/findfile.asp?filename=X60043

250 Medicinal Products Act of 2005, http://www.sam.ee/219

251 http://www.sam.ee/1533

Table 7.1 contains an overview of the relevant stakeholders introduced in sections 7.1.1 and 7.1.2.

Table 7.1: Estonia - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Sotsiaalministeerium (SM) / Ministry of Social Affairs	Ministry of Social Affairs, in charge of Reimbursement and Pricing (e.g. fixing of reference price)	Health Care Department Head of department Heidi Gil Gonsiori 29 EE-15027 Tallinn Estonia Tel.: +372 6269 125 Fax: +372 6992 209 heidi.gil@sm.ee www.sm.ee/eng/pages/index.html	Ms. Katrin Pudersell Chief Specialist Gonsiori 29 EE-15027 Tallinn Estonia Tel.: +372 6269 139 Fax: +372 6992 209 katrin.pudersell@sm.ee
Eeesti Haigekassa / Estonian Health Insurance Fund (EHIF)	Third Party Payer, Pricing and Reimbursement, advises Ministry	EHIF Lembitu 10 EE-10114 Tallinn Estonia Tel.: +372 6696 630 Fax: +372 6208 449 info@haigekassa.ee www.haigekassa.ee/eng	Mr. Hannes Danilov Chairman of Management Board Lembitu 10 EE-10114 Tallinn Estonia Tel.: +372 6208 430 Fax: +372 6208 449 Hannes.danilov@haigekassa.ee
Ravimiamet / State Agency of Medicines (SAM)	Medicines Agency (Authorisation, Classifiation, Vigilance, etc.), advises Ministry in Terms of Reimbursement	SAM Director general Dr. Kristin Raudsepp 1, Nooruse Street EE-50411 Tartu Estonia Tel.: +372 7374 140 Fax: +372 7374 142 sam@sam.ee Kristin.Raudsepp@sam.ee www.sam.ee	Ms. Katrin Kiisk Head of Department of Human Medicines Nooruse Street 1 EE-50411 Tartu Estonia Tel.: +372 7374 140 Fax: +372 7374 142 Katrin.kiisk@sam.ee www.sam.ee
Rahvusvaheliste Ravimitootjate Liit Eestis (RRLE) / Association of International Pharmaceutical Manufacturers in Estonia	Association of Pharmaceutical Industry (International Manufacturers)	RRLE Toompuiestee 10 EE-10137 Tallinn Estonia Tel.: +372 50 82 860 www.rrle.ee	Mr. Helve Remmel Managing Director Toompuiestee 10 EE-10137 Tallinn Estonia Tel.: +372 66 16 614 helve.remmel@rrle.ee

Institution	Task	Contact details/URL	Responsible person
Eesti Geneeriliste Ravimite Liit (EGRAL) / Estonian Generic Medicines Association	Association of Generic Manufacturers and Traders	EGRAL Pirita tee 20T EE-10127 Tallinn Estonia Tel.: +372 5661 8636 www.egral.ee	Mr. Risto Kukk Communication Officer EE-10127 Tallinn Estonia Tel.: +372 5661 8636 info@egral.ee
ERHL / Estonian Association of Pharmaceutical Wholesalers	Wholesaler Association	President Virkko Pullinen Pärnu mnt. 139c EE-11619 Tallinn Estonia Tel.: +372 6501 901 Fax: +372 6501 900 Virkko.pullinen@magnum.ee	Ms. Jana Laasalu Pärnu mnt. 139c EE-11619 Tallinn Estonia Tel.: +372 6501 901 Fax: +372 6501 900 janalaasalu@hot.ee
Eesti Apteekrite Liit / Estonian Pharmacists' Association	Association of Pharmacists'	Association of Pharmacists' President Ms. Kai Kimmel Endla 31 EE-10122 Tallinn Estonia Tel.: +372 6620 323 www.apteekriteliit.ee/eng/english.html	Head Pharmacist Ms. Kaidi Vendla Endla 31 EE-10122 Tallinn Estonia Tel.: +372 6620 323 Fax: +372 6621 054 Aptliit@hot.ee

Source: ÖBIG 2006

7.1.2 Market Players

7.1.2.1 Pharmaceutical Industry

In Estonia, there are almost no national pharmaceutical manufacturers, however some companies are producing generics. They are represented in the Estonian Generic Medicines Association (Eesti Geneeriliste Ravimite Liit, EGRAL[252]). Besides, there are 18 international pharmaceutical companies representativs located in Estonia. They are organised in the Association of International Pharmaceutical Manufacturers (Rahvusvaheliste Ravimitootjate Liit Eestis, RRLE[253]).

7.1.2.2 Distribution

On the wholesale level in Estonia, there is a multi-channel system with 32 companies with a wholesale licence. The largest wholesaler is Magnum Medical AS, covering around 50% of the market.

252 www.egral.ee

253 www.rrle.se

Other important wholesale companies are Tamro Esti OÜ, TopMed AS, Oriola AS, Pharma MS AS and Armila Esti OÜ. They are organised in the Estonian Association of Pharmaceutical Wholesalers (ERHL).

Pharmaceuticals in Estonia are dispensed in 316 pharmacies and 158 dispensaries (pharmacy branches and stations). However, one-fourth of the pharmacies are located in the capital Tallinn. In the last few years more and more pharmacy chains were established, which are often owned by wholesale companies. This trend is seen as problematic, since these chains are mainly provided by their own wholesalers. Consequently they thereby have a stronger market position. Pharmacies are organised in seven different Associations, the Estonian Pharmacists' Association (Eesti Apteekrite Liit) being a major one.

Self-dispensing doctors and the dispensing of pharmaceuticals over the internet is not allowed.

7.1.2.3 Patients

Patients must pay both a flat fee of EEK 20.- / € 1.28 for pharmaceuticals in the reimbursement categories 100% and 75% and a percentage charge according to reimbursement categories (cf. 7.2.3).

As pharmacy retail prices vary in different pharmacies, patients may shop for the cheapest pharmaceutical (cf. 7.2.3). Patients are very price sensitive and therefore encourage the use of generics (cf. 7.3.4.2).

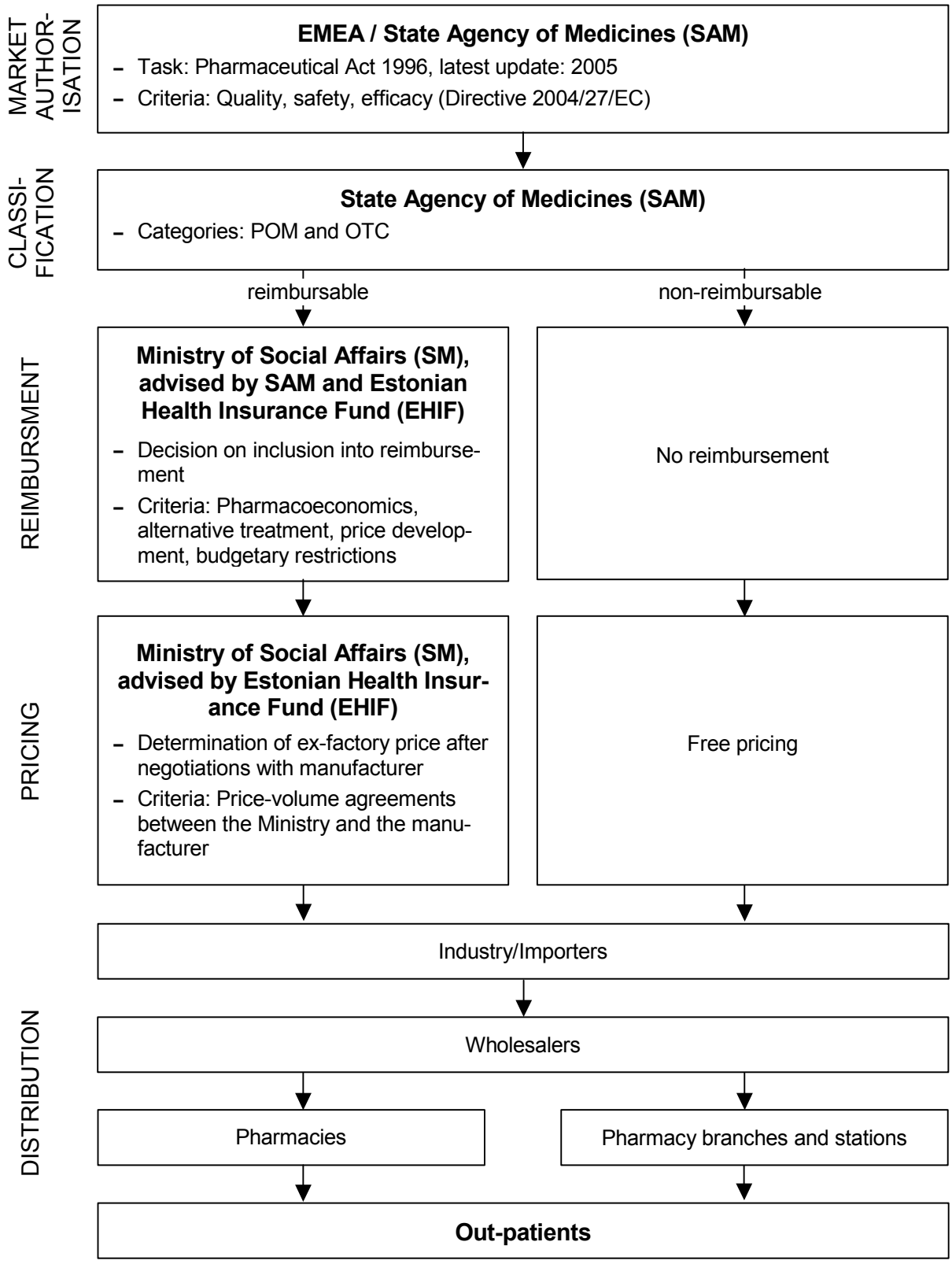
Patients have the possibility to access pharmaceutical prices that are listed on the positive publicly on the website of the EHIF[254] (cf. 7.2.4).

7.1.3 Overview of the Pharmaceutical System

Figure 7.1 shows an overview of the pharmaceutical system in Estonia.

[254] http://www.raviminfo.ee/otsing.php

Figure 7.1: Estonia - Pharmaceutical System, 2006



Source: ÖBIG 2006

7.2 Pricing

7.2.1 Scope of Price Control

In Estonia, there is statutory pricing (after negotiations) for reimbursable pharmaceuticals and free pricing for non-reimbursable pharmaceuticals. The decision on the manufacturer price should be taken after the decision on reimbursement; but in reality the process of pricing is incorporated into the reimbursement procedure (cf. 7.3).

The current statutory margin schemes for wholesalers (cf. Table 7.3) and for pharmacies (cf. Table 7.4), which were latest updated in 2002, are applicable for all pharmaceuticals (reimbursable and non-reimbursable pharmaceuticals)[255]. Table 7.2 provides an overview of the Estonian pricing system.

Table 7.2: Estonia - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Non-reimbursable pharmaceuticals	Not applied	Not applied
Statutory Pricing	Reimbursable pharmaceuticals	All pharmaceuticals regulated via a regressive maximum mark-up scheme for wholesalers	All pharmaceuticals regulated via a regressive maximum mark-up scheme for pharmacies
Price Negotiations	Price-volume agreements between the manufacturer and SM	Not applied	Not applied
Price/volume agreements, discounts/rebates	Price-volume agreements between the manufacturer and SM	No	No
Institution in charge of pricing	SM		
Legal Basis	Regulation No. 328, 2002 Regulation No. 121, 2004		

SM = Ministry of Social Affairs

Source: ÖBIG 2006

[255] Regulation No. 328, 2002, http://www.sm.ee/eng/pages/goproweb1274

7.2.1.1 Manufacturer Price

The SM sets the manufacturer price in line with price-volume agreements[256] with the manufacturer. The decision on the manufacturer price is usually taken once the issue of reimbursement has been settled, but in reality they are discussed as part of reimbursement negations (cf. 7.3).

The price application by pharmaceutical companies needs to include information on:

- the INN, the ATC classification, the pharmaceutical form, strength, and package size of the pharmaceutical
- the manufacturer price, the wholesale and the pharmacy price of the pharmaceutical
- the manufacturer prices in reference countries (Latvia, Lithuania, France, Portugal and Hungary)
- expected retail volume of the pharmaceutical

The SM examines the price application's conformity with the legal requirements. In case of an expected substantial financial impact on the health insurance budget, the SM then asks the EHIF for advice. EHIF prepares its written opinion and sends it back to the SM. Within 30 days of the receipt of the company's proposal the SM has to write a draft price agreement. This is then sent again to the EHIF and after another round of consultations, the SM finally decides on the manufacturer price.

This pricing procedure is applied for all pharmaceuticals, including generics. However, the prices of generics are set at 70% of the original pharmaceutical.

Price-volume agreements are valid for 1 year and companies are prohibited to raise their prices during the price-volume agreement period.

7.2.1.2 Wholesale Price

In Estonia the wholesale mark-ups for all pharmaceuticals are regulated by the state[257].

A newly regulated regressive maximum mark-up scheme, displayed in Table 7.3, is in place. The mark-up scheme is limited by a maximum mark-up of EEK 100 / € 6.4 per prescription.

256 Regulation 121, 2004, http://www.sm.ee/eng/pages/goproweb1274

257 Regulation No. 328, 2002, http://www.sm.ee/eng/pages/goproweb1274

Table 7.3: Estonia - Maximum Wholesale Mark-up Scheme, 2006

Manufacturer price from…to…in EEK / €	Wholesale mark-up in % of the manufacturer price
up to EEK 25.- / € 1.60	20%
from EEK 25.01 / € 1.6 to EEK 45.- / € 2.80	15%
from EEK 45.01 / € 2.8 to EEK 100.- / € 6.40	10%
from EEK 100.01 / € 6.4 to EEK 200.- / € 12.80	5%
from EEK 200.- / € 12.80 on	3% (max. EEK 100 / € 6.4 per prescription)

Source: Regulation No. 328, 2002

7.2.1.3 Pharmacy Retail Price

For pharmacies, a maximum regressive mark-up scheme is also applied[258]. Table 7.4 displays the maximum pharmacy mark-ups. This scheme is valid for all pharmaceuticals.

Table 7.4: Estonia - Maximum Pharmacy Mark-up Scheme, 2006

PPP from…to…in EEK / €	Maximum pharmacy mark-up	
	Coefficient in % of PPP	Fixed mark-up in EEK / €
up to EEK 10.- / € 0.60	-	EEK 6.- / € 0.40
from EEK 10.01 / € 0.60 to EEK 20.- / € 1.30	40%	EEK 6.- / € 0.40
from EEK 20.01 / € 1.30 to EEK 30.- / € 1.90	35%	-
from EEK 30.01 / € 1.90 to EEK 40.- / € 2.50	30%	-
from EEK 40.01 / € 2.50 to EEK 50.- / € 3.20	25%	-
from EEK 50.01 / € 3.20 to EEK 100.- / € 6.40	20%	-
from EEK 100.01 / € 6.40 to EEK 700.- / € 44.70	15%	-
from EEK 700.01 / € 44.70 on	-	EEK 80.- / € 5.10

PPP = Pharmacy Purchase Price

Source: Regulation No. 328, 2002

In general, the maximum mark-ups are not fully utilised, consequently the prices in pharmacies may vary. Therefore patients have the possibility to shop for the cheapest pharmaceutical.

7.2.1.4 Value Added Tax (VAT)

As of January 2001, all pharmaceuticals - both OTC and POM - are subject to 5% VAT.

[258] Regulation No. 328, 2002, http://www.sm.ee/eng/pages/goproweb1274

7.2.2 Price related Cost-containment Measures

7.2.2.1 Pharmaco-economic Evaluation

In the course of the application for reimbursement in the category 100% and 75%, manufacturers have been required to submit a pharmaco-economic analysis, in accordance with the requirements of the SM[259], based on the Baltic Guideline for Economic Evaluation of Pharmaceuticals[260].

In 2002, the common Baltic Guideline for Economic Evaluation of pharmaceuticals was developed in a cooperation by the Latvian Pricing and Reimbursement Agency (ZCA), the Estonian Health Insurance Fund and the Lithuanian Department of Pharmacy (FD) to simplify the application for reimbursement for pharmaceutical manufacturers. This Guideline gives information, among others, on the preferred perspective (health care system); on costs to be included in the analysis, on how they shall be established and on discount rates to be used. The Guidelines aim at harmonising of pharmaceutical prices in the Baltic States.

7.2.2.2 Internal Price Referencing

In the course of an application for reimbursement, the applied price is compared with prices of other pharmaceuticals with the same active ingredient or with pharmaceuticals from the same therapeutic group. There is a reference price system in place, introduced in January 2003 (cf. 7.3.2).

7.2.2.3 External Price Referencing / Cross Country Referencing

Pharmaceutical companies need to include information on the manufacturer prices in reference countries, which are Latvia, Lithuania, France, Portugal and Hungary (cf. 7.2.1.1).

7.2.2.4 Price Freezes / Stops

In Estonia, there have been no statutory price freezes in the last 5 years.

7.2.2.5 Margin Cuts

Wholesale and pharmacy margins are regulated through a regressive maximum mark-up scheme (cf. 7.2.1.2 and 7.2.1.3), which was last changed in 2002.

7.2.2.6 Discounts and Rebates

In Estonia, there are no statutory discounts or rebates. Nevertheless, the pharmaceutical industry is free to grant rebates or discounts to wholesalers and pharmacies on a voluntary basis.

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259 Regulation No. 129, 2002, http://www.haigekassa.ee/files/eng_legislation/129eng.pdf

260 Baltic Guideline of Economic Evaluation of Pharmaceuticals (Pharmaco-economic Analysis), http://www.zca.gov.lv/docs/new2002/doc24-1.pdf

7.2.2.7 Company Profit Controls

In Estonia, there are no company profit controls.

7.2.2.8 Parallel Trade

Parallel trade currently plays no role, therefore there are no specific regulations in place for parallel imported pharmaceuticals. In any occasion Estonia is more an export than an import country.

7.2.3 Co-Payments

Patients must pay both a flat fee of EEK 20.- / € 1.28 for pharmaceuticals in the reimbursement categories 100% and 75% and a percentage charge according to the reimbursement categories (cf. Table 7.5), as well as any difference between the reference price (cf. 7.3.2) and the pharmacy retail price.

Patients who spend more than EEK 6,000 / € 383.- a year on pharmaceuticals are offered supplementary reimbursement by EHIF which is limited to EEK 9,500 / € 607.- a year[261].

Patients have to pay their co-payment to the pharmacy and, after receiving the prescription electronically, the EHIF pays the remainder to the pharmacy.

For non-reimbursable pharmaceuticals patients have to pay the full price out-of-pocket. Taking into account the differences in pharmacy retail prices, patients have the possibility to shop for the cheapest pharmaceutical (cf. 7.1.2.3).

7.2.4 Information Transparency and Marketing

In Estonia, prices of pharmaceuticals are publicly accessible on the website of SAM[262]. Besides information on the ATC code, brand name, available pharmaceutical forms, dosage and pack size the website also indicated which pharmacies sell that pharmaceutical. There can be price differences from pharmacy to pharmacy (cf. 7.2.1.3), and patients have the possibility to shop for the cheapest pharmaceutical.

SAM publishes guidelines[263] on the labelling of pharmaceuticals and on package leaflets which are fully compatible with the EU's patient information provisions.

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261 http://www.haigekassa.ee/eng/health/outline/

262 http://www.raviminfo.ee/otsing.php

263 Common Baltic Package Guidance http://monitor.isa/482059952/1466448T060508105112.txt.binXMysM0dapplication/mswordXsysM0dhttp://www.sam.ee/5167

Generally speaking doctors, pharmacies and pharmaceutical companies are allowed to inform patients about the characteristics of the pharmaceutical as long as the EU provisions on pharmaceuticals advertising[264] are fulfilled.

7.3 Reimbursement

The SM is responsible for the decision on reimbursement[265] and for defining which diagnoses are considered as reimbursable[266]. On the basis of the diagnoses the SM advised by SAM and EHIF, establishes the positive list, which covers the pharmaceuticals that are reimbursed by the EHIF. Since 2003 Estonia has a reference price system, which is a relevant element in the reimbursement process (cf. 7.3.2). The reimbursement process is very much linked to the decision on the manufacturer prices (cf. 7.2.1).

The application for the reimbursement procedure differs depending on the level of reimbursement applied for and whether a pharmaceutical with the same active ingredient in the same pharmaceutical form is already listed:

- General Procedure - Reimbursement at 100% or 75%[267]

  Manufacturers have to submit an application, which needs to be written in Estonian, to the SM. Besides general information about the pharmaceutical (including information on the planned indication) the application also needs to state the proposed wholesale price of all pharmaceutical forms, active substances and packages of the pharmaceutical in EKK. Since 2002 manufacturers also have to include pharmaco-economic analysis (cf. 7.2.2.1).

  The SM examines the application for conformity with the legal requirements before forwarding it to the EHIF and SAM. EHIF and SAM then prepare a written opinion within 45 days. Among others, SAM takes into account the financial justification for the use of the pharmaceutical to other available pharmaceuticals/treatment alternatives. EHIF rather considers financial and budgetary aspects.

  Taking into account the written opinions by SAM and EHIF, SM advised by the Committee for Medicinal Products[268] announces the final reimbursement decision within 180 days from the start of the application.

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264 Directive 92/28/EC as implemented by the Health Insurance Act, 2002, http://www.legaltext.ee/failid/findfile.asp?filename=X60043

265 Regulation No. 123, 2004, http://www.sm.ee/eng/pages/goproweb1274

266 Regulation No. 308, 2002, http://www.sm.ee/eng/pages/goproweb1274

267 Regulation No. 123, 2004, http://www.sm.ee/eng/pages/goproweb1274

268 The Committee for Medicinal Products is composed of 7 members representing the SM, EHIF, SAM, Patients' Association, Medical Association and GPs

- Simplified Procedure - Reimbursement at 50% and pharmaceuticals with an active ingredient already listed[269]

  Applications, in Estonian, are also submitted to the SM. The main criteria considered in the simplified procedure are financial justification for use, patient need for the pharmaceutical, proven medical effectiveness, availability of alternatives and budgetary considerations. The SM may also ask for the opinion of the EHIF, SAM and the Committee for Medicinal Products, but it is not mandatory.

7.3.1 Pharmaceutical Lists and Reimbursement Categories

As mentioned in section 7.3, the SM establishes a positive list. EHIF reimburses all pharmaceuticals that are listed in the positive list. As of 1.1.2006 the number was about 2,300 pharmaceuticals.[270]

The level of reimbursement of pharmaceuticals is not product-specific, but depends on the diagnosis. For example, diclofenac is 100% reimbursed in oncology, 75% in rheumatoid arthritis and 50% in all other treatments.

There are the following reimbursement categories[271]:

- 100% reimbursement (for 26 different diseases)
- 75% reimbursement (for 40 different diseases), plus a higher reimbursement level of 90% for certain people (children under the age of 10, disabled people and retired people over the age of 63)
- 50%

Table 7.5 gives an overview of the reimbursement categories and co-payment.

269 Regulation No. 123, 2004, http://www.sm.ee/eng/pages/goproweb1274

270 Written information by SM in June 2006

271 Regulation No. 308, 2002, http://www.sm.ee/eng/pages/goproweb1274

Table 7.5: Estonia - Reimbursement Categories and Co-payment, 2006

Reimbursement categories	Reimbursement by the Health Insurance	Co-payment
100%	Excess above EEK 20.- / € 1.28 (= flat fee[1])	EEK 20.- / € 1.28 (= flat fee[1])
90%[2]	plus 90% of excess above flat fee[1] (EEK 20.- / € 1.28)	EEK 20.- / € 1.28 plus 10% of excess above flat fee[1]
75%	plus 75% of excess above flat fee[1] (EEK 20.- / € 1.28)	EEK 20.- / € 1.28 plus 25% of excess above flat fee[1]
50%	plus 50% of excess above flat fee[1] (EEK 50.- / € 3.20), but limited to EEK 200.- / € 12.80 per prescription	EEK 50.- / € 3.20 plus 50% of excess above flat fee[1]

[1] Fixed xo-payment = prescription fee

[2] For children under the age of 10, disabled people and patients over the age of 63 at the reimbursement category of 75%

Source: Regulation No. 308, 2002, information gathering by ÖBIG

7.3.1.1 Reimbursement Price

In case of 100% or 75% reimbursement, the reference price (cf. 7.3.2) is the basis for the reimbursement price. The pharmacy retail price is the maximum reimbursement price for pharmaceuticals reimbursed at 50%, which are subject to a maximum reimbursement amount of EEK 200.- / € 12.80. Manufacturers may adapt their prices as long as this maximum limit is not exceeded.

7.3.1.2 Selection Criteria

The selection criteria for a pharmaceutical to be included in the positive list are pharmacoeconomic studies, information about treatment alternatives, information on the expected development of the wholesale price and information on budgetary restrictions (cf. 7.3).

7.3.1.3 Pharmaceuticals on Positive List

The positive list covers around 3,200 pharmaceuticals (counting different pharmaceutical forms, dosages and pack sizes). The majority of the reimbursable pharmaceuticals are POM, although a limited number of OTC are included.

7.3.1.4 Generics

In general, the same procedure applies to pricing and reimbursement of generics - although a simplified procedure is applied for the reimbursement decision if the active ingredient is already listed (cf. 7.3).

Generic substitution through the pharmacist is not mandatory but doctors are obliged to write prescriptions by INN (International Non-Proprietary Name), meaning that the pharmacist must dispense the cheapest available product.

However, doctors and patients may oppose the substitution (cf. 7.3.4.2 for details).

7.3.1.5 Non-reimbursable Pharmaceuticals

Most of the non-reimbursable pharmaceuticals are OTC products. Patients may purchase the non-reimbursable pharmaceuticals at their own expense. There is no exemption, e.g. for old-age pensioners or children from this rule.

7.3.1.6 Delisting and Switches

Procedures for the exclusion of a pharmaceutical from the positive list, a decrease in the rate of reimbursement and imposition of restrictions in the use commence either on behalf of the SM, SAM or EHIF or with the submission of an application to the SM by a manufacturer. The SM requests opinions from the manufacturer, SAM and the EHIF and also written evidence in justification.

A revision of the list of diseases in each reimbursement category, in line with treatment priorities are planned.

Estonia respects European guidelines in the switching of pharmaceuticals from POM to OTC status. Applications for changing a pharmaceutical's classification are considered and approved by SAM. The decision on the switches is taken within 60 days of receipt of the application.

7.3.2 Reference Price System

Since January 2003 Estonia has a reference price system[272], which is relevant for the decision on the reimbursement categories of 100% and 75% (cf. 7.3.1.1).

Reference prices are calculated for groups of pharmaceuticals with the same active ingredient (ATC 5 level) based on the Defined Daily Dose, DDD. The reference prices are calculated as follows:

- Where 2 preparations fall into the same reference price group, the DDD reference price shall be calculated on the basis of the cheaper preparation.
- Where more than 2 preparations fall into the same reference price group, the preparation with the lowest maximum wholesale price shall be disregarded and the price of the second cheapest preparation shall be taken as the basis. The DDD price of this preparation shall be the DDD reference price.

[272] Regulation No. 114, 2004, http://www.sm.ee/eng/pages/goproweb1274

- Preparations containing a larger quantity of pharmaceuticals than needed for a real treatment period shall not be taken into account in the calculation of reference prices.
- The reference price of a preparation shall be calculated by multiplying the DDD reference price by the number of DDD in the preparation.

The reference price is the basis for the reimbursement price which may be lower than the reference price.

7.3.3 Pharmaceutical Budgets

In Estonia, there are no pharmaceutical budgets being applied for doctors or other health care providers, meaning that there are no fixed prescribing budgets in terms of money for health care professionals.

7.3.4 Other Volume Control Oriented Measures

7.3.4.1 Prescription Monitoring and Other Doctors-related Measures

In order to control health expenditure, doctors are only permitted to prescribe one pharmaceutical per prescription. Only up to six months' supply can be prescribed and dispensed at one time. Doctors are obliged to prescribe by INN. There are compulsory treatment guidelines for certain diagnoses, such as asthma and coronary heart disease.

The EHIF also collects prescribing data to assess the prescribing habits of individual doctors[273]. This information is then sent out to the doctors in order to present them their prescribing behaviour compared to the local average. However, there are no penalties or incentives to enforce cost-effective prescribing.

Additionally, doctors receive a Drug Information Bulletin[274] to encourage rational prescribing. The Drug Information Bulletin covers topics as risk-benefit assessments of pharmaceuticals and considerations as the price of alternative pharmaceuticals. It is published bimonthly by SAM[275].

7.3.4.2 Generics

Generics account for approximately 35% of pharmaceuticals by volume and 15% by value. With the introduction of the reference price system in 2003 (cf. 7.3.2) the usage of less expensive generics was actively promoted. Doctors are obliged to prescribe by INN (cf. 7.3.4.1), and pharmacies must offer patients the cheapest available pharmaceutical.

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273 http://www.haigekassa.ee/eng/ehif/

274 http://www.sam.ee/383

275 http://www.sam.ee/

However, for medical reasons doctors are allowed to prescribe by trade name with a note. In this note doctors have to clearly state why they prohibit the substitution.

Patients may ask for another pharmaceutical than the cheapest available one, but in this case they have to pay the difference between the reimbursed amount and the retail price (cf. 7.2.3 and 7.3.2).

7.4 Overview of the Reimbursement Market in Estonia

Tasks / Duties	Yes	No	Comments	Legal bases
Public Authorities				
Decide on prescription status	X		SAM	Medicinal Products Act of 2005, http://www.sam.ee/219
Decide on manufacturer price	X		SM, price-volume agreements with pharmaceutical industry	Regulation No. 121, 2004, http://www.sm.ee/eng/pages/goproweb1274
Agree on manufacturer price	X			
Fix wholesale margin	X		Via mark-up scheme	Regulation No. 328, 2002, http://www.sm.ee/eng/pages/goproweb1274
Fix pharmacy retail price	X		Via mark-up scheme	
Decide on reimbursement status	X		SM	Regulation No. 123, 2004, http://www.sm.ee/eng/pages/goproweb1274 http://www.sm.ee/eng/HtmlPages/HaigekassaravimiteloeteluEN_ok_ED_C1/$file/Haigekassa%20ravimite%20loetelu%20EN_ok_ED_C1.doc
Agrees on reimbursement price	X		SM	
Decide on reimbursement price	X		SM	
Use Pharmaco-economic guidelines	X		In deciding about the status of reimbursement	
Use Internal reference pricing	X		If the pharmaceutical of same active ingredient and pharmaceutical form is being reimbursed already	Regulation No. 123, 2004, http://www.sm.ee/eng/pages/goproweb1274
Use External reference pricing	X		Information on the manufacturer prices in reference countries, which are Latvia, Lithuania, France, Portugal and Hungary	Regulation No. 123, 2004, http://www.sm.ee/eng/pages/goproweb1274
Price freezes		X		
Margin cuts		X		
Discounts and Rebates		X		
Company profit control		X		
Country specific:				
Pharmaceutical Industry				

Tasks / Duties	Yes	No	Comments	Legal bases
Sets manufacturer price freely	X		Non-reimbursable pharmaceuticals	
Notifies manufacturer price	X		Price-volume agreement with SM	Regulation No. 121, 2004, http://www.sm.ee/eng/pages/goproweb1274
Negotiates manufacturer price	X			
Is free to set price below fixed manufacturer price	X		Companies are allowed to do so, but are unlikely to do it	
Decides on application for reimbursement	X		SM	Regulation No. 123, 2004, http://www.sm.ee/eng/pages/goproweb1274
Negotiates reimbursement price	X			
Free to grant rebates / discounts to wholesalers	X		On a voluntary basis	
Free to grant rebates / discounts to pharmacies	X		On a voluntary basis	
Can engage in marketing towards doctors	X		In line with code of conduct	
Can engage in public advertising	X		Only for OTC	
Can provide information toward patients	X		Through the public advertising mostly	
Applies for switches and de-listing	X		To SM	
Promotional control	X		SAM	
Country specific:				
Distribution Chain				
Wholesaler				
Margins are fixed by statute	X		By SM	Regulation No. 328, 2002, http://www.sm.ee/eng/pages/goproweb1274
Margins are subject to statutory discounts / rebates		X		
Free to grant discounts / rebates to pharmacies	X		On a voluntary basis	
Pharmacists				
Margins are fixed by statute	X		By SM	Regulation No. 328, 2002, http://www.sm.ee/eng/pages/goproweb1274
Free to set retail price		X		

Tasks / Duties	Yes	No	Comments	Legal bases
Obliged to inform patient on cheaper product	X			
Obliged to substitute by a generic		X		
Allowed to substitute by a generic	X		Doctors are obliged to write prescriptions using INN.	
Obliged to substitute by a parallel import	X		Pharmacist is obliged to dispense the cheapest available pharmaceutical (except doctor has interdicted it)	
Allowed to substitute by a parallel import	X		Plays no role	
Therapeutic / analogous substitution is allowed		X		
Are subject to statutory discounts/ rebates		X		
Claw back system exists		X		
May grant rebates to customers	X		On a voluntary basis	
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			
Are obliged to inform on co-payment / deductibles	X			
Prescription habits are monitored	X		By EHIF mostly	
Are subject to prescription guidelines	X		Indicative	
Budgets are controlled		X		
Allowed to prescribe INN	X			
Obliged to prescribe INN	X			
Can oppose generic substitution	X		Doctors needs to note this on the prescription	
Can oppose therapeutic substitution			N. app.	
Can oppose substitution by parallel import			Plays no role	
Country specific:				

Tasks / Duties	Yes	No	Comments	Legal bases
Patients				
Can shop for cheapest price of the product	X			
Pay a flat rate per prescription / pack	X		Flat fee of EEK 20.- / € 1.28	http://www.haigekassa.ee/eng/health/outline/
Pay a certain percentage per prescription / pack or a deductible	X		A percentage charge according to reimbursement categories	http://www.haigekassa.ee/eng/health/outline/
Annual minimum co-payment		X		
Annual maximum co-payment		X		
May ask for substitution by a generic	X			
May oppose substitution by a generic	X		Then they have to pay the difference to the reference price	
May ask for substitution by a parallel import	X		In general yes, but parallel import plays no role at all	
Can oppose substitution by a parallel import	X			
Can oppose substitution only on payment of price difference	X			
Has to pay the difference between reimbursement price and retail price	X			
Has access to full public information on prices and products	X		On the website of EHIF	www.raviminfo.ee
Country specifics:				

N. app. = Not applicable, N. a. = Not available

Source: ÖBIG 2006

FINLAND

8 Finland

8.1 Pharmaceutical System

8.1.1 Regulatory Framework and Authorities

The Finnish health care system is mainly funded by general taxation and organised through a National Social Health Service system covering all Finnish residents. Public funding accounts for more than three quarters of total health expenditure and flows down two different parallel channels. The widest channel is the municipal health expenditure, which is financed through municipal taxation and the state subsidy to the municipalities. The responsibility for organising health care lies with the 431 municipalities (2006)[276]. These can either provide health care services independently or together with neighbouring municipalities in joint municipal boards which maintain a joint health centre. A municipality can also buy in health care services from other municipalities, non-governmental organisations or the private sector.

The second channel carrying public funding into the Finnish health care system is the Social Insurance Institution (Kansaneläkelaitos, KELA), which provides a National Health Insurance scheme that covers all Finns for part of the cost of a range of health services. The services covered include: prescribed pharmaceuticals for ambulatory patients, private medical and dental consultations, private diagnostic tests and treatments, patient transportation and some rehabilitation services and student health services. For all of these services, the patient pays the provider and can seek reimbursement for part of the cost from NHI, which is funded through health insurance contributions.[277]

The Finnish Ministry of Social Affairs and Health (Sosiaali - ja terveysministeriö, STM) is in charge of planning and supervising, e.g. formulation health care targets and guidelines and also decides on health care subsidies to municipalities and the National Health Insurance regulation. Voluntary health insurance is, with the exception of complementary insurance, only of minor relevance.

The most relevant players in the Finnish pharmaceutical system are:

- The National Agency for Medicines (Lääkelaitos, NAM) and the STM, that are in charge of pharmaceutical issues, whereby the STM looks after legislation in this area and NAM takes care of market authorisation, post-licensing monitoring, market surveillance and clinical trials. NAM also classifies pharmaceuticals into Prescription-only (POM) and Pharmacy-only (Over-the-Counter, OTC) medicines, makes decisions about the establishment of pharmacies and pharmacy outlets and grants pharmacy licences for pharmacists.

276 http://www.kunnat.net/k_perussivu.asp?path=1;29;374;36984;31661;4869

277 STM 2006

- The Pharmaceutical Pricing Board (Lääkkeiden hintalautakunta, HILA), being STM-affiliated, approves the requested wholesale price as well as the reimbursement category of a pharmaceutical to qualify it for reimbursement (cf. 8.3). HILA also deals with applications of pharmaceutical companies to increase the wholesale prices of pharmaceuticals.

  Since 1 January 2006 HILA is in charge of all reimbursement decisions, i.e. deciding if a pharmaceutical qualifies for the basic and/or special reimbursement category (cf. 8.3).

- The services covered by the National Health Insurance scheme are administrated by the Social Insurance Institution of Finland (Kansaneläkelaitos, KELA). KELA also has a consulting role when HILA decides on the "reasonable" wholesale price and the reimbursement status.[278, 279]

HILA consists of seven members and their deputies, who are nominated by the STM. Two members each represent the STM and KELA, in addition to one member each from NAM, the National Research and Development Centre for Welfare and Health (STAKES) and the Ministry of Finance.[280]

All board members must have a Masters' degree and at least one member must be a representative of a the medical, pharmaceutical, legal and economic discipline. The Chairman convenes the HILA meetings and cases are presented by the Chief Pharmaceutical Officers, or the Pharmaceutical Officers of the Secretariat under the supervision of the Secretary General.[281] In the abbreviated procedure (cf. 8.3.1.4) the Secretary General may approve a wholesale price or decide on a reimbursement category without contacting the Board Members.

Pharmaceuticals are regulated in general by the Medicines Act (395/1987) and Decree (693/1987), that are being amended from time to time. The latest amendment so far occurred in February 2006, allowing the dispensing of Nicotine Replacement Therapy products outside pharmacies in special licensed grocery stores or supermarkets.[282]

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278 Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 5 and 6
http://www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/legislation.htx.i209.pdf

279 Government Decree 1110/2005 amending the Decree on the Pharmaceuticals Pricing Board 1356/2004

280 Government Decree on the Pharmaceuticals Pricing Board 1356/2004, section 1

281 Sirkia/Rajaniemi 2002

282 http://www.nam.fi/uploads/english/Legislation/Medicines_act_and_decree_041210.pdf

Table 8.1: Finland - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Sosiaali- ja terveysministeriö (STM) / Ministry of Social Affairs and Health	Ministry of Health (legal framework)	STM Meritullinkatu 8 P.O. Box 33 FI-00023 Government Finland Tel.: +358 9 1600 1 Fax: +358 9 1607 4126 www.stm.fi	Mr. Pekka Järvinen Meritullinkatu 8 P.O. Box 33 FI-00023 Government Finland Tel.: +358 9 1607 3800 pekka.jarvinen@stm.fi
Lääkkeiden hintalautakunta (Hila) / Pharmaceuticals Pricing Board	Pharmaceutical Pricing and Reimbursement Committee	Hila - Pricing Board P.O. Box 33 Snellmaninkatu 13, 5th floor FI-00023 Government Finland Tel.: +358 9 1600 1 Fax: +358 9 1607 4495 www.hila.fi	Ms. Sinikka Rajaniemi General Secretary P.O. Box 33 FI 00023 Government Finland Tel: +358 9 1607 3171 Sari.vainionpaa@stm.fi Sinikka.rajaniemi@stm.fi
Lääkelaitos / National Agency for Medicines (NAM)	Medicines Agency (market authorisation, classification, surveillance, etc.)	Director Prof. Hannes Wahlroos Mannerheimintie 103b P.O. Box 55 FI-00301 Helsinki Finland Tel.: +358 9 47334 1 Fax: +358 9 714 469 hannes.wahlroos@nam.fi www.nam.fi	Ms. Ulla Närhi Mannerheimintie 103b P.O. Box 55 FI-00301 Helsinki Finland Tel.: +358 9 4733 4385 Fax: +358 9 4733 4297 ulla.narhi@nam.fi
Lääkehoidon kehittämiskeskus (ROHTO) / Centre for Pharmacotherapy Development	Promote and monitor rational use of pharma-ceuticals	Mannerheimintie 103b, 4th floor P.O. Box 55 FI-00301 Helsinki Finland Tel: +358 9 4733 446 Fax: +358 9 4733 4431 www.rohto.fi	Ms. Taina Mäntyranta Director P.O. Box 55 FI-00301 Helsinki Finland Tel: + 358 9 4733 4427 Mobile: +358 40 581 2769 Taina.Mäntyranta@rohto.fi
Kansaneläkelaitos (KELA) / Social Insurance Institution of Finland	Third Party Payer	KELA P.O. Box 450 FI-00101 Helsinki Finland Tel.: +358 20 4341 1 Fax: +358 20 4341 700 www.kela.fi	Ms. Jaana Martikainen Research Department P.O. Box 450 FI-00101 Helsinki Finland Tel.: +358 20 4341 953 jaana.martikainen@kela.fi

Institution	Task	Contact details/URL	Responsible person
Suomen Apteekkariliitto / Association of Finnish Pharmacies	Association of Pharmacists	Association of Finnish Pharmacies Pieni Roobertinkatu 14C FI-00120 Helsinki Finland Tel.: +358 9 2287 11 Fax: +358 9 6471 67 http://www.apteekkariliitto.fi	Mr. Reijo Kärkkäinen Executive Director Pieni Roobertinkatu 14C FI-00120 Helsinki Finland Tel.: +358 9 2287 1300 Fax: +358 9 6471 67 Reijo.karkkainen@salnet.fi
Suomen Lääkerinnakkaistuojien Yhdistys (SLRTY)	Association of Parallel Importers	SLRTY Valkjarventie 1 FI-00022 Helsinki Finland	Mr. Matti Pulkkinen Tel.: +35 89 7746 870 Fax: +35 89 7746 8727 mpu@orifarm.fi
Lääketeollisuus ry / Pharma Industry Finland (PIF)	Association of Pharmaceutical Industry	PIF Eteläranta 10 P.O. Box 109 FI-00131 Helsinki Finland Tel.: +358 9 6150 4900 jarmo.lehtonen@pif.fi http://www.pif.fi	Mr. Erkki Alanko Communication Director Eteläranta 10 P.O. Box 109 FI-00131 Helsinki Finland Tel.: +358 9 6150 4904 erkki.alanko@laaketietokeskus.fi
Rinnakkaislääketeollisuus ry / Finnish Generic Pharmaceutical Association (FGA)	Generic Manufacturers Association	FGA Bulevardi 2-4 A FI-00120 Helsinki Finland Tel.: +358 9 6150 7430 Fax: +358 9 6150 7400	Ms. Jaana Meklin Bulevardi 2-4 A FI-00120 Helsinki Finland Tel.: +358 9 6150 7430 Fax: +358 9 6150 7400
Suomen Lääkäriliitto / Finnish Medical Association (FMA)	Medical Doctors' Association	FMA Mäkelänkatu 2, P.O. Box 49 FI-00501 Helsinki Finland Tel.: +358 9 393 091 Fax: +358 9 393 0794 fma@fimnet.fi www.laakariliitto.fi/e/	Mr. Heikki Pälve Chief Executive Officer Mäkelänkatu 2, P.O. Box 49 FI-00501 Helsinki Finland Tel.: +358 9 393 0702 heikki.palve@fimnet.fi
Kuluttajavirasto / Consumer Agency	Patients' Representative	Consumer Agency Haapaniemenkatu 4 P.O. Box 5 FI-00531 Helsinki Finland Tel.: +358 9 7726 1 Fax: +358 9 7726 7557 www.kuluttajavirasto.fi	Ms. Pirjo Tomperi Haapaniemenkatu 4 P.O. Box 5 FI-00531 Helsinki Finland Tel.: +358 9 7726 1 posti@kuluttajavirasto.fi

Source: ÖBIG 2006

8.1.2 Market Players

8.1.2.1 Pharmaceutical Industry

Most pharmaceutical companies operating in Finland are members of the Finnish Association of Pharmaceutical Industry Lääketeollisuus ry (Pharma Industry Finland, PIF), in June 2006 their number was 64 (as compared to 65 in 2005).[283]

The three leading companies by market share are Pfizer, Orion Pharma and AstraZeneca. In 2004 6,123 persons were employed at the Finnish pharmaceutical industry compared to 6,648 in 2004.[284]

8.1.2.2 Distribution

The Finnish wholesale market is organised as single-channel distribution system, meaning that wholesalers have exclusive distribution contracts with the individual pharmaceutical companies, thus only offering a part range of pharmaceuticals to pharmacies. The market is dominated by Tamro and Oriola (part of Orion group), which together have a market share of 100%.[285]

Wholesalers are only allowed to deliver to pharmacies, veterinarians, hospitals and community health centres, but not directly to patients. The only exception is, that since 1.2.2006 wholesalers are also allowed to deliver Nicotine-Replacement-Therapy (NRT) products also to those shops and kiosks with permission to sell these medicines.

Dispensing of pharmaceuticals to patients happens mainly through pharmacies, their subsidiary pharmacies (= branch pharmacies) and for a limited selection of OTC through so-called medicine chests, that operate under the supervision of a pharmacy. The dispensing of pharmaceuticals through other outlets, such as drugstores or through internet pharmacies, is not allowed in Finland, with the exception of NRT-products, which were liberalised from 1.1.2006 on to tobacco selling shops.[286]

The number of pharmacies in Finland and subsidiary pharmacies in Finland has increased by 7% since 1990 (53 outlets).[286] In 2005 there were 802 pharmacies, thereof 197 branch pharmacies and two university pharmacies. On average a Finnish pharmacy serves about 6,510 inhabitants. Doctors are not allowed to dispense pharmaceuticals or own a pharmacy.[287]

Pharmacies are also allowed to offer their patients a dose dispensing service. This service was enhanced by 1 January 2006 for a three year test period as it is now partly reimbursed

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283 http://www.laaketeollisuus.fi/page.php?page_id=193

284 PIF 2005; http://www.laaketeollisuus.fi/tiedostot/PHARMAFACTS040406_(ID_1101).pdf

285 http://www.girp.org

286 Suomen Apteekkariliitto 2005 and 2006

287 ÖBIG 2006

by KELA for persons aged 75 or above, who are being prescribed at least six reimbursable pharmaceuticals qualifying for dose dispensing, i.e. tablets, caps etc.[288]

8.1.2.3 Patients

Finnish patients have to be fully informed on their medication by the prescribing doctor in the first place and by the dispensing pharmacists in the second place.[289] The latter has to inform the patient on his/her co-payments as patients almost always have to pay a co-payment for a reimbursable pharmaceutical. Pharmacists are also obliged to inform the patient of the cheap generic alternatives, if their prescribed medicine can be substituted.[290]

The changes in the reimbursement system that took place in 1 January 2006 were formulated to be cost-neutral for patients, cf. section 8.3.1 for details and STM, HILA and KELA will do a follow-up study upon the effects on patients. For instance in the meanwhile several market authorisation holders have withdrawn their products from the reimbursement system and some products have been de-facto delisted due to the newly introduced Zero-reimbursement category cf. 8.3.1.5). A list of these withdrawn/delisted products is published quarterly in the internet.[291]

Still, there is no necessity for patients to shop around to search for cheap pharmaceuticals, as retail prices of reimbursable pharmaceuticals have - according to the Medicines Act[292] – to be the same throughout the country and pharmacy mark-ups are statutorily fixed (cf. 8.2.1).

8.1.3 Overview of the Pharmaceutical System

On 13 June 2006 6,904 pharmaceuticals (including different pharmaceutical forms and strengths) were authorised in Finland, thereof 93 percent POM. Approximately 60% of the authorised pharmaceuticals are actually on the market.

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288 Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 5, Section 10
http://www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/legislation.htx.i209.pdf

289 Act on patient's rights 785/1992

290 Medicines Act 395/1987

291 http://www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/notices.htx.i1781.pdf

292 Medicines Act 395/1987, amendment 2006/22

Table 8.2: Finland - Number of Pharmaceuticals, 1990, 1995 and 2000 - 2006

Pharmaceuticals[1]	1990	1995	2000	2001	2003	2004	2005	2006[2]
Authorised ph.	3,259	3,360	4,210	4,385	4,907	5,330	6,078	6,904
Ph. on the market	> 90%	N.a.	94%.	N.a.	72%	N.a.	60%	60%
POM	82%	82%	87%	N.a.	N.a.	N.a.	93%	~ 93%

ph. = pharmaceuticals, POM = Prescription-only medicines, N.a. = Not available

[1] Data per 1 January. Pharmaceuticals for human use, excluding magistral preparations/ officinal formula, counted including different pharmaceutical forms and strengths.

[2] Data per 13 June 2006

Source: Written information by Suomen Apteekkariliitto (August 2005 and June 2006) on basis of NAM

In 2004, pharmaceutical sales in Finland totalled approximately € 2.3 billion, which is an increase of 7.1% compared to 2003; the increase was greater than during the previous year (6.4%).[293] In monetary terms, however, generic substitution and subsequent price competition, as well as the re-evaluation of the approved wholesale prices by HILA continued to control the growth of sales of prescription-only medicines (POM).

Of the total sales, 74% was attributable to POM used in out-patient care, 14% to pharmaceuticals used in in-patient care and 12% to OTC.[294]

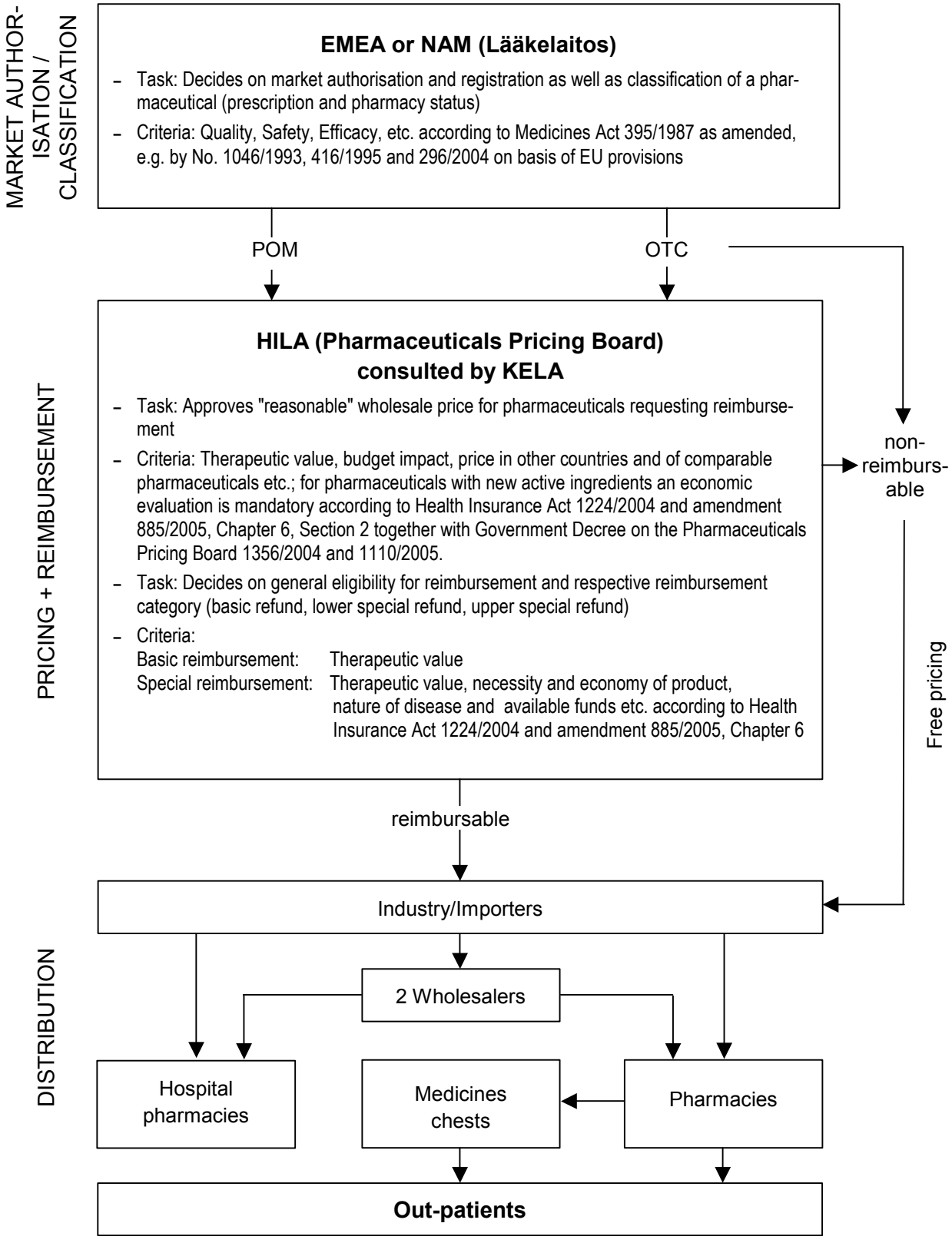
The sales value of out-patient POM, hospital products and OTC increased by 7.7%, 7.8% and 3.0% respectively. Reimbursement payments were provided to 3.3 million individuals for pharmaceuticals used in out-patient care. The cost of these payments was approximately € 1 billion, which corresponds to an increase of 10.6% compared to the previous year.

The following figure shows the pharmaceutical system in Finland in a concise form.

293 NAM/KELA 2005

294 Out-patient pharmaceutical sales calculated at pharmacy retail prices (incl. VAT and pharmacy tax), in-patient pharmaceutical sales calculated at wholesale prices.

Figure 8.1: Finland - Pharmaceutical System, 2006



Source: ÖBIG 2006

8.2 Pricing

8.2.1 Scope of Price Control

In general there is free pricing for all pharmaceuticals on manufacturer and wholesale price level in Finland, but in reality prices are indirectly controlled through the reimbursement system. Pharmaceuticals companies wishing to make their pharmaceutical eligible for reimbursement have to apply for approval of a so-called "reasonable" wholesale price at HILA. KELA is allowed to state its opinion but has no direct influence on the decision (cf. 8.3.1.1 for details).

So in most cases only OTC - the majority of non-reimbursable pharmaceuticals - are really priced freely, whereas all other pharmaceuticals are subject to indirect price control through the reimbursement system.

The pharmacy retail price is regulated by a statutory mark-up scheme. The current pharmacy mark-up scheme (cf. 8.2.1.3) is valid for all pharmaceuticals (POM and OTC, reimbursable and non-reimbursable, (branded) originals and generics).

Table 8.3: Finland - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Non-reimbursable pharmaceuticals, mostly OTC	Non-reimbursable pharmaceuticals, mostly OTC	Not applied
Statutory Pricing	To be eligible for reimbursement the marketing authorisation holder has to apply for a so-called reasonable wholesale price.		All pharmaceuticals are regulated via a regressive mark-up scheme
Price Negotiations	This price needs formally to be approved by HILA.		Not applied
Price/volume agreements, discounts/rebates	Commercial discounts granted to wholesalers	Not applied	Not applied
Institution in charge of pricing	- HILA for reimbursement price - KELA has consultancy right for reasonable wholesale price		
Legal Basis	- Government Decree on the pharmacy mark-up 2002/1087 - Health Insurance Act 1224/2004 and amendment 885/2005 - Government Decree on the Pharmaceuticals Pricing Board 1356/2004 and amendment 1110/2005 - Decree by the Ministry of Social Affairs and Health on applications for a reasonable wholesale price and reimbursement status of medicinal product and on the documentation to be appended to the application 1111/2005		

HILA = Lääkkeiden hintalautakunta, KELA = Kansaneläkelaitos, OTC = Over-the-Counter pharmaceuticals,

Note: The reasonable wholesale price is the maximum wholesale price that can be set for a reimbursable pharmaceutical and the pharmaceutical can be freely priced equal or below the reasonable wholesale price by the marketing authorisation holder

Source: ÖBIG 2006

8.2.1.1 Manufacturer Price

As already mentioned, pharmaceutical companies may freely set the price for pharmaceuticals when placing them on the market. There is also no legal obligation to inform authorities on the price of the product.

However, pharmaceutical companies applying for inclusion of a product to reimbursement have to seek approval of a so-called "reasonable" wholesale price by HILA. Usually there are several negotiation rounds between HILA and company representatives necessary before the "reasonable" wholesale price is officially approved by HILA.

When deciding on the reasonable price, HILA takes several aspects (information on that have to be included in the application of the manufacturer) into account.[295] The most important criteria are:

- The therapeutic value of the pharmaceutical.
- The proposed wholesale price compared to major competitors and the price in other European countries (cf. 8.2.2.2 and 8.2.2.3).
- The research, development and production costs of the pharmaceutical.
- The cost of the therapy and the budget impact on the National Health Service system.
- For pharmaceuticals containing a new active ingredient and for others on request of HILA an pharmaco-economic evaluation of the pharmaceutical compared to major competitors or prevailing treatment options (e.g. including information on the patent status and benefits to be gained, an estimation of the potential sales of the product - the estimation shall include the potential numbers of patients and forecast of the probable trend in the number of users over the following three years).[296]

The above mentioned pharmaco-economic evaluation for pharmaceuticals containing a new active ingredients has been obligatory since 1 January 1998.[297] STM has published detailed guidelines on the necessary documents and the procedure[298], cf. 8.2.2.1 for details.

The approved wholesale price (i.e. the maximum wholesale price) remains valid, i.e. binding for the manufacturer for a maximum of five years, for new active ingredients this period is three years.[299] This wholesale price or pharmacy purchase price (PPP) is the basis for the calculation of the pharmacy retail price, and therefore the base price for reimbursement (cf. 8.2.1.3).

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295 Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 6, Section 2 together with Government Decree on the Pharmaceuticals Pricing Board and 1356/2004

296 Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 6, Section 2, Art. 7

297 Sirkia/Rajaniemi 2002, AESGP 2005

298 Decree of the Pharmaceuticals Pricing Board (1280/97), latest amended by the Decree by the Ministry of Social Affairs and Health on applications for a reasonable wholesale price and reimbursement status of a medicinal product and on the documentation to be appended to the application (1111/2005)

299 AESGP 2005

Applications by manufacturers for price increases of reimbursable pharmaceuticals have to be submitted to HILA, but are hardly approved. Prior to price confirmations or approval of price changes HILA has to consult KELA.[300]

Unapproved price increases usually result in delisting, i.e. exclusion from reimbursement (cf. 8.2.2.4 and 8.3.1.7 for further information).

8.2.1.2 Wholesale Price

Wholesalers in general may freely set their prices as there is no statutory mark-up scheme in place in Finland. But as already explained in section 8.2.1.1 the wholesale price of reimbursable pharmaceuticals is indirectly controlled through the reimbursement system. To be eligible for reimbursement pharmaceuticals need an approved "reasonable" wholesale price.

There is a oligopoly situation in Finnish wholesale, as because of the single-channel system wholesalers have exclusive contracts with pharmaceutical companies (cf. 8.1.2.2). The profit share, i.e. the wholesale margin, is therefore freely negotiated between pharmaceutical companies and wholesalers with the granting of discounts being allowed. However these agreements between manufacturers and wholesalers are not public. On average the wholesale margin is 4%.[301]

8.2.1.3 Pharmacy Retail Price

Pharmacies are remunerated via a statutory regressive mark-up scheme based on the so-called "approved" wholesale or pharmacy purchase price (PPP).[302] The current scheme (cf. Table 8.4) is valid for all pharmaceuticals (POM and OTC, reimbursable and non-reimbursable, on- and off-patent products) and came into force in 2002.

In addition pharmacists receive a fixed dispensing ("expedition") fee per prescribed pharmaceutical of € 0.42 including VAT.[303]

Table 8.4: Finland - Pharmacy Mark-ups for Pharmaceuticals, 2006

PPP from...to...in €	Net PRP in €
until 9.25	PPP x 1.5 + € 0.50
9.26 - 46.25	PPP x 1.4 + € 1.43
46.26 - 100.91	PPP x 1.3 + € 6.05
100.92 - 420.47	PPP x 1.2 + € 16.15
> 420.47	PPP x 1.125 + € 47.68

PPP = Pharmacy Purchase Price, Net PRP = Pharmacy Retail Price excluding VAT and pharmacy tax

Source: Government Decree on the pharmacy mark-up 2002/1087

300 Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 6, Section 2a

301 Pekurinen/Häkkinen 2005

302 Government Decree on the pharmacy mark-up 2002/1087

303 Peura 2006, PPR 2005

The pharmacy retail price (PRP) is the same throughout the country - even in case of non-reimbursable pharmaceuticals, where the wholesale price is not approved by HILA (i.e. not fixed) - as the wholesale price to be applied for the calculation of the pharmacy mark-ups has to be the same for all pharmacies.

Neither voluntary nor statutory discounts - granted to or by individual pharmacies - are in place as these is forbidden by law (cf. 8.2.2.6).

8.2.1.4 Value Added Tax (VAT)

Value added tax (VAT) is currently 8% for pharmaceuticals, the standard VAT rate being 22%[304].

Depending on their sales all pharmacies - except the two university pharmacies who pay a fee to their owners - have to pay a progressive, tax-like pharmacy fee to the state.[305] This tax revenues are used to secure the country-wide provision of services by subsidising pharmacies in remote areas. On average the pharmacy tax is 7% (6.7% in 2004), ranging from zero to 11 percent.[306]

In the course of the discussions on reducing the prices of pharmaceuticals (cf. 8.2.2.4) in 2005 it was proposed to halve the pharmacy tax, but this proposal was dropped by the end of the year.[307]

8.2.2 Price related Cost-containment Measures

8.2.2.1 Pharmaco-economic Evaluation

Pharmaceutical companies are obliged to present a pharmaco-economic evaluation of their product to HILA when applying for an "approved" wholesale price of for pharmaceutical containing a new active ingredient, i.e. claiming reimbursement status (cf. 8.2.1). The STM has already published guidelines on the conduct of pharmaco-economic studies in 1999, thus being one of the first European countries to do so. The evaluations have to demonstrate the therapeutic value and cost-effectiveness of the pharmaceutical in question, i.e. they have to contain data on effectiveness and experience of usage in daily life.[308] The annex to the guidelines contains detailed explanations on e.g. the quality of acceptable studies (e.g. in terms of

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304 European Commission/DG Taxation and Trade Union 2006

305 Pharmacy Fee Act 1946/148

306 STM 2006

307 PPR 11/2005

308 Decree by STM on applications for a reasonable wholesale price and reimbursement status of a medicinal product and on the documentation to be appended to the application (1111/2005); http://www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/legislation.htx.i212.pdf

sensitivity analysis) and the necessary adoptions to the Finnish health care system (i.e. economic modelling).[309]

This regulation was the statutory background for the two-year "probation" or waiting period for innovative pharmaceuticals in the basic reimbursement category before they became eligible for one of the two special reimbursement categories. However, this waiting period was abolished after a letter of formal Notice of the European Court of Justice from 30 March 2004 and led to the introduction of the current reimbursement system (cf. 8.3.1). [310]

Under the new legislation pharmaceutical companies still are obliged to provide pharmacoeconomic evaluation studies for innovative pharmaceuticals and if requested by HILA also for other applications (like a new pharmaceutical form of a pharmaceutical already being on the Finnish market).[311]

8.2.2.2 Internal Price Referencing

When approving a reasonable wholesale price, which is the basis for reimbursement eligibility, HILA takes in the case of off-patent pharmaceuticals (i.e. generics and the branded original) the price of bioequivalent products and other pharmaceuticals used for the treatment of the same disease into account.[312]

In addition, the price of the cheapest available pharmaceutical (generic or parallel import) containing the same amount of the same active ingredient (identified by the International Non-Proprietary Name, INN) is the basis for the reimbursed amount if generic competition has been established. All products, for which generic competition has been established are included in the so-called “List of interchangeable (= substitutable) pharmaceuticals”, that is up-dated quarterly in the internet.[313] Generic equivalents contain the same active substance in the same amount as the substitutable product, and their biological equivalence has been proven (cf. section 8.3.1.4 for details).

8.2.2.3 External Price Referencing / Cross Country Referencing

When applying for a reasonable wholesale price, which is the basis for reimbursement eligibility, manufacturers have to provide HILA with the wholesale price and the reimbursement status of the pharmaceutical in other European countries.[314] The countries taken into consideration are Members of the European Economic Area (EEA), i.e. EU Member States plus Norway, Iceland and Liechtenstein.

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309 Guidelines for Preparing a Health Economic Evaluation (Annex to the Decree 1111/2005); http://www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/legislation.htx.i197.pdf

310 PIF 2/2004

311 Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 6, Section 2, Art. 7

312 Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 6, Section 2, Art. 4 and 5

313 List of substitutable medicinal products (1.7.-30.9.2006) http://www.nam.fi/uploads/rinnakkaislaakeluettelo/q32006/Vaihtokelpoiset_Q32006.pdf

314 Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 6, Section 2, Art. 6

However there is no formal external price referencing performed by HILA and the price in other EEA countries is only one criteria among many others that are considered when approving the "reasonable" wholesale price (cf. 8.2.1.1).

8.2.2.4 Price Freezes / Stops

On 1 January 2006 the Finnish government followed the example of other EU Member States (e.g. like Portugal) and for the first time statutorily cut the approved reasonable wholesale prices for all reimbursable pharmaceuticals by 5%.[315] This price cut happened on top of the changes in the reimbursement system that also became valid on 1 January 2006.[316] Due to this price cuts manufacturer of 81 pharmaceuticals opted to withdraw their products from reimbursement (cf. 8.3.1.7).

Before that, HILA was evaluating prices of reimbursable pharmaceuticals only on an individual basis and often decided to reduce the reasonable wholesale price if any of the following situations occurred:[317]

- The indications (~ diseases qualifying for treatment) had been significantly expanded.
- A generic equivalent is available for a significantly lower price. [318]
- The price of the pharmaceutical is significantly lower in other Nordic Countries or EU Member States.

Between the years 1998 - 1999 and 2004 - 2005 HILA evaluated the prices of reimbursable pharmaceuticals for selected ATC-Codes, which in some cases led to considerable price reductions.[319]

It has to be added that the "reasonable" wholesale price is approved by HILA for a period of five years at maximum. For pharmaceuticals containing new active ingredients the period is three years. Manufacturers are in principle allowed to change their prices but a change of the approved "reasonable" wholesale price leads to delisting, i.e. an automatic exclusion from reimbursement. Therefore most companies together with wholesalers accepted this indirect price stop.

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315 Health Insurance Act 1224/2004 and amendment 885/2005, Annex

316 PPR 10/2005 and 2/2006

317 Martikainen/Rajaniemi 2003

318 According to the list of substitutable medicinal products, cf. 8.3.1.4

319 Peura 2006

8.2.2.5 Margin Cuts

The pharmacy mark-up scheme as well as the pharmacy tax system have been unchanged for almost a decade. The last margin cut occurred in April 1998 to reflect the gradual shift towards a use of more expensive pharmaceuticals.[320]

Since that time there have only been minor adaptations to the scheme, when the Euro was introduced in the year 2002.

8.2.2.6 Discounts and Rebates

Manufacturers and wholesalers may grant discounts to each other. However, there are no legal provisions in place and agreements between wholesalers and manufacturers are not public, therefore no details are available.

Neither wholesalers nor pharmaceutical industry are allowed to give discounts to individual pharmacies as this is forbidden by law.[321]

Pharmacies may grant discounts on OTC to their customers but only if this is the case for all customers in the same way. In addition war veterans are entitled to an obligatory 10% discount.[322, 323] However, the discount doesn't apply to the costs of the medicines for which the special refund or a restricted basic refund is granted nor the costs above the annual ceiling sum.

8.2.2.7 Company Profit Controls

There are neither direct nor indirect company profit control mechanisms like claw-back systems or controls over companies' promotional expenditure in place in Finland.[324]

8.2.2.8 Parallel Trade

As prices of pharmaceuticals tend to be below the European average - especially with the 5% price cut in January 2006 - parallel trade is not a major feature of the Finnish market.[325] Parallel importing started in 1996, but its share of the pharmaceutical market is low, accounting for 1.4% of pharmaceutical sales by value and 0.5% by volume in 2004.[326]

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320 Sirkia/Rajaniemi 2002

321 Medicines Act 395/1987, amendment 2006/22

322 ÖBIG 2006

323 Government Decree on the mark-up 2002/1087

324 PPR 2005

325 PIF 1/2006

326 PPR 2005

This was a small boost compared to former times where the market share was around 0.2%.[327] The reason is that not only generics but also parallel imported products fall under the obligatory substitution system that was introduced in 2003 (cf. 8.3.4.2).

Finland, on the other hand, is no significant source of parallel export to other EU Member States.

8.2.3 Co-Payments

In Finland proportional co-payments are in place, thus patients are obliged to pay a defined share of the gross pharmacy retail price for reimbursable pharmaceuticals. Co-payment rates have been changed along with the reimbursement rates from 1 January 2006 on.[328]

The amount of co-payment depends on the reimbursement category of the pharmaceutical that is fixed by HILA (cf. 8.3.1).[329]

- **Basic Refund Category:** 58% of the gross pharmacy retail price of the pharmaceutical. All pharmaceuticals having approved reimbursement status as well as a "reasonable" wholesale price by HILA qualify for this basic reimbursement category.
- **Lower Special Refund Category:** 28% of the gross pharmacy retail price of the pharmaceutical.
- **Upper Special Refund Category[330]:** The full cost of the pharmaceutical above a flat rate deductible of € 3.- is covered by KELA.

The annual maximum co-payment limit ("ceiling") for a patient, independent from age, disease or income is € 616.72 in 2006. Expenses for reimbursable pharmaceuticals above this ceiling are covered fully (100% reimbursement) - minus a € 1.50 flat rate deductible per purchased, prescribed pharmaceutical - by KELA.[331] The costs of reimbursable clinical nutritional preparations and basic ointments are also included in the ceiling sum.

Expenses for non-reimbursable pharmaceuticals, i.e. mainly OTC and pharmaceuticals on the newly introduced “Zero reimbursement” category (cf. 8.3.1.5), are not taken into account in the calculation of the annual ceiling.

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327 Tilson/Barry 2005

328 For instance the flat rate deductible of € 10.- in the basic refund category and of € 5.- in the lower special refund category was abolished.

329 Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 5 and Decree by the Ministry of Social Affairs and Health on applications for a reasonable wholesale price and reimbursement status of medicinal product and on the documentation to be appended to the application (1111/2005)

330 In some documents also referred to as “Higher Special Refund Category”

331 Peura 2006 basing on Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 5, Section 8

8.2.4 Information Transparency and Marketing

Basic marketing regulations of pharmaceuticals, e.g. terms of advertising to general public, that is allowed for all OTC, including reimbursable ones, are stated in the Medicines Act.[332] EU patient information provisions were first implemented in 1995, the most recent amendment covering labelling and package leaflets came into force on 1.1.2004.[333]

In addition Pharma Industry Finland (PIF) voluntarily controls the marketing of pharmaceuticals: The Code of Conduct for the marketing of pharmaceuticals was renewed by 1 January 2005.[334] Special attention was paid to the relations between the pharmaceutical industry and health care personnel, for instance rules on events organised or supported by the industry were specified and rules on hospitality and incentives were tightened.

Regarding self-medication products the biggest change was that TV and radio advertisements now have to pass preliminary approval. All member companies of PIF are committed to the Code of Conduct, that is in place for more than 15 years.[335]

Information on pharmaceuticals is available to all interested persons via internet, provided through the Drug Information Unit of NAM, e.g. containing all product summaries and patient information leaflets of thousands of pharmaceuticals and herbal medicines on sale in Finland.[336] Since autumn 2005 also pending market authorisation decisions are published on this website. In February 2006 NAM also published a report called "Drug information for consumers and patients - a review of the research" summarising all available information sources in Finland.[337] Additionally Suomen Apteekkariliitto (Association of Finnish Pharmacies)[338] and the Pharmaceutical Information Centre (owned by PIF) with the Layman's edition of the Pharmaca Fennica[339] offers web based patient information. This information is also available for customers at pharmacies.

Community pharmacies use frequently updated database for oral patient counselling (Tietotippa), provided by Suomen Apteekkariliitto. Additionally, Suomen Apteekkariliitto keeps a database for self care and self medication in the internet.[340] Pharmacies also run several drug information and health education campaigns annually.[341]

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332 Decree 1184/2002, Amendment of Art. 25 Medicines Act http://www.nam.fi/uploads/english/Legislation/Medicines_act_and_decree_041210.pdf, page 54ff.

333 NAM Regulation 3/2003

334 The Code for the Marketing of Medicinal Products, http://www.pif.fi/tiedostot/kE2jBcIb.pdf

335 Suomen Apteekkariliitto 2006

336 http://www.nam.fi

337 Närhi 2006, http://www.nam.fi/uploads/julkaisut/laakkeet/Drug_information_pdf.pdf

338 http://www.apteekit.net/do/frontpage

339 http://www.laaketietokeskus.fi/page.php?page_id=33

340 http://www.apteekit.net/itsehoito-opas

341 Suomen Apteekkariliitto 2006

The prices of pharmaceuticals are publicly available, e.g. on the KELA website.[342] The list of substitutable pharmaceuticals is available in the internet and is up-dated on a quarterly basis.[343]

8.3 Reimbursement

8.3.1 Pharmaceutical Lists and Reimbursement Categories

In Finland there is a positive list of reimbursable pharmaceuticals in place and in 1 January 2006 a so-called “zero reimbursement” category, i.e. a negative list, was introduced.

8.3.1.1 Reimbursement Price

With the changes in the Health Insurance Act which by 1 January 2006 the powers of HILA have been extended meaning that all reimbursement decisions are now made by HILA.[344]

The basis for reimbursement is the so-called "approved" or "reasonable" wholesale price, that is approved by HILA. This price approved by HILA - together with the statutory fixed pharmacy mark-up and all taxes (i.e. Gross Pharmacy Retail Price) - is the maximum reimbursable price. Manufacturers may adapt their prices as long as this upper limit is not exceeded.[345]

Before reaching a decision on the price, HILA requests KELA to submit a formal statement on how reasonable or fair the wholesale price or price increase seems from the viewpoint of the National Health Insurance Scheme, and how other costs under the Scheme are anticipated to change or be affected.[346]

After having approved reimbursability and a wholesale price the product qualifies for reimbursement in the basic refund category, if the manufacturer has applied for reimbursement (cf. 8.3.1.2).

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342 http://kelaapp.kela.fi/laakekys_app/LaakekysApplication?kieli=en

343 List of substitutable medicinal products (1.7.-30.9.2006) http://www.nam.fi/uploads/rinnakkaislaakeluettelo/q32006/Vaihtokelpoiset_Q32006.pdf and http://www.apteekkariliitto.fi/geneerinen/geneerinen.koti

344 Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 5

345 PPR 2005

346 Government Decree 1110/2005 amending the Decree on the Pharmaceuticals Pricing Board 1356/2004

In selected occasions[347], e.g. if the concerned pharmaceutical

- is already on the positive list and the application is for
  - a new package size within defined limits or
  - a new strength provided that the wholesale price proposed for the new strength is at least 10% below that of the lower strength as calculated per active substance or combination of substances or
- is a corresponding generic or a parallel imported pharmaceutical for a pharmaceutical provided that the proposed wholesale price is not higher than the wholesale price approved for a corresponding product used in the treatment of the same disease

the Secretary General of HILA may approve the wholesale price without consultation of KELA.

Since 1 January 2006 HILA also has the power to terminate the reimbursement status and the confirmed wholesale price, if actual sales exceed the estimates the company has delivered with its application.[348]

Hospital-only pharmaceuticals are normally not included in the reimbursement system and also have no "approved" wholesale price. Pharmaceutical companies negotiate their prices directly with hospitals.[349]

8.3.1.2 Pharmaceuticals on Positive List

According to the Health Insurance Act the reimbursement of pharmaceuticals is divided in three different categories (cf. 8.3.1.3 for selection criteria):[350]

- **Basic Refund Category:** 42% reimbursement of the gross pharmacy retail price of the pharmaceutical.
- **Lower Special Refund Category:** 72% reimbursement of the gross pharmacy retail price of the pharmaceutical. Here pharmaceuticals for 10 chronic conditions such a hypertension, asthma, coronary heart disease and rheumatoid arthritis are included.
- **Upper Special Refund Category:** 100% reimbursement of the gross pharmacy retail price of the pharmaceutical above a deductible of € 3.-. This category covers pharmaceuticals for 34 severe chronic conditions and life-threatening diseases such as diabetes, breast cancer and epilepsy.

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347 Section 1 of the Decision of the Pharmaceuticals Pricing Board on authorizing the Secretary General of the Board to confirm a reasonable wholesale price for a medicinal product as the basis for reimbursement and to approve the special reimbursement status of a medicinal product on basis of Section 5a, subsection 10 of the Health Insurance Act (364/1963), Amendment 1151/2003

348 Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 6, Section 8

349 Tilson/Barry 2005

350 Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 5 and Decree by the Ministry of Social Affairs and Health on applications for a reasonable wholesale price and reimbursement status of medicinal product and on the documentation to be appended to the application (1111/2005)

By 1 June 2006 4,615 pharmaceuticals were reimbursable[351], thereof:

- 554 different active ingredients
- 1,314 different brand names
- 458 different strengths
- 127 different pharmaceutical forms
- 639 different pack sizes

If the annual expenses of patients for reimbursable pharmaceuticals reach a ceiling of € 616.72 (year 2006) the additional expenditure above a deductible of € 1.50 per pharmaceutical and per purchase is also 100% reimbursed by KELA independent of the refund category of the pharmaceutical.[352,] However, since 1 January 2006 "zero"-reimbursement is possible. for selected pharmaceuticals, but it has not been decided yet, which pharmaceuticals will be moved there (cf. 8.3.1.5).[353] Detailed information on patient co-payments in Finland are given in section 8.2.3.

8.3.1.3 Selection Criteria

Before the year 2006 pharmaceuticals with a "reasonable" wholesale price approved by HILA were automatically included in the basic refund category (cf. 8.3.1.2) unless legislation[354] has restricted the basic reimbursement status of products to defined indications because of:

- the particularly high price of the pharmaceutical or
- the high burden the product puts on the Social Health Insurance Scheme.

These restrictions are applicable for some lifestyle products as well as Alzheimer and multiple sclerosis medications.

KELA in addition has defined specific indications as prerequisite for the reimbursement of some pharmaceuticals in the basic refund category which became valid by 1 September 2005.[355] Examples are Xenical® for patients with pathological obesity or Taxotere® only for the treatment of selected types of cancer. Doctors have to state medical reasons for the prescription of such pharmaceuticals and document them individually for each patient.

Since 1 January 2006 manufacturers wishing to include their products in the basic refund category have to file an application to HILA. It is permitted to apply for a price approval (cf.

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351 i.e. those with “valid” prices

352 Peura 2006 quoting Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 6, Section 8

353 STM 2006

354 Health Insurance Act 1224/2004 and amendment 885/2005, Section 2a(3)

355 Government decree on medicinal products with reimbursement status granted on special grounds and diseases regarded as severe on medical grounds 616/2005
http://www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/legislation.htx.i214.pdf

8.2.1.1) and reimbursement inclusion simultaneously.[356] Already since 1 January 2004 manufacturers had to apply directly to HILA for inclusion of their pharmaceuticals in one of the both special refund categories.

A prerequisite for the potential inclusion of a pharmaceutical in either of the two special reimbursement categories is, that is intended

- for the treatment of a severe and chronic disease in case of the lower special refund category[357] and
- for pharmaceuticals having a replacement or remedial effects and which are indispensable in the treatment of a severe and chronic disease in case of the upper special refund category[358]

Section 1 respective 2 of Government Decree 1108/2005 lists all diseases falling in either category.

When deciding on the inclusion of pharmaceuticals into a special reimbursement category HILA furthermore considers the following criteria:[359]

- Therapeutic value and necessity of the product;
- Benefits gained from and costs of special reimbursement status;
- Cost-effectiveness; and
- Market forecast of the pharmaceutical (expected number of patients etc.).

8.3.1.4 Generics

In general, the same rules apply to pricing and reimbursement of generics - although a simplified procedure is applied for the reimbursement decision if the active substance is already reimbursed. In this case the Secretary General of HILA may approve reimbursability and a the "reasonable" wholesale price without consultation of KELA.[360].

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356 PPR 10/2005 quoting Health Insurance Act 1224/2004 and amendment 885/2005

357 Section 2 of the Government decree 1108/2005 on the diseases considered severe and chronic on medical grounds and the medicinal costs for which a 75 or 100% percent reimbursement is made under Chapter 5, Section 6(2) of the Health Insurance Act

358 Section 1 of the Government Decree 1108/2005 on the diseases considered severe and chronic on medical grounds and the medicinal costs for which a 75 or 100% percent reimbursement is made under Chapter 5, Section 6(2) of the Health Insurance Act

359 PPR 2005 and Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 6, Section 5

360 Section 1 of the Decision of the Pharmaceuticals Pricing Board on authorizing the Secretary General of the Board to confirm a reasonable wholesale price for a medicinal product as the basis for reimbursement and to approve the special reimbursement status of a medicinal product on basis of Section 5a, Subsection 10 of the Health Insurance Act (364/1963), Amendment 1151/2003

Generic prescribing (by INN) has been allowed since 1996[361], but not very common especially as by 1 April 2003 generic substitution was introduced.[362]

Since that time the pharmacist is obliged to substitute the prescribed pharmaceutical with its cheapest, or close to the cheapest, generic or parallel imported alternative if the price difference between the prescribed and the cheapest product[363]

- is € 2.- or more if the pharmacy retail price (PRP) is below € 40.-
- is € 3.- or more if the PRP is € 40.- or above.

Both the prescribing doctor and the patient have the right to refuse the substitution without sanctions. However, the doctor has to document scientific or therapeutic grounds for the refusal.

Refusal of substitution does not reduce the reimbursement level of the originally prescribed pharmaceutical, i.e. patients do not need to pay the price difference to the more expensive pharmaceutical if they oppose substitution.[364]

The list of the interchangeable ("substitutable ") pharmaceuticals is compiled and administrated by NAM and is up-dated on a quarterly basis. [365] Pharmaceutical companies are obliged to report prices of substitutable products at least 21 days before the first day of each calendar quarter.[366]

The basic criteria for inclusion in the list of substitutable medicinal products are that the respective pharmaceuticals[367]

- contain the same active ingredient,
- contain the same quantity of the active ingredient,
- have the same pharmaceutical form, although tablets may be substituted for capsules or capsules for tablets,
- have been reliably shown to be biologically equivalent, and
- belong to an ATC group in which the substitution may be performed safely.

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361 Decree by the Ministry of Social Affairs and Health on the prescribing of medicines 726/2003

362 Medicines Act 395/1987 as amended in 2005 and Decree 210/2003

363 Medicines Act as quoted in Pekurinen/Häkkinen 2005 and PPR 6/2003

364 Medicines Act 395/1987 as amended and Decree 210/2003

365 List of substitutable medicinal products (1.7.-30.9.2006) http://www.nam.fi/uploads/rinnakkaislaakeluettelo/q32006/Vaihtokelpoiset_Q32006.pdf

366 http://www.finlex.fi/fi/laki/alkup/2003/20030210?search%5Btype%5D=pika&search%5Bpika%5D=vaihtokelpo%2A

367 http://www.nam.fi/english/medicines/substitutable_medicinal_products/criteria_used/index.html

The list of substitutable medicinal products may not include[368]:

- Hospital-only medicines,
- Pharmaceuticals given
  - in medicated plaster form,
  - given parenterally or
  - as an inhalation,
- Pharmaceuticals belonging to ATC groups where substitution by other products is not appropriate for pharmacological or clinical reasons (substitution by a parallel import or parallel distribution product is possible); these include insulins and insulin analogues, haematological medicines, cardiac glycosides, anti-arrhythmics, antiserums, immunoglobulins and vaccinations, anti-epileptics and inhalable pharmaceuticals for obstructive respiratory diseases and
- Pharmaceutical being protected by a process patent in Finland.

The last point is currently only applicable for six pharmaceuticals (Proscar®, Amaryl®, Cozaar®, Efexor®, Imigrain® and Risperdial®).[369]

8.3.1.5 Non-reimbursable Pharmaceuticals

With the major changes in the Health Insurance Act[370] valid from 1 January 2006 HILA was given the power to include pharmaceuticals in a so-called "Zero reimbursement category", i.e. a sort of negative list.

HILA may deny reimbursement to pharmaceuticals if:[371]

- The product is only used temporarily or for minor illnesses with mild symptoms;
- The therapeutic value is limited;
- It is used for other purposes than treatment of illnesses[372]; or if
- It is a herbal medicine, a homeopathic or a antroposophic product.

So far no products have been moved to the „Zero reimbursmentcategory“ yet and it has to be noted that herbal medicines and homeopathic or anthroposophic products were not reimbursed before the changes in the legislation either.[373] Generally speaking about 4,600 pharmaceuticals (mainly OTC, vitamin preparations etc.) are not reimbursable,[374]

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368 Medicines Act 395/1987 as amended in 2005

369 PPR 2/2006

370 Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 6

371 Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 6, Section 2a(2)

372 This is likely to refer to lifestyle drugs, contraceptives, etc. but the scope of pharmaceuticals was not yet determined according to a STM spokesperson in July 2006

373 STM 2006

374 Suomen Apteekkariliitto 2006

HILA has announced to initiate systematic evaluations for the zero reimbursement category, so that a preliminary list of therapeutic groups to be evaluated will be available by summer 2006.[375]

8.3.1.6 Appeal Procedure

In case a manufacturer wants to price the product above the approved wholesale price or does not agree on a price cut, it is always possible to apply for price increase or withdraw a medicinal product from the reimbursement system and change the price to his/her discretion. However, non-approval of such a price increase could lead to exclusion of the pharmaceutical from reimbursement (i.e. delisting, cf. next point).

In case pharmaceutical companies are not satisfied with the decision of HILA or intend to claim too long processing times (e.g. longer than the 90 resp. 180 days stated in the EU Transparency Directive) they have to appeal to the Supreme Administrative Court.[376]

One of the reasons for the establishment of new reimbursement rules during the last years was that the European Court of Justice had condemned Finland guilty of the breach of the EU Transparency Directive 89/105/EEC on 12 June 2003.[377] It had ruled that the regulations and timelines on pharmaceutical reimbursement within the special reimbursement category (= the method of approving a drug into special reimbursement category by statute of the Council of State instead of petition proceedings, cf. 8.3.1.2) contravened the Transparency Directive.

8.3.1.7 Delisting, Withdrawals and Switches

There are no specific rules regarding switches in place and the number of annual switches is low (2003: 1 active substance, 2004: 4 active substances).[378] Switching decisions are taken by NAM on a case-by-case basis either because requested by the manufacturer of the pharmaceutical or on its own intent. In most cases switches are denied by NAM. Between 1989 and 1998 altogether 36 active substances were switched.[379]

Until the beginning of 2006 there have only be a minor number of de-listings, i.e. pharmaceuticals which are being excluded from basic reimbursement, as each pharmaceutical that was granted an "approved" wholesale price (cf. 8.2.1.2) was reimbursable. The major reason for delisting was the withdrawal of the product from the reimbursement system by the manufacturer in order to price the product freely as price decisions of HILA are binding for a maxi-

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375 PPR 2/2006

376 Administrative Judicial Procedure Act (586/1996)

377 ECJ Case C229/00, http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&Submit=Submit&alldocs=alldocs&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=&datefs=2003-06-12&datefe=2003-06-12&nomusuel=&domaine=&mots=&resmax=100

378 AESGP 2005

379 Suomen Apteekkariliitto 2006

mum of five respectively for pharmaceuticals containing new active ingredients of three years.[380]

Due to the new legislation delisting is possible, but HILA, who is in charge of delisting, has not yet published concrete decisions.[381] Criteria for inclusion in the negative list are explained in point 8.3.1.5.

Because of the 5% price cut, that took place on 1 January 2006 (cf. 8.2.2.4) several pharmaceutical companies opted for withdrawal rather than to reduce their prices. So far manufacturers of 81 pharmaceuticals (44 active ingredients) opted for withdrawal.[382] Some of this pharmaceuticals (e.g. Cialis®, Levitra® or Viagra®) are expected to be placed on the newly introduced "Zero reimbursement" category anyway.[383]

The greatest reaction in public was caused by the withdrawal of two oncology pharmaceuticals - Taxotere® and Gemzar® - as these meant full self payment for the patients.[384]

8.3.2 Reference Price System

There is no reference price system applied in Finland. Nevertheless, the generic substitution system, that is explained in detail in point 8.3.4.2 displays elements of a reference price system as a sort of reference price is set as basis for reimbursement. In contrary to a reference price system patients do not need to pay the price difference between the branded pharmaceutical and the generic or parallel imported substitute in case they reject substitution.

Yet, a working group for has been nominated for the period of 12.6.2006 to 28.2.2007 to discuss the introduction of a reference price system, The background is, that the government has set 5% limit for the growth of pharmaceutical expenditure (in terms of reimbursement costs) between 2008 and 2011, and a reference price system shall be one of the methods to reach this goal.[384]

8.3.3 Pharmaceutical Budgets

As most out-patient doctors are paid with monthly salaries, there are neither soft nor fixed nor indicative pharmaceutical spending budgets in place for doctors.[385] Additionally there are no "ear-marked" regional budgets in place for the municipalities - like for other health care

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380 Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 6, Section 12

381 PPR 10/2005, STM 2006

382 STM 2006

383 PPR 2/2006

384 Suomen Apteekkariliitto 2006

385 Pekurinen/Häkkinen 2005

services - as all public pharmaceutical expenses except the medication of infectious disease are carried by KELA.

8.3.4 Other Volume Control Oriented Measures

8.3.4.1 Prescription Monitoring and Other Doctors-related Measures

Between 1998 and 2002 a program for rational prescribing, ROHTO, was implemented[386]. Since 2003 the Centre for Pharmacotherapy Development (Lääkehoidon kehittämiskeskus ROHTO) is in charge of promoting rational use of pharmaceuticals and supporting the implementation of such activities in Finland.[387] ROHTO is an independent expert unit under the STM collecting and disseminating information to monitor prescribing habits of doctors and proving information to doctors. As of 1 January 2006 ROHTO has the right to request from HILA information on the cost-effectiveness and other details submitted by pharmaceutical companies with their application for pricing and reimbursement.[388]

Although there are no sanctions in place for "over-spending" doctors or those who oppose generic substitution, doctors must act on good medical reasons for refusing and document his/her decision (cf. 8.3.4.2).[389]

Already since the year 1997 doctors, who prescribe more than 200 reimbursable pharmaceuticals per annum, i.e. the vast majority of doctors, receive a summary of their prescriptions and their respective cost from KELA. The data provided include the number of prescriptions and their distribution by patients' age and gender as well as the average cost per prescription etc. compared to those of other doctors in the same region and are intent to raise the prescribing awareness of doctors.[390]

Until June 2006 the Finnish Medical Society 'Duodecim' has issued 70 national clinical treatment guidelines for common diseases and health problems compiled under the name "Current Care". The preparation of about 20 further guidelines are under way.[391]

Only the most recently published "Current Care" guidelines include an economic component and so far neither the effect of ROHTO program nor "Current Care" guidelines on prescribing behaviour have been thoroughly evaluated.

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386 Pekurinen/Häkkinen 2005

387 http://www.rohto.fi

388 PPR 10/2005

389 Peura 2006

390 Pekurinen/Häkkinen 2005

391 http://www.duodecim.fi

8.3.4.2 Generics and Parallel Trade

Between 1993 and 1996 generic substitution through the pharmacist was allowed in Finland, when the prescribing doctor marked his/her prescription with a "G". This system was then replaced by the right of doctors to write prescriptions generically, i.e. using the INN, which is still valid.[392]

As these voluntary measures didn't have the desired effect[393], to curb pharmaceutical expenditure, by 1 April 2003 obligatory generic substitution was introduced. Regulations now oblige pharmacies to offer customers a cheaper substitute (generic or parallel import) if a doctor has prescribed a more expensive medicine beyond a pre-determined price corridor (cf. 8.3.1.4 for a detailed presentation of the system).

Still the Finnish substitution system is rather "patient-friendly" as patients and also prescribing doctors may refuse the substitution and there is no reference price system in place.[394] Refusal of substitution will furthermore not diminish the reimbursement level of the originally prescribed pharmaceutical, i.e. patients need not pay the price difference to the more expensive pharmaceutical if they oppose substitution.[395]

There are also no sanctions for doctors in place who over-prescribe branded pharmaceuticals, still in average only 0.3% of doctors forbade substitution in the first 18 months of the system.[396] Doctors may also oppose substitution by parallel import by simply adding the name of the marketing authorisation holder on the prescription and refusing the substitution.[397]

The obligatory substitution system is considered as a tremendous success, as e.g. in the first 12 months (April 2003 - April 2004) KELA obtained savings of € 49.1 million and patients paid € 39.2 million less co-payment.[398]

The generic share of the market is estimated to be about 44 percent in terms of volume and 18.4% in terms of value (data: 2004).[399]

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392 Decree by the Ministry of Social Affairs and Health on the prescribing of medicines 726/2003

393 According to Pekurinen/Häkkinen 2005 out of 2.6 million monthly prescriptions only 600 were prescribed using a generic name.

394 ÖBIG 2006

395 Medicines Act 395/1987 as amended

396 Pekurinen/Häkkinen 2005

397 Medicines Act 395/1987 as amended and Decree 210/2003

398 Tilson/Barry 2005 basing on KELA prescription data

399 Written information by Suomen Apteekkariliitto from 23.8.2005, PPR 2005

8.4 Overview of the Reimbursement Market in Finland

Tasks / Duties	Yes	No	Comments	Legal bases
Public Authorities (Ministries, Pricing Body, Social Health Insurance)				
Decide on prescription status	X			Medicines Act 395/1987
Decide on manufacturer price		X	Indirectly influenced via "agreed wholesale" price for reimbursable pharmaceuticals	Not applicable
Agree on manufacturer price		X		
Fix wholesale margin		X		
Fix pharmacy retail price	X		Via regressive mark-up scheme.	Government Decree on the mark-up 2002/1087
Decide on reimbursement status	X			Health Insurance Act 1224/2004 and amendment 885/2005
Agrees on reimbursement price		X		
Decide on reimbursement price	X			Government Decree on the Pharmaceuticals Pricing Board 1356/2004 Health Insurance Act 1224/2004 and amendment 885/2005
Use Pharmaco-economic guidelines	X		On the evaluation process of reimbursed price	Decree by the Ministry of Social Affairs and Health on applications for a reasonable wholesale price and reimbursement status of a medicinal product and on the documentation to be appended to the application (1111/2005)
Use Internal reference pricing	X		Reimbursement decisions for comparable preparations	
Use External reference pricing		X		
Price freezes		X		
Margin and price cuts	X		Pharmacy mark-up 1998 Reimbursed prices by ATC in 1998-1999 and 2004 -2005 5% cut in reimbursed "agreed" wholesale prices by 1.1.2006	Government Decree on the mark-up 2002/1087 Health Insurance Act 1224/2004 and amendment 885/2005
Discounts and Rebates		X	Forbidden	Medicines Act 395/1987
Company profit control		X		
Country specific:				

Tasks / Duties	Yes	No	Comments	Legal bases
Pharmaceutical Industry				
Sets manufacturer price freely	X		Free to change	
Notifies manufacturer price		X		
Negotiates manufacturer price			Not applicable	
Is free to set price below fixed manufacturer price			Not applicable	
Decides on application for reimbursement	X		Basic reimbursement category (42%) and special reimbursements (72% and 100%) have separate application methods	Health Insurance Act 1224/2004 and amendment 885/2005; Decree by the Ministry of Social Affairs and Health on applications for a reasonable wholesale price and reimbursement status of medicinal product and on the documentation to be appended to the application (1111/2005)
Applies for reimbursement price	X		Negotiates reimbursable wholesale price (= manufacturer price including wholesaler's share)	Health Insurance Act 1224/2004 and amendment 885/2005; Decree by the Ministry of Social Affairs and Health on applications for a reasonable wholesale price and reimbursement status of medicinal product and on the documentation to be appended to the application (1111/2005)
Free to set price below reimbursement level	X			
Free to grant rebates / discounts to wholesalers	X		N.a., as agreements between wholesalers and manufacturers are not public	
Free to grant rebates / discounts to pharmacies		X	All rebates/discounts are forbidden by law	Medicines Act 395/1987, amendment 2006/22
Can engage in marketing towards doctors	X		In line with code of conduct and Medicines Act: only in events specially organized for presentations, professional publications and electronically	Medicines Act 395/1987

Tasks / Duties	Yes	No	Comments	Legal bases
Can engage in public advertising	X		only for OTC excluding products containing narcotics or psychotropic substances	Medicines Act 395/1987
Applies for switches and de-listing	X		Switching can equally be initiated by HILA	
Promotional control	X		Through NAM. Self-control of industry: pre-control for TV advertisements, post-control for printed marketing	Medicines Act 395/1987
Country specific:				
Distribution Chain				
Wholesaler				
Margins are fixed by statute		X		
Margins are subject to statutory discounts / rebates		X		
Free to grant discounts / rebates to pharmacies		X	All rebates/discounts are forbidden by law.	Medicines Act 395/1987, amendment 2006/22
Pharmacists				
Margins are fixed by statute	X		Regressive scheme based on wholesaler price	Government Decree on the mark-up 2002/1087
Free to set retail price		X	Retail prices must be equal in all pharmacies	Medicines Act 395/1987, amendment 2006/22 Government Decree on the mark-up 2002/1087
Obliged to inform patient on cheaper product	X		In the scheme of generic substitution (substitution is obligatory for pharmacy if the price difference between prescribed and the cheapest product is € 2-3.- or more: € 2.- if the price is below € 40.- and € 3.- > € 40.-	Medicines Act 395/1987 as amended and Decree 210/2003
Obliged to substitute by a generic	X		In the scheme of generic substitution (if pharmaceutical is on the interchangeable list)	Medicines Act 395/1987 as amended and Decree 210/2003
Allowed to substitute by a generic	X		In the scheme of generic substitution	Medicines Act 395/1987 as amended and Decree 210/2003
Obliged to substitute by a parallel import	X		If there is price difference of € 2-3.- or more.	Medicines Act 395/1987 as amended and Decree 210/2003
Allowed to substitute by a parallel import	X			
Therapeutic / analogous substitution is allowed		X		
Are subject to statutory discounts		X	All rebates/discounts are forbidden by law	Medicines Act 395/1987, amendment 2006/22

Tasks / Duties	Yes	No	Comments	Legal bases
Claw back system exists		X		
May grant rebates to customers	X	X	Retail prices must be equal in all pharmacies. Discounts for regular customers may exist, but they must be equal for all. War veterans must be given a 10% discount.	Medicines Act 395/1987, amendment 2006/22 Government Decree on the mark-up 2002/1087
Country specific:			Additional pharmacy tax (pharmacy fee) applied (progressive, up to 11% of pharmacy turn-over) to secure services countrywide, in average about 7 %	Pharmacy Fee Act 1946/148
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			Act on patient's rights 785/1992
Are obliged to inform on co-payment / deductibles		X		
Prescription habits are monitored	X		For information purposes only by KELA: collects data on prescriptions and costs per doctor annually for the doctor. Covers only reimbursed medication.	
Are subject to prescription guidelines	X		Not compulsory.	
Budgets are controlled		X		
Allowed to prescribe INN	X			Decree by the Ministry of Social Affairs and Health on the prescribing of medicines 726/2003
Obliged to prescribe INN		X		
Can oppose generic substitution	X			Medicines Act 395/1987 as amended and Decree 210/2003
Can oppose therapeutic substitution		X	Therapeutic substitution is not possible.	

Tasks / Duties	Yes	No	Comments	Legal bases
Can oppose substitution by parallel import	X		By adding the name of the marketing authorisation holder on the prescription and refusing the substitution	Medicines Act 395/1987 as amended and Decree 210/2003
Country specific:			Some pharmaceuticals are only reimbursed if prescribed by a specialist or for a specific disease.	Government decree on medicinal products with reimbursement status granted on special grounds and diseases regarded as severe on medical grounds 616/2005
Patients				
Can shop for cheapest price of the product		X	Retail prices must be equal in all pharmacies. Discounts for regular customers may exist, but they must be equal for all.	Government Decree on the mark-up 2002/1087 Medicines Act 395/1987, amendment 2006/22
Pay a flat rate per prescription and purchase	X		Pharmacy adds € 0.42 (incl. 8% VAT) expedition fee to all prescriptions. € 3.- deductible for pharmaceuticals in Upper special reimbursement € 1.5 deductible for pharmaceuticals above annual maximum co-payment	Government Decree on the mark-up 2002/1087 Health Insurance Act 1224/2004 and amendment 885/2005
Pay a certain percentage per prescribed pharmaceutical	X		Basic reimbursement: 58% Special reimbursement: 28%	Health Insurance Act 1224/2004 and amendment 885/2005
Annual minimum co-payment		X		
Annual maximum co-payment	X		Threshold in 2006 is € 616.72	Health Insurance Act 1224/2004 and amendment 885/2005
May ask for substitution by a generic	X			Medicines Act 395/1987
May oppose substitution by a generic	X			Medicines Act 395/1987
May ask for substitution by a parallel import	X			Medicines Act 395/1987
Can oppose substitution by a parallel import	X		Refusal of substitution will not diminish the reimbursement level of the originally prescribed phar-	Medicines Act 395/1987 Medicines Act 395/1987

Tasks / Duties	Yes	No	Comments	Legal bases
Can oppose substitution only on payment of price difference	X	X		
Has to pay the difference between reimbursement price and reference price		X		
Has access to full public information on prices and products	X			Available on the internet and in pharmacies
Country specifics:				

N.a. = Not available; NAM = National Agency for Medicines, OTC = Over-the Counter pharmaceutical

Source: ÖBIG 2006

FRANCE

9 France

9.1 Pharmaceutical System

9.1.1 Regulatory Framework and Authorities

Virtually the whole French population is covered by the social insurance system. In 2000, a reform in the health insurance system enabled the coverage of all citizens (Couverture Maladie Universelle, CMU), including 0.7 million people who had been without health coverage before.

The main health insurance scheme (Régime General) for employees and their families covers around 80% of the population. Its health insurance fund at the national level (Caisse Nationale de l'Assurance Maladie des Travailleurs Salariés, CNAMTS) is thus the largest one. Important health insurance funds are furthermore those for self-employed (Caisse Nationale d'Assurance Maladie des Professions Indépendantes, CANAM) and for farmers (Mutualité Sociale Agricole, MSA).

To cover the large extent of co-payments, about 85% of the population has concluded a contract with one of the „Mutuelles", which are supplementary sickness funds (cf. 9.2.3).

The most relevant players in the French pharmaceutical system are:

- the French Ministry of Health (Ministère de la Santé et Solidarités) which is in charge of the Medicines Agency and which hosts the Medicinal Products' Pricing Committee (Comité Economique des Produits de Santé, CEPS)[400]
- the Medicines Agency (Agence Francaise de Sécurité Sanitaire des Produits de Santé, AFSSAPS) which is responsible for evaluating and surveying the safety of pharmaceuticals (market authorisation authority, pharmacovigilance)
- the High Authority for Health (Haute Autorité de Santé, HAS[401]), which was newly established and became operational in January 2005, and which is responsible for evaluating the medical benefit of pharmaceuticals and in charge of the Transparency Committee (Commission de la Transparence)

[400] Enactment on Prices and Margins for reimbursable pharmaceuticals: Arrête du 12 février 2004 modifiant l'arrêté du 4 août 1987 modifié relatif aux prix and aux marges des médicaments remboursables

[401] Health Insurance Reform Law 2004 (Loi n° 2004-810 du 13 août 2004 relative à l'assurance maladie), http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=SANX0400122L

- the National Union of Health Insurers (Union Nationale des Caisses d'Assurance Maladie, UNCAM[402]), formed in 2005 by grouping the three main health insurers (CNAMTS, CANAM, MSA), who is in charge of reimbursement

The latest health insurance reform in 2004[403] brought institutional changes, including the establishment of two new institutions, the HAS and the UNCAM in 2005. With the foundation of the HAS, who is also in charge of the evaluation of medical devices and medical practices, the responsibility for the evaluation of the medical benefit of pharmaceuticals was shifted from the AFSSAPS to this new authority. Before 2005, the Transparency Commission was also hosted by AFSSAPS. Usually the Transparency Commission examines reimbursement dossiers and transfers its advice directly to the CEPS for pricing decisions and to the UNCAM for reimbursement purposes; however, the HAS may also choose to assess certain pharmaceuticals and give its own advice on pricing and reimbursement.

The CEPS has, since 2000, been in charge of pricing for medical products. Until end of 1999 the Committee, who was then called "Pharmaceutical Pricing Committee" (Comité Economique du Médicament, CEM), was only in charge of pricing of pharmaceuticals. The health insurance reform 2004 focussed on the cohesion between the government's pricing and reimbursement policies (thus increasing CEPS's role in cost-containment) and on strengthened CEPS's decision-making powers. The increased role of the CEPS is also reflected in its inclusion of more health insurance representatives[404]. Before, the three large health insurance funds had been represented by one member each.

Table 9.1 contains an overview of relevant French stakeholders.

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402 Health Insurance Reform Law 2004 (Loi n° 2004-810 du 13 août 2004 relative à l'assurance maladie), http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=SANX0400122L

403 Health Insurance Reform Law 2004 (Loi n° 2004-810 du 13 août 2004 relative à l'assurance maladie), http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=SANX0400122L

404 CEPS is composed of representatives of ministries (Ministry of Health and Solidarity and Ministry of Economy, Finance and Industry) and health insurance funds. Since 2005, there have been two CNAMTS representatives, one member nominated jointly by MSA and CANAM and one UNCAM representative.

Table 9.1: France - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Ministère de la Santé et des Solidarité / Ministry of Health	Ministry of Health (general pharmaceutical policy)	Ministère de la Santé et des Solidarité 8, avenue de Ségur F-75350 Paris SP 07 France Tel.: +33 1 4056 6000 Fax: +33 1 4056 4056 www.sante.gouv.fr	Mr. Benoît Bohnert Directeur du cabinet 8, avenue de Ségur F-75350 Paris SP 07 France Tel.: +33 1 4056 6000 Fax: +33 1 4056 4056
Haute Autorité de Santé (HAS) / High Authority of Health	Regulatory body (evaluation of pharma-ceuticals hosting the Transparent Commission)	HAS 2, avenue du Stade de France F-93218 Saint-Denis La Plaine Cedex France Tel.: +33 1 5593 7000 Fax: +33 1 5593 7400 www.has-sante.fr/	Mr. Xerri Bertrand 143-147 Boulevard Anatole F-93285 Saint-Denis Cedex France Tel.: +33 1 5587 3698 Fax: +33 1 5587 3832 b.xerri@has-sant.fr
Comité Economique des Produits de Santé (CEPS)	Regulatory Body (pricing committee hosted by HAS)	CEPS 2, avenue du Stade de France F-93218 Saint-Denis La Plaine Cedex France Tel.: +33 1 5593 7000 Fax: +33 1 5593 7400 www.has-sante.fr/ceps	Ms. Sylvette Laplanche 2, avenue du Stade de France F-93218 Saint-Denis La Plaine Cedex France Tel.: +33 1 5593 7000 Fax: +33 1 5593 7400
Union des Caisses d'Assurance Maladie (UNCAM) / Union of Social Health Insurances	Third Party Payer (federation of the 3 largest French social health insurance institutions)	UNCAM 26-50 avenue du professeur André Lemierre F-75986 Paris cedex 20 France Tel.: +33 1 7260 1000	Mr. Michel Regereau 26-50 avenue du professeur André Lemierre F-75986 Paris cedex 20 France Tel.: +33 1 7260 1000
Caisse Nationale d' Assurance Maladie des Travailleurs Salaries (CNAMTS) / National Sickness Fund of the Employees	Third Party Payer (reimburse-ment - largest sickness fund)	CNAMTS 26-50 avenue du professeur André Lemierre F-75986 Paris cedex 20 France Tel.: +33 1 72 60 10 00 www.ameli.fr/	Mr. Christian Marty 26-50 avenue du professeur André Lemierre F-75986 Paris cedex 20 France Tel.: +33 1 72 60 10 00

Institution	Task	Contact details/URL	Responsible person
Agence Francaise de Sécurité Sanitaire des Produits de Santé (AFSSAPS) / French Agency of Security for Medical Products	Medicines agency (authorisation and vigilance)	AFSSAPS 143-147, Bld Anatole France F-93200 Saint-Denis France Tel.: +33 1 5587 3298 Fax: +33 1 5587 3292 www.afssaps.sante.fr/	Mr. Jean-Hugues Trouvin 143-147, Bld Anatole France F-93200 Saint-Denis France Tel: +33 1 5587 3298 Fax:+33 1 5587 3292
Les Entreprises du Médicament (LEEM)	Association of pharmaceutical industry	LEEM 88, rue de la Faisanderie F-75016 Paris France Tel.: +33 1 4503 8887 Fax: +33 1 4503 8875 www.leem.org/	Mr. Gallard 88, rue de la Faisanderie F-75016 Paris France Tel.: +33 1 4503 8887 Fax: +33 1 4503 8875 mgallard@leem.org
Association Francaise des Producteurs de Spécialités Grand Public (AFSGP) / French Association of Self-Medication Industry	Association of self-medication industry	AFSGP 4 bis, rue Michel Charles F-75012 Paris France Tel.: +33 1 5302 4400 Fax: +33 1 5302 4404	Ms. Estelle 4 bis, rue Michel Charles F-75012 Paris France Tel.: +33 1 5302 4400 Fax: +33 1 5302 4404 afsgp@wanadoo.fr
Chambre Syndi-cale de la Répartition Pharmaceutique (CSRP) / Union of Pharma-ceutical Distribution	Association of wholesalers	CSRP 47, rue de Liége F-75008 Paris France Tel.: +33 1 4294 0125 Fax: +33 1 4294 1984 www.csrp.fr/	Mr. Benoît Ducroux 47, rue de Liége F-75008 Paris France Tel.: +33 1 4294 0125 Fax: +33 1 4294 1984 Ducroux@csrp.fr
Association Générique Méme Médicament (GEMME) / Association of Generics	Association of generic industry	GEMME 34 rue Citeaux F-75012 Paris France Tel.: +33 1 4928 5775 http://www.presstvnews.fr/moisgenerique/gemmepresent.htm	Mr. Philippe Ranty President 34 rue Citeaux F-75012 Paris France Tel.: +33 1 4928 5775

Institution	Task	Contact details/URL	Responsible person
Fédération des Syndicats Pharmaceutiques de France (FSPF) / Federation of the Pharmacy Unions of France	Association of pharmacies	FSPF 13 rue Ballu F-75311 Paris Cedex 09 France Tel.: +33 1 4453 1925 Fax: +33 1 4453 2175 www.fspf.fr/	Mr. Patrice Ossent 13 rue Ballu F-75311 Paris Cedex 09 France Tel.: +33 1 4453 1925 Fax: +33 1 4453 2175 administration@fspf.fr
Conseil National de l'ordre des Médecins (CNOM) / National Medical Doctors Association	Medical Doctors' Association	CNOM 180, boulevard Haussmann F-75389 Paris Cedex 06 France Tel.: +33 1 5389 3334 Fax: +33 1 5389 3227 www.conseil- national.medecin.fr/	Jacques Lucas 180, boulevard Haussmann F-75389 Paris Cedex 06 France Tel.: +33 1 5389 3334 Fax: +33 1 5389 3227 paris@75.medecin.fr
Fédération de Médecins de France / French Association of Medical Doctors	Medical doctors' association	Fédération de Médecins de France 60, rue Laugier F-75017 Paris France Tel.: +31 1 4763.4052 Fax: +31 1 4764 9341 www.fmfpro.com/	Mr. Jean-Paul Hamon President 60, rue Laugier F-75017 Paris France Tel.: +31 1 4763 4052 Fax: +31 1.4764 9341
Consommation, Logement et Cadre de Vie	Association of Consumers and Patients	Consommation, Logement et Cadre de Vie 13 rue Niepce F-75014 Paris France Tel.: +33 1 5654 3210 Fax: +33 1 4320 7202 www.clcv.org/	Consommation, Logement et Cadre de Vie 13 rue Niepce F-75014 Paris France Tel.: +33 1 5654 3210 Fax: +33 1 4320 7202 dechartres.clcv@free.fr

Source: ÖBIG 2006

9.1.2 Market Players

9.1.2.1 Pharmaceutical Industry

France has a significant pharmaceutical industry, and is an important pharmaceutical exporting country. The interests of the pharmaceutical industry are represented through the Association of Pharmaceutical Industry (Les Entreprises du Médicament, LEEM), which used to

be called Syndicat National des Industries Pharmaceutiques (SNIP) in the 1990s. According to LEEM[405] there are at the moment around 300 pharmaceutical companies based in France.

LEEM has a strong role in the pricing process of pharmaceuticals. In 1994, the first framework agreement (Accord Cadre) between then SNIP and the government was concluded. That framework agreement covered various aspects such as sales growth, pricing and promotion.

The current framework agreement (Accord Cadre) between LEEM and CEPS[406], which is valid from 2003 to 2006, is relevant for pricing decisions of reimbursable pharmaceuticals (cf. 9.2.1), as well as for the promotion (cf. 9.2.2.8) and the financial regulations of pharmaceuticals.

The interests of the generic industry are represented through the Association of Generic Industry (Association Générique Méme Médicament, GEMME).

9.1.2.2 Distribution

There are 11 wholesalers in France. The four largest are: OCP, Alliance Santé, le réseau CERP and PHOENIX Pharma, who account for 99% of the market share in value. Their interests are represented through the Association of Wholesalers (Chambre Syndicale de la Répartition Pharmaceutique, CSRP).

In 2003, there were 22,691 retail pharmacies, corresponding to one pharmacy for an average of 2,615 inhabitants. Only qualified pharmacists may own a pharmacy and, if they do so, they are obliged to be present in their own pharmacy during opening hours. The formation of pharmacy chains is thus prohibited. Mail order and internet sale of pharmaceuticals is also not permitted.

There are only a dozen self-dispensing doctors, mostly located in rural and isolated areas where there is no local pharmacy. If there are any pharmacies in these areas then it is not allowed to close them down for any reasons.

9.1.2.3 Patients

The role of French patients in the choice of a medication is rather minor for POM. It is criticised that patients lack sensitivity concerning pharmaceutical expenditure although there are high co-payments (cf. 9.2.3). However, these co-payments are mainly covered by the supplementary insurances “Mutuelles” which the majority of the population have concluded (cf. 9.2.3).

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405 http://www.leem.org/industrie/ind_frame.htm

406 Framework Agreement between CEPS and LEEM for the period 2003-2006: Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006 and Framework Agreement between CEPS and LEEM on hospital medicines: Accord cadre sur le médicament à l’hopital entre le Comité Economique des produits de santé et les entreprises du medicament, http://www.leem.org/industrie/legal13.htm

With regard to generic promotion, the government addressed the public to convince them of the benefits of generics. For instance, in early 2003, before the introduction of the reference price system (cf. 9.2.3), a large-scale campaign for the promotion of generics was launched.

Already before 2003, patients who had been registered with so-called “reference doctors” were likely to get more generics prescribed. “Reference doctors” could join on a voluntary basis an agreement, concluded between the social health insurance and the doctors association in 1997, thus committing themselves to ensure that 15% of their prescriptions by value is for less expensive pharmaceuticals, including 5% for generics. In return, the “reference doctors” receive an annual fee per registered patient. Since June 2002, “reference doctors” have received an increased fee, if they agreed to ensure that 25% of their prescriptions was written either for a specific generic or using the international non-proprietary name (INN).

A burning issue in France is the high pharmaceutical consumption. As a reason for this the large pack sizes of pharmaceuticals are often mentioned. In the current health insurance reform bill there is a provision to better target pack sizes to treatment duration. The CEPS is considering measures to encourage the production of new (smaller) pack sizes. This includes the introduction of both 30- and 90-day presentations for chronic conditions and small packs for short-term treatment. One measure, which is under discussion, is to enforce a price cut for larger pack sizes.

9.1.3 Overview of the Pharmaceutical System

There were 4,830 pharmaceuticals, corresponding to 8,790 authorised presentations (different dosages, pharmaceutical forms and packs counted) on the French market in 2004[407].

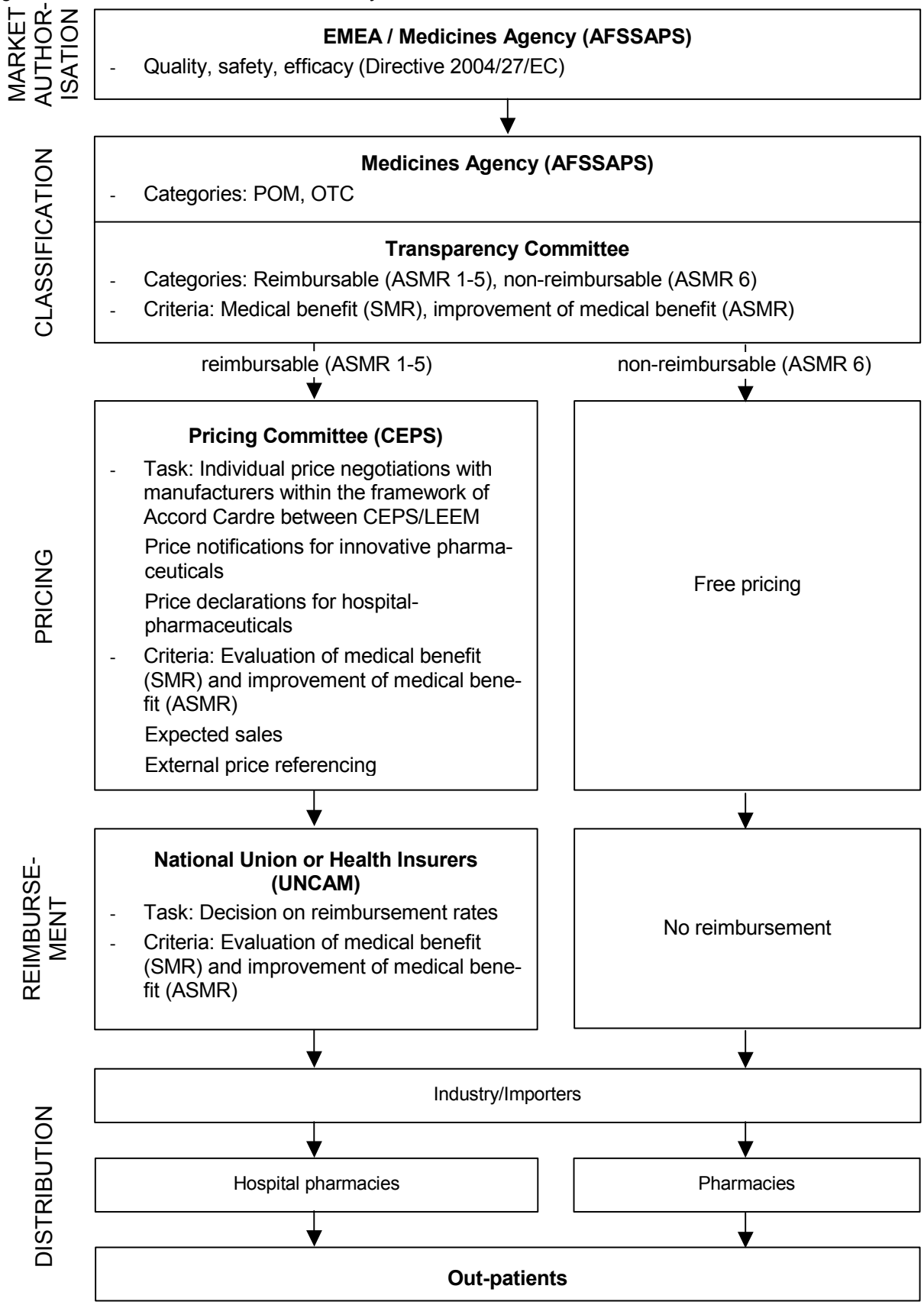
Pharmaceuticals are classified in a two-step process: One classification regards the prescription status (POM and OTC products), which is decided on by the AFFSAPS, the other one is the rating on the “improvement on the medical benefit” (the so-called ASMR rating) by the Transparency Committee[408] (cf. 9.2.1.1). The ASMR rating has consequences on the reimbursement level, and thus the pricing procedure (as there is free pricing for non-reimbursable pharmaceuticals, cf. 9.2.1), and the reimbursement rate (cf. 9.3.1). These two classifications are independent from each other; however, OTC products are, in general, non-reimbursable pharmaceuticals.

Figure 9.1 gives an overview of the pharmaceutical system in France.

[407] LEEM 2005

[408] Sécretariat Général de la Commission de la Transparence 2005

Figure 9.1: France - Pharmaceutical System, 2006



Note: The ASMR rating (reimbursement status) is independent from the prescription status (POM and OTC).
Source: ÖBIG 2006

9.2 Pricing

9.2.1 Scope of Price Control

The pricing procedure depends on the reimbursement status of the pharmaceutical. In general, the prices of reimbursable pharmaceuticals (in the out-patient sector and to a great extent also in the hospital sector) are negotiated between the manufacturer and CEPS. The pricing decision is taken after the analysis and evaluation of the medical benefit (Service Médical Rendu, SMR), which is the criterion for the inclusion into reimbursement or not (cf. 9.3). Within this general price negotiation scheme for reimbursable pharmaceuticals, there are also price notification procedures for certain groups of pharmaceuticals.

There is free pricing for non-reimbursable pharmaceuticals.

The prescription status of a pharmaceutical plays no role with regard to pricing. OTC products may also be considered as reimbursed, in that case their prices are also negotiated.

At the moment, the basis for pricing is formed by two framework agreements[409] (Accords Cadre) between CEPS and the pharmaceutical industry association (Les Entreprises du Médicament, LEEM), which are valid for the period from 2003 to 2006 (cf. 9.1.2.1): one for the out-patient sector and one for the hospital sector. Following these agreements, manufacturers each had to sign an individual agreement with CEPS in order that the provisions of the Accord Cadre (e.g. the price notification system for certain pharmaceuticals and the exemption from the safeguard clause, cf. 9.2.2.7) are applied to them. In 2004, 174 out of 180 manufacturers had signed such a multi-annual agreement with the CEPS. Thus, virtually the whole market is covered, as the remaining companies represented less than 0.1% of the reimbursed sale of pharmaceuticals.

The statutory margin schemes for wholesalers and for pharmacies are applicable for reimbursable pharmaceuticals.

Table 9.2 gives an overview of the French pricing system.

409 Framework Agreement between CEPS and LEEM for the period 2003-2006: Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006 and Framework Agreement between CEPS and LEEM on hospital medicines: Accord cadre sur le médicament à l'hopital entre le Comité Economique des produits de santé et les entreprises du médicament, http://www.leem.org/industrie/legal13.htm

Table 9.2: France - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Non-reimbursable pharmaceuticals; price declaration for certain hospital pharmaceuticals (outside the DRG system); in addition price notification for innovative pharmaceuticals in the outpatient sector	Not applied	Not applied
Statutory Pricing	Not applied	Reimbursable pharmaceuticals regulated via a regressive mark-up scheme	Reimbursable pharmaceuticals regulated via a regressive mark-up scheme
Price Negotiations	Prices of reimbursable pharmaceuticals are negotiated between CEPS and manufacturer	Not applied	Not applied
Discounts/rebates	Yes	No	No
Institution in charge of pricing	- Pricing Committee CEPS		
Legal Basis	- Arrête du 12 février 2004 modifiant l'arrêté du 4 août 1987 modifié relatif aux prix and aux marges des médicaments remboursables (Enactment on Prices and Margins for reimbursable pharmaceuticals) - Loi n° 2004-810 du 13 août 2004 relative à l'assurance maladie (Health Insurance Reform Law 2004) - Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006 (Framework Agreement between CEPS and LEEM for the period 2003-2006) - Accord cadre sur le médicament à l'hopital entre le Comité Economique des produits de santé et les entreprises du médicament (Framework Agreement between CEPS and LEEM on hospital medicines)		

CEPS = Pricing Committee, DRG = Diagnose related groups, LEEM = Association of Pharmaceutical Industry

Source: ÖBIG 2006

9.2.1.1 Manufacturer Price

The usual pricing procedure for reimbursable pharmaceuticals consists of a price negotiation between the manufacturer and the CEPS. Non-reimbursable pharmaceuticals may be freely priced.

Before the pricing negotiation pharmaceuticals are evaluated by the Transparency Committee with regard to their SMR and their innovation rate, which is expressed as the improvement in medical benefit (Amélioration du Service Médical Rendu, ASMR) on a scale of 1 to 6, and which has consequences on the price as well as on the reimbursement rate (cf. 9.3).

The ASMR rating is as follows:

ASMR 1 significant therapeutic value

ASMR 2 significant improvement in terms of efficacy, and/or reduction of adverse effects

ASMR 3 modest improvement in terms of efficacy, and/or reduction of adverse effects, as compared with existing products

ASMR 4 minor improvement of benefit (e.g. user-friendliness, smaller interaction risk), as compared with existing products

ASMR 5 no therapeutic improvement of benefit, as compared with existing products (still recommended for reimbursement)

ASMR 6 negative opinion regarding inclusion into reimbursement

The criteria in the price negotiations for reimbursable pharmaceuticals (i.e. those with a ASMR 1 to ASMR 5 rating) are the ASMR rating, the expected sales of the pharmaceutical as well as the prices of the pharmaceutical in other EU Member States:

- ASMR rating: The prices of pharmaceuticals with an ASMR 1 to 4 will be set higher than that of alternative products, while ASMR 5 rated pharmaceuticals will not be granted a price exceeding that of existing products.
- Sales: If the consumption of the entire group is expected to increase due to a new pharmaceutical, a price lower than that of the existing pharmaceuticals might be negotiated.
- External price referencing: Pharmaceutical companies are requested to provide the prices of that pharmaceutical in other EU Member States. There is no formal methodology for external price referencing, but in general CEPS wants the price not to exceed the average price in the EU (cf. 9.2.2.3).

Innovative Pharmaceuticals

Apart from the standard negotiations in the out-patient sector, there is a special fast-track pricing procedure for innovative pharmaceuticals. This regards pharmaceuticals with an ASMR 1 or ASMR 2 rating, as well as ASMR 3 rated products with an expected turnover of less than € 40.- million in the third year of commercialisation.

For these pharmaceuticals a price notification system was introduced: Immediately following the ASMR rating by the Transparency Commission, a manufacturer may suggest a price to the CEPS, and if the CEPS does not object within 2 weeks, the price is accepted. The price proposed must be in line with the price in Germany, the UK, Spain and Italy. Furthermore, the company has to deliver information on the expected sales for the pharmaceutical. If the actual sales exceed these forecasts in the first 4 years, pay-backs may be required (cf. 9.2.2.7).

The manufacturer who sets the price under the notification system is guaranteed to remain at the same level for at least five years. If CEPS objects to a price proposal, the usual pricing procedures, i.e. price negotiations, are followed.

To be eligible for the price notification procedure, manufacturers must have signed a multi-annual agreement with CEPS which most of them did (cf. 9.2.1). However, manufacturers may reject price notification in favour of the standard procedure and negotiate the price.

In fact, price notification is not so often used. In its first year of application (2003), Abbott's protease inhibitor Kaletra was the first and only product of the new system. For two other pharmaceuticals where price notification could be applied in 2003, manufacturers decided to use the normal price negotiations. In 2004, the price notification procedure was initiated for 8 pharmaceuticals.

Already before the introduction of that fast-track procedure in the Accord Cadre[410], signed on June 2003, innovative pharmaceuticals (then defined as the ones with an ASMR 1 or ASMR 2 rating) were granted higher prices in the negotiations.

Hospital Pharmaceuticals

Originally, all hospital-only pharmaceuticals were freely priced in France.

Since the hospital accord LEEM-CEPS[411], signed in 2003, some hospital pharmaceuticals are now subject to a price declaration system. These pharmaceuticals are divided into two groups:

- Pharmaceuticals excluded from T2A funding: The T2A (Tarification à l'activité) is a Diagnosis Related Groups (DRG)-type hospital funding based on the actual services performed which was introduced in 2004. A small number of pharmaceuticals (mainly expensive and innovative pharmaceuticals, in particular treatments for cancer) are invoiced separately from the tariffs.
- Pharmaceuticals on the "retrocession list"[412]: This list includes pharmaceuticals which may be dispensed to out-patients by hospital pharmacies since 2004. "Retrocession pharmaceuticals" (mainly for hepatitis C and HIV treatment) are charged to the health insurance funds.

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410 Framework Agreement between CEPS and LEEM for the period 2003-2006: Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006, http://www.leem.org/industrie/legal13.htm

411 Framework Agreement between CEPS and LEEM on hospital medicines: Accord cadre sur le médicament à l'hopital entre le Comité Economique des produits de santé et les entreprises du médicament http://www.leem.org/industrie/legal13.htm

412 „Décret n° 2004-546 du 15 juin 2004 relatif aux catégories de médicaments à prescription restreinte et à la vente de médicaments au public par certains établissements de santé et modifiant le code de la santé publique et le code de la sécurité sociale" (relevant Act) and "Arrêté du 17 décembre 2004 fixant la liste prévue à l'article L. 5126-4 du Code de la Santé Publique" (its Enactement)

In most cases, the price of T2A excluded and retrocession pharmaceuticals declared by manufacturers to CEPS was accepted. Main reasons for objecting to the prices were that they were significantly higher compared with prices in other European countries or compared to prices in 2003.

The rest of hospital-only pharmaceuticals (i.e. those included in the T2A funding system) are still freely priced.

9.2.1.2 Wholesale Price

In France, the wholesale margins for reimbursable pharmaceuticals are regulated by the state[413]. The latest change in wholesale margins took place at the beginning of the year 2004 when margins were reduced (cf. 9.2.2.5).

The mark-ups is 10.3% on the manufacturer price for a price range up to € 22.90. In the price range of € 22.91 to € 150.- a mark-up of 6% is added, and finally for the portion exceeding € 150.- a mark-up of 2% is additionally applied. Table 9.3 displays the wholesale mark-up scheme for reimbursable pharmaceuticals.

Table 9.3: France - Wholesale Mark-up Scheme for Reimbursable Pharmaceuticals, 2006

Manufacturer price	Coefficient
0 - € 22.90	0.103
€ 22.91 - € 150.-	0.06
> € 150.-	0.02

Source: Enactment on Prices and Margins for reimbursable pharmaceuticals 2004

The prices of non-reimbursable pharmaceuticals may be freely set by the wholesalers.

9.2.1.3 Pharmacy Retail Price

In France, the pharmacy margins for reimbursable pharmaceuticals are regulated by the state[414]. The latest reduction in pharmacy margins took place, together with the wholesale margins cuts, at the beginning of 2004 (cf. 9.2.2.5 and 9.2.1.2).

The pharmacy mark-up scheme is applied in the same way as the wholesale mark-up scheme, i.e. different rates are applied and added according to the range of the manufacturer price. Additionally, a flat of € 0.53 is granted for each pack sold. For generics not included in the reference price scheme (cf. 9.3.2), the pharmacist is permitted to get the same amount of Euro as if applied the mark-up to the branded pharmaceutical, whose price is 30-40% higher.

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413 Enactment on Prices and Margins for reimbursable pharmaceuticals: Arrête du 12 février 2004 modifiant l'arrêté du 4 août 1987 modifié relatif aux prix and aux marges des médicaments remboursables

414 Enactment on Prices and Margins for reimbursable pharmaceuticals: Arrête du 12 février 2004 modifiant l'arrêté du 4 août 1987 modifié relatif aux prix and aux marges des médicaments remboursables

Table 9.4 gives an overview of the pharmacy mark-ups for reimbursable pharmaceuticals.

Table 9.4: France - Pharmacy Mark-up Scheme for Reimbursable Pharmaceuticals, 2006

Manufacturer price	Coefficient
0 - € 22.90	0.261
€ 22.91 - € 150.-	0.10
> € 150.-	0.05
Flat rate of € 0.53	

Source: Enactment on Prices and Margins for reimbursable pharmaceuticals 2004

Margins for non-reimbursable pharmaceuticals whose price may be freely set by the pharmacies are usually higher.

9.2.1.4 Value Added Tax (VAT)

In France (with a standard VAT of 20.6%) the value-added tax is 2.1% for reimbursable pharmaceuticals and 5.5% for non-reimbursable pharmaceuticals.

9.2.2 Price Related Cost-containment Measures

9.2.2.1 Pharmaco-economic Evaluation

Guidelines for pharmaco-economic evaluation have been compiled by the scientific community (Colleges Des Économistes de la Santé); however there are no official requirements.

9.2.2.2 Internal Price Referencing

Since 2003, a reference price system (called Tarif Forfaitaire de Responsabilité, TFR), has been place, which focuses on pharmaceuticals with a low generic penetration (cf. 9.2.2.2).

9.2.2.3 External Price Referencing / Cross Country Referencing

As stated in section 9.2.1.1, external price referencing is one of the elements in deciding on a price for a new reimbursable pharmaceutical, in particular case of an innovative pharmaceutical. Pharmaceutical companies are required to provide the price of the pharmaceutical in question in other EU Member States. However, there are no formal mechanisms for external price referencing. With regard to innovative pharmaceuticals (those with an ASMR 1 to

AMSR 3 rating), the price shall not be lower than the lowest price in one of the reference countries, which are Germany, UK, Spain and Italy[415].

Furthermore, the current Accord Cadre[416] determines that in case the price in one of the reference countries decreases, the price in France should be adjusted accordingly.

9.2.2.4 Price Cuts

In the past 5 years, price cuts have been a major cost-containment instrument used in France. Price cuts have been affecting top-selling pharmaceuticals as well as products of minor therapeutic benefit, and generics. Price cuts have been accepted by manufacturers in order to avoid delisting (cf. 9.3.1.6).

After an extensive review of reimbursable pharmaceuticals, all pharmaceuticals assessed with a low medical benefit (SMR, cf. 9.3.1.2) are subject to an average price cut of 20% over a period of 3 years.

In 2005, CEPS and the pharmaceutical industry have negotiated price cuts for patented pharmaceuticals which have been on the market for more than 5 years. In March 2005, the prices of omeprazole, fluxotine and enalapril were reduced.

At the beginning of 2006, price cuts of 15% targeted generics and the corresponding original off-patent products. In the course of the year, the prices of branded off-patent pharmaceuticals will be further reduced by 10%, and those of generics by 4%.[417]

In addition, contracts between CEPS and the individual manufacturer may also provide for price cuts, e.g. in case of increases in sales volume.

9.2.2.5 Margin Cuts

Wholesale and pharmacy margins for reimbursable pharmaceuticals are regulated by law (cf. 9.2.1.1 and 9.2.1.2).

Major changes in the margin schemes (margin cuts) at wholesale and pharmacy level took place in 1999 (introduction of a two-scale regressive scheme instead of a linear mark-up for wholesalers; reduction in the number of scales in the regressive pharmacy margin scheme plus introduction of an additional fee for certain pharmaceuticals) and in 2004 (change to three-scale regressive schemes at wholesale and pharmacy level).

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415 Framework Agreement between CEPS and LEEM for the period 2003-2006: Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006, http://www.leem.org/industrie/legal13.htm

416 Framework Agreement between CEPS and LEEM for the period 2003-2006: Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006, http://www.leem.org/industrie/legal13.htm

417 PPR 1/2006

9.2.2.6 Discounts and Rebates

Wholesalers and pharmacies do not have to grant discounts to the Social Insurance.

Wholesalers and pharmacies are free to grant discounts to their customers. For pharmacies the discounts may not exceed 2.5% of the manufacturer price for original products and 10.74% of the manufacturer price for generics.

9.2.2.7 Claw-back

The current Accord Cadre between the CEPS and the pharmaceutical industry[418] foresees, in return for faster pricing procedures for new pharmaceuticals, paybacks if sales exceed set targets (the so-called ONDAM target, cf. 9.3.3). The provision on claw-backs (the so-called "safeguard clause") in the Accord Cadre has been incorporated into the Social Insurance Financing Laws[419].

The Social Insurance Financing Law sets annual targets for pharmaceutical expenditure in the reimbursed market (cf. 9.3.3), which is currently defined at a growth rate of 1%. The individual paybacks of pharmaceutical industry are calculated on the basis of reimbursement spending targets by therapeutic class. The total payback according to therapeutic class is divided: 65% of the amount is paid back pro-rata by companies who have pharmaceuticals within the class, and 35% is paid back by manufacturers whose pharmaceuticals contributed to the over-spending. The CEPS defines the growth rates for each therapeutic class; the level of rebates is fixed at 28% of the excessive spending above the rate set by the CEPS.

In order to promote the use of low-price pharmaceuticals on the one hand as well as award innovation on the other hand, there are certain exemptions:

- Generics and pharmaceuticals with prices similar to those of generics are exempt from the payback mechanism.
- Innovative pharmaceuticals with an ASMR 1 rating are exempt from paybacks for the first three years after commercialisation, while ASMR 2 rated pharmaceuticals have a 2-year exemption. ASMR 3 and ASMR 4 rated pharmaceuticals are exempt from 50% and 25% respectively of the levy during their first two years on the market.

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418 Framework Agreement between CEPS and LEEM for the period 2003-2006: Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006

419 The Social Insurance Finance Laws are valid for one year. The Social Insurance Finance Law 2006 is: Loi n° 2005-1579 du 19 décembre 2005 de financement de la sécurité sociale pour 2006 (LFSS 2006), http://www.securite-sociale.fr/secu/lfss/lfss2006/lfss2006.htm

However, paybacks are a rather rare phenomenon: If manufacturers sign individual agreements with the CEPS[420], they are exempt from the payback under the Social Insurance Financing Law. As explained in 9.1.2.1, nearly all manufacturers signed an individual agreement.

Even though the Accord Cadre will run out at the end of 2006 and a new framework agreement will be negotiated, it is expected that this policy will continue.

9.2.2.8 Company Profit Control and Promotion Control

In France, a sales tax on turnover is in place, which is payable on revenue of all authorised pharmaceuticals, except generics.

It is set annually and included in the Social Insurance Finance Law[421]. In 2005, this tax was set at 0.6% (the initially proposed rate amounted to 0.525%). In 2006, the tax is raised to 1.5% (rather than the proposed 1.96%)[422].

A further key aspect of the framework agreements between CEPS and the pharmaceutical industry[423] has been the limiting on promotional expenditures of pharmaceutical companies.

There is a tax on promotional expenditures. Currently, there is a threshold of € 2.5 million, so that companies with less expenditure on promotion are exempted. Above the threshold, a sliding scaled tax is applied, ranging from less than 6.5% of promotional expenditure on total sales, on which a tax of 19% is liable, to over 14%, with a tax of 39%.

According to LEEM, pharmaceutical manufacturers spend on average around 10% of their turnover on promotion, with medical sales representatives accounting for the major share.

In addition to the promotional tax, the pharmaceutical industry is expected to follow a promotion code of practice. At the end of 2004, a best practice charter for medical sales representatives was signed.[424] In addition, at the end of 2005 an agreement on the frequency of the representatives' visits was reached between the pharmaceutical industry's association and the government. As of 2006, the number of visits should be reduced to certain therapeutic groups; exceeding the limits may lead to price reductions.

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[420] The Accord Cadre is a general framework agreement between the industry association and the government; in order to benefit from its provision (e.g. price notification for innovative medicines - cf. 9.2.1.1, exemption from safeguard clause), the individual manufacturers have to conclude an agreement with CEPS.

[421] The Social Insurance Finance Laws are valid for one year. The Social Insurance Finance Law 2006 is: Loi n° 2005-1579 du 19 décembre 2005 de financement de la sécurité sociale pour 2006 (LFSS 2006), http://www.securite-sociale.fr/secu/lfss/lfss2006/lfss2006.htm

[422] Loi n° 2005-1579 du 19 décembre 2005 de financement de la sécurité sociale pour 2006 (LFSS 2006), http://www.securite-sociale.fr/secu/lfss/lfss2006/lfss2006.htm

[423] Framework Agreement between CEPS and LEEM for the period 2003-2006: Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006

[424] PPR 10/2005

9.2.2.9 Parallel Trade

Due to its relatively low price levels, France is a primary source of parallel trade.[425]

In 2003, a price notification system for innovative pharmaceuticals (cf. 9.2.1.1) was introduced. This system should guarantee that the prices of innovative pharmaceuticals remain at the same level for at least five years. Through the implementation of this notification system, French prices should creep closer to the European average, making parallel export less attractive.[426]

For parallel imported pharmaceuticals, the legal basis was given by a decree[427] in January 2004, defining the obligations for the holder of a parallel import licence.[428]

9.2.3 Co-Payments

Reimbursable pharmaceuticals are either reimbursed at 100% (i.e. no co-payment), 65% (35% co-payment) or 35% (65% co-payment) (cf. 9.3.1.2). In practice, the percentage co-payments are covered by the supplementary health insurance funds (Mutuelles), with which the majority of the population has a contract (cf. 9.1.1). As a consequence, it is criticised that French patients are not very much aware of pharmaceutical expenditure in the reimbursed sector. For non-reimbursable pharmaceuticals, which account for more than half of all commercialised pharmaceuticals, patients have to pay the full price.

In addition, with the introduction of the reference price system (Tarif Forfaitaire de Responsabilité, TFR, cf. 9.3.2) in 2003, patients are now obliged to pay the difference between the (reimbursed) reference price and the retail price of the pharmaceutical dispensed. Since, due to the coverage by the Mutuelles, patients are not used to paying for their reimbursable (often prescription-only) pharmaceuticals, they are seldom prepared to pay this difference.

In France, there is no prescription fee.

About 7 million people (about 11% of the population) are exempt from co-payments; these are patients with long-term illnesses (Affections de longue durée, ALD). The ALD scheme includes around 5,000 medical conditions grouped in 30 serious diseases. As an estimated 10-15% of ALD prescriptions for pharmaceuticals are considered to be erroneously for 100% reimbursed, some initiatives have been introduced to assist physicians in ensuring that full reimbursement for ALD patients is limited to the treatment of the ALD condition only. Physicians agreed to meet this objective in a convention signed with the UNCAM in 2005. As a consequence, there are currently new arrangements for co-payment exemptions: Besides improved information policy (i.e. distribution of information on the ADL scheme to the patients

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425 Tilson, L.; Barry, M. 2005

426 PPR 2005

427 Décret 2004-83 du 23 janvier, relatif aux médicaments à usage humain

428 AFSSAPS 2005, p. 26

and pharmaceutical information on each ADL for physicians), the use of two-zone scripts has become compulsory in order to separate treatments (including pharmaceuticals) which are fully reimbursed under the ADL scheme from those reimbursed at the standard rate.

In general, co-payments in health care are a controversial topic in France. In the wave of protests, a co-payment of € 1 per medical action or consultation (limited to € 50.- per year) was introduced at the beginning of 2005. On 1 January 2006, a family doctor system (médecin traitant) with gate-keeping function was enforced, with higher co-payments for patients addressing specialists directly instead of a being referred through the family doctor.

9.2.4 Information Transparency and Marketing

In France, the prices of pharmaceuticals are not publicly available. People interested in pharmaceutical prices usually make use of a price database published by an editing house[429].

French people are generally not very much informed about pharmaceutical expenditure, as co-payments for reimbursable pharmaceuticals are usually covered by the Mutuelles (cf. 9.2.3).

With regard to generics, there have been large-scale campaigns launched by the government to inform the public and to promote these pharmaceuticals (cf. 9.3.4.2). On the website of the AFSSAPS[430], there is a list of all generics available (Répertoire des groupes génériques). With the TFR (cf. 9.3.2), the reference price is made known to the customers in pharmacies.

On the website of AFSSAPS, a list of authorised pharmaceuticals and a list of pharmaceutical companies are also available.

9.3 Reimbursement

Reimbursement of pharmaceuticals in France depends on the evaluation by the Transparency Committee of the HAS, which is undertaken following the market authorisation. The Transparency Committee analyses the medical benefit of a pharmaceutical and gives ratings regarding the medical benefit (SMR) and the improvement in medical benefit (ASMR) (cf. 9.3.1.2).

As a consequence of this evaluation a pharmaceutical may be considered as reimbursable, in which case it is put on one of the two positive lists (cf. 9.3.1.3).

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429 http://www.vidal.fr/

430 http://afssaps.sante.fr

The normal procedure is that, after the examination by the Transparency Committee, its advice is - in case of reimbursable pharmaceuticals - simultaneously forwarded to CEPS for pricing decisions and to the UNCAM for fixing the reimbursement rate. Independent from the advice given by the Transparency Committee (hosted at the HAS), the HAS itself may choose to assess certain pharmaceuticals and give its own advice on pricing and reimbursement.

The legal basis is the Social Security Code, with the Law on the latest relevant change[431].

An important instrument within the French reimbursement system is the reference price system (cf. 9.3.2), combined with a general policy of generic promotion.

9.3.1 Pharmaceutical Lists and Reimbursement Categories

In France, there are two **positive lists**: one for the out-patient sector (la liste des médicaments remboursables agrées aux assurés sociaux) and one for the hospital sector (la liste des médicaments agrées aux collectivités).

9.3.1.1 Reimbursement Price

On the basis of the evaluation by the Transparency Committee according to the selection criteria (cf. 9.3.1.2), the CEPS determines, in negotiations, the reimbursement price at manufacturer level (cf. 9.2.1).

It is up to the UNCAM (a grouping of the three main social health insurance funds) to decide on a reimbursement rate within a 10% range: either 30-40% or 60-70%, instead of the standard 35% or 65%. At the time of writing, the UNCAM had not used this privilege and only the usual rates of 35%, 65% or full reimbursement (100%) have been granted. The three reimbursement rates depend on the main indication of the pharmaceuticals (cf. 9.3.1.2).

9.3.1.2 Selection Criteria

The assessment by the Transparency Committee to determine if a pharmaceutical should be included in one of the positive lists is based on the following criteria:[432]

- Medical benefit (Service Médical Rendu, SMR) provided by the pharmaceutical:
  The SMR is defined by
  - the efficacy of a pharmaceutical and its side effects,
  - the characteristics of the underlying disease,

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431 Décret n° 2004-1398 du 23 décembre 2004 relatif aux médicaments remboursables par l'assurance maladie et modifiant le code de la sécurité sociale, http://www.has-sante.fr/has/transparence/htm/comm/indtrans.htm

432 Code de la Sécurité Sociale. The two relevant articles for the two positive lists are: Art. L 162-17 and L 5123-2. The latest amendment is: Décret n° 2004-1398 du 23 décembre 2004 relatif aux médicaments remboursables par l'assurance maladie et modifiant le code de la sécurité sociale, http://www.has-sante.fr/has/transparence/htm/comm/indtrans.htm

  - existing alternative therapies,
  - the role of the pharmaceuticals within the overall therapeutic strategy, and
  - the impact to public health
- The SMR is expressed as a 3 point scale rating:
  - SMR 1: pharmaceutical of major therapeutic value
  - SMR 2: pharmaceutical of modest therapeutic value
  - SMR 3: pharmaceutical of insufficient therapeutic value
- Improvement in the medical benefit (Amélioration du Service Médical Rendu, ASMR): As explained in section 9.2.1.1, there is a 6 scale rating for the ASMR, based mainly on therapeutic value.

As stated above, there are three reimbursement rates in France:

- 100% reimbursement: for pharmaceuticals applied in the treatment of "life-threatening" conditions (e.g. cancer, AIDS) and in certain chronic illnesses (a list of approx. 30 illnesses)
- 65% reimbursement: for pharmaceuticals treating "serious" diseases (e.g. antibiotics)
- 35% reimbursement: for pharmaceuticals in the treatment of acute illnesses and "comfort" medicines

9.3.1.3 Pharmaceuticals on Positive List

Less than half of the pharmaceuticals on the market are included in one of the reimbursement lists. There are around 5,100 reimbursable pharmaceuticals, with 4% of the products being 100% reimbursed, 19.5% with a 65% reimbursement rate and 76.5% with a 35% reimbursement rate (2001).[433]

The number of reimbursable pharmaceuticals has decreased since the end of the 1990s, and several re-classifications of reimbursable pharmaceuticals have taken place. In 1999, a review of all reimbursable pharmaceuticals was commenced. Its outcome, at its completion in 2001, was that nearly 20% of all pharmaceuticals were considered to have an "insufficient" SMR rating, which led to price cuts (cf. 9.2.2.4). In 2003, the reimbursement rate was lowered from 65% to 35% for around 600 pharmaceuticals, which were judged as providing insufficient medical benefit.

9.3.1.4 Generics

The reimbursement prices of generics at manufacturer level have to be lower than those of original products. Whereas the difference was set at 30-40% in previous years, from 2004 on the range has progressively been widened to about 40-50%. In 2005, prices of existing generics were cut by 10%, resulting in reimbursement prices 40-60% lower than those of the

[433] L'Assurance Maladie 2003

original off-patent pharmaceuticals. New generics are now automatically priced at a 50% lower level.[434]

9.3.1.5 Non-reimbursable Pharmaceuticals

In France, there are no explicit negative lists. Pharmaceuticals with an unfavourable advice by the Transparency Commission (an ASMR 6 rating, cf. 9.2.1.1) are not included into reimbursement. More than 80% of the pharmaceutical expenditure in the out-patient market are reimbursed.[435]

9.3.1.6 Delisting

In recent years, the Transparency Commission has undertaken several re-evaluations of reimbursable pharmaceuticals. The latest review, which regarded a re-evaluation of pharmaceuticals with an insufficient medical benefit (SMR), was completed in the summer of 2005. After such a review, it is up to the HAS to give recommendations for the total or gradual delisting of the affected pharmaceuticals and to send these recommendations to the Ministry of Health, which in turn issues the final decisions.

There are critics on a series of delistings or reductions in reimbursement rates which took place in the past years in France. According to a survey, in case of the delisting of their usual pharmaceutical, 90% of the patients would ask their physician to prescribe another, reimbursable pharmaceuticals instead of buying the delisted one. The French pharmacist association has suggested introducing a lower reimbursement rate for pharmaceuticals with a low medical benefit rather than excluding them from reimbursement in order to avoid shifts in prescribing to more expensive reimbursed pharmaceuticals.[436]

9.3.2 Reference Price System

In France, a reference price system, called Tarif Forfaitaire de Responsabilité (TFR), was introduced in October 2003.

At the introduction of the TFR system, pharmaceuticals with generic penetration below 45% were included in the system. In this initial wave in 2003, around 30 active ingredients in 72 therapeutic groups were included in the reference price system.

The CEPS sets the reference price for reimbursement at the average of prices of generic versions of the off-patent molecule on the French market. As common for reference price systems, the patient has to pay the difference between the (reimbursed) reference price and the (higher) retail price of the pharmaceutical dispensed. Confronted with patients reluctant

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434 Social Insurance Finance Law 2006: Loi n^{o} 2005-1579 du 19 décembre 2005 de financement de la sécurité sociale pour 2006 (LFSS 2006), http://www.securite-sociale.fr/secu/lfss/lfss2006/lfss2006.htm

435 Data on total pharmaceutical expenditure (out-patient; at public prices): LEEM 2005; data on reimbursable pharmaceutical expenditure (out-patient; at public prices): CNAMTS study, quoted in PPR 1/2006

436 Tilson, L.; Barry, M. 2005

to pay the difference out-of-pocket, two thirds of the original products affected in 2003 had their price reduced to match the reference price, entailing cuts of around 30%. The savings of the first wave of the TFR are estimated as being € 115.- million, with € 95.- million resulting from lower prices of original products and € 20 million from increased generic sales.

This first round of TFR was to be followed by further rounds, bringing further savings. In this context, the Generics Follow-up Committee (Comité de Suivi des Génériques) under the Health Insurance Reform Law 2004[437] was established. This Committee, presided by the CEPS President and composed of representatives of the pharmaceutical industry and pharmacies, is in charge of evaluating generic penetration and, in consequence, assessing which generic groups should be included in the TFR system. Abandoning the 45% mark, the Committee now considers generic penetration below 60% after one year on the off-patent market as the cut-off point for underperformance.

The monthly meetings of the Generics Follow-up Committee have resulted in three waves of reference pricing since their first meeting in 2004 (November 2004, June 2005 and November 2005).

9.3.3 Pharmaceutical Budgets

In France, there are no pharmaceutical budgets being applied for doctors or other health care providers, meaning there is no fixed prescribing budgets in terms of money for health care professionals.

However, since the implementation of the 1996 Social Insurance reform (the so-called Juppé plan), there has been an annual ceiling for the health expenditure growth, funded under the Social Security system. This target, called Objectif National des Dépenses d'Assurance Maladie (ONDAM), is decided on in Parliament. One strand is a growth index for public pharmaceutical expenditure.

The framework agreements (Accord Cadre, Accord Sectoriel) between government and pharmaceutical industry included cost-containment measures (e.g. cap on promotional expenditure, ceiling on reimbursed pharmaceutical sales cf. 9.2.2.8) under the framework of the ONDAM targets. In general, paybacks are planned in case of overspending. However, pharmaceutical companies, having signed an individual agreement with the CEPS under the framework agreement (cf. 9.2.1), are exempted from paybacks (cf. 9.2.2.7). Additionally, in the 1990s, the Conseil d'État withdrew decisions on paybacks resulting from overspending and ignorance of prescribing guidelines (cf. 9.3.4.1).[438]

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[437] Loi n° 2004-810 du 13 août 2004 relative à l'assurance maladie, http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=SANX0400122L

[438] ÖBIG 2001; http://www.conseil-etat.fr/ce/actual/index_ac_lc9912.shtml

The ONDAM limit is regularly exceeded. For the year 2004, the growth rate for reimbursable pharmaceutical expenditure was set at 3%; for the years 2005 to 2007 the limit was reduced to 1% per year[439]. In fact, a growth in public expenditure of about 3.2% is expected for 2005.

9.3.4 Other Volume Control Oriented Measures

9.3.4.1 Prescription Monitoring and Other Doctors-related Measures

In France, there are medical guidelines (Références Médicales Opposables, RMO) which regard not only prescribing, but also medical practice:[440] Thus, they can cover "medical, surgical, and diagnostic areas as well as treatment protocols"[441]. The guidelines take the form of negative recommendations: Doctors are required to mark patients' records with an „R" if the RMOs have been followed, or an „HR" (hors réference) if treatment is not covered by the RMO.

The first RMO were introduced in 1994; between 1994 and 1997 more than 240 RMO were published to 60 therapy groups, with 77 regarding pharmaceuticals. The RMO were a compromise between Social Insurance and the doctors' association to avoid pharmaceutical budgets for physicians.[442]

Later, some RMO were taken back.[443] In case of non-compliance with the RMO, financial sanctions were foreseen. However, in 2000 the French Conseil d'État rejected the penalty possibility.[444]

With regard to generic prescribing, there were voluntary agreements in 1997 and 2002 between the Social Insurance and physicians (cf. 9.1.2.3): In the 2002 agreement, physicians obliged themselves to prescribe 25% generically. However, they have not met this target, and there seems no sign of pursuing this.

In 2005, physicians signed an agreement with Social Insurance, to curb the prescribing of specific product groups (among them statins and antibiotics).

In general, the CNAM's database allows for analyses of prescription pattern of physicians. Suspected excessive prescribers are followed up, although with limited impact.

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439 Health Insurance Reform Law 2004 (Loi n° 2004-810 du 13 août 2004 relative à l'assurance maladie), http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=SANX0400122L

440 There are, for example, RMO regarding the prescription of anti-depressants (which, among others, says that at the beginning of a treatment an anti-depressant should be prescribed together with a anxiolytic, a hypnotic, a thymo-regulator, or a neuroleptic). In addition, there are guidelines for the treatment of prostate cancer, asthma, manic-depressive psychosis or sterility of couples.
The RMO are listed at: http://agmed.sante.gouv.fr/htm/5/5210c.htm#gener

441 Durieux, P. 2002

442 ÖBIG 2001

443 http://www.sante.gouv.fr/assurance_maladie/pdf/plfss2004/anx_b1f.pdf

444 http://www.conseil-etat.fr/ce/actual/index_ac_lc9912.shtml

9.3.4.2 Generics

For years, the generic market has been considered as underdeveloped. Several measures have been undertaken in the course of the years, some of them have already been described in other sections (e.g. large-scale public campaign cf. 9.1.2.3).

A key measure in this context was generic substitution, introduced in June 1999[445]. Based on a framework agreement between the government and the pharmacist's association, pharmacists were given the right to substitute generics for the original product unless the physician indicates that the original product prescribed has to be dispensed.

To encourage generic substitution, at the same time (1999) a new mark-up scheme was put into place (cf. 9.2.2.5), allowing pharmacists to apply on a generic the same mark-up in money as they would for the original product. Additionally, discounts of 10.74% on the manufacturer price are permitted for generics, compared to 2.5% for original products.

However, the introduction of the reference price system was feared to undermine generic substitution as the strategy of manufacturers of original products bringing their prices down to the reference price level (cf. 9.3.2) was expected, in particular by generic manufacturers, to remove the incentive for pharmacists to substitute. Despite these concerns, the generic market developed satisfactorily in the last few years, as the recently published CEPS report on the year 2004 demonstrated: In 2004, generics accounted for 13.4% of the total pharmaceutical market by volume (11.3% in 2003) and 7.0% by value (5.5% in 2003). Generic sales (in terms of manufacturer price) amounted to € 1,170 million, a 35% increase against 2003.

The year 2004 has seen the adoption of three measures[446] to promote generics:

- Application of the European definition of a generic: The definition of an active molecule has been extended to all molecules derived from it (esters, sales, isomers, etc.).
- Market authorisation for a generic can now be granted prior to expiry of the patent of the original product. Thus, the commercialisation of generics can start as soon as the original product enters the off-patent market.
- The additional 10-year data protection, automatically granted for line extensions of existing products when dosage and/or pharmaceutical form differ, no longer applied.

AFSSAPS published all generics in a "generics list" (Répertoire des groupes génériques), which is made available on their website (cf. 9.2.4). AFSSAPS includes generics in its lists as soon as they are approved rather than waiting for market entry.

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445 Décret no 99-486 du 11 juin 1999 relatif aux spécialités génériques et au droit de substitution du pharmacien et modifiant le code de la santé publique et le code de la sécurité sociale

446 PPR 1/2006

9.4 Overview of the Reimbursement Market in France

Tasks / Duties	Yes	No	Comment	Legal bases
Public Authorities				
Decide on prescription status	X		AFSSAPS (Medicines Agency)	
Decide on manufacturer price		X		
Agree on manufacturer price	X		Price negotiations between CEPS and manufacturer for reimbursable medicines	Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006
Fix wholesale margin	X		Regulated via a regressive mark-up scheme for reimbursable medicines	
Fix pharmacy retail price	X		Regulated via a regressive mark-up scheme for reimbursable medicines	
Decide on reimbursement status	X		UNCAM (National Union of Health Insurers)	Health Insurance Reform Law 2004 (Loi n° 2004-810 du 13 août 2004 relative à l'assurance maladie)
Decide on reimbursement price	X			
Agrees on reimbursement price	X		Price negotiations between CEPS and manufacturer for reimbursable medicines. In addition, fixing of the reference price for those medicines included in the reference price system	Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006
Use Pharmaco-economic guidelines		X	Voluntary guidelines by the scientific community	
Use Internal reference pricing	X		A reference price system since 2003	
Use External reference pricing	X		Pricing of new reimbursable pharmaceuticals, in particular for innovative pharmaceuticals	Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006
Price freezes		X		
Margin cuts	X		In 1999 and in 2004	

Tasks / Duties	Yes	No	Comment	Legal bases
Discounts and Rebates	X		Clawback for manufacturers	Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006;
Company profit control	X		Sales tax on the revenue of all authorised pharmaceuticals except generics	Social Insurance Financing Law
Country specific:				
Pharmaceutical Industry				
Sets manufacturer price freely	X		For non-reimbursable pharmaceuticals	
Notifies manufacturer price		X		
Negotiates manufacturer price	X		Price negotiations between CEPS and manufacturer for reimbursable pharmaceuticals	Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006
Is free to set price below fixed manufacturer price	X			Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006
Decides on application for reimbursement	X			Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006
Negotiates reimbursement price	X		Price negotiations between CEPS and manufacturer for reimbursable pharmaceuticals	Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006
Free to keep manufacturer price above reimbursement price	(X)		In theory, yes. In reality manufacturers will bring the price down to the reference / reimbursement price for strategic reasons.	
Free to grant Rebates / discounts to wholesalers	X			
Free to grant Rebates / discounts to pharmacies	X		On a voluntary basis	
Can engage in marketing towards doctors	X		Only for OTC	

Tasks / Duties	Yes	No	Comment	Legal bases
Can engage in public advertising	X			
Can provide information toward patients	X			
Applies for switches and de-listing	X			
Promotional control	X		Limiting on promotion expenditure	Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006
Country specific:				
Distribution Chain				
Wholesaler				
Margins are fixed by statute	X		Regulated via a regressive mark-up scheme for reimbursable pharmaceuticals	Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006
Margins are subject to statutory discounts and rebates		X		
Free to grant rebates and discounts to pharmacies	X			
Pharmacists				
Margins are fixed by state	X		Regulated via a regressive mark-up scheme for reimbursable pharmacetuicals	Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006
Free to set retail price		X		
Obliged to inform patient on cheaper product		X		
Obliged to substitute by a generic		X		
Allowed to substitute by a generic	X		Introduced in 1999	Health Insurance Reform Law 2004 (Loi n° 2004-810 du 13 août 2004 relative à l'assurance maladie)
Obliged to substitute by a parallel import			N.app.	
Allowed to substitute by a parallel import			N.app.	

Tasks / Duties	Yes	No	Comment	Legal bases
Therapeutic substitution is allowed		X		
Claw back system exists		(X)	There is a claw back system - in practice of no importance. Claw back system does not apply to manufacturers having signed an individual agreement with the CEPS under Framework Agreement - which nearly all of them have done.	Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006
Are subject to statutory discounts and rebates		X		
May grant rebates to customers	X		Limit of 2.5% of the manufacturer price for original products and 10.74% of the manufacturer price for generics	
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			
Are obliged to inform on co-payment	X			
Prescription habits are monitored	X		Only contract doctors	
Are subject to prescription guidelines	X		Compulsory	
Budgets are controlled		X		
Allowed to prescribe INN	X			
Obliged to prescribe INN		X		
Can oppose generic substitution	X			Décret no 99-486 du 11 juin 1999 relatif aux spécialités génériques et au droit de substitution du pharmacien et modifiant le code de la santé publique et le code de la sécurité sociale

Tasks / Duties	Yes	No	Comment	Legal bases
Can oppose therapeutic substitution	X			
Can oppose substitution by parallel import			N.app.	
Country specific:				
Patients				
Can shop for cheapest price of the product		X		
Pay a flat rate per prescription / pack		X		
Pay a certain percentage per prescription / pack or a deductible	X		- Patients have to pay 35% or 65% co-payment, usually covered by supplementary health insurance funds (Mutuelles) - Patients have to pay the difference between the (reimbursed) reference price and the price of the pharmaceutical dispensed	
Annual minimum co-payment		X		
Annual maximum co-payment		X		
Can ask for substitution by a generic	X			
Can oppose substitution by a generic	X			
Can ask for substitution by a parallel import		X		
Can oppose substitution by a parallel import		X		
Can oppose substitution only on payment of price difference	X			

Tasks / Duties	Yes	No	Comment	Legal bases
Has to pay the difference between reimbursement price and retail price	X		Patients have to pay the difference between the (reimbursed) reference price and the price of the pharmaceutical dis-pensed	
Has access to full public information on prices and products	X		On products - on prices it is of charge	http://www.vidal.fr/
Country specifics:				

N.app. = Not applicable, N.a. = Not available

Source: ÖBIG 2006

GERMANY

10 Germany

10.1 Pharmaceutical System

10.1.1 Regulatory Framework and Authorities

The German healthcare system is characterised by a mix of public and private funding through the statutory health insurance system (Gesetzliche Krankenversicherung, GKV). About 88.9% of the total population is insured in 280 competing sickness funds (Krankenkassen), 9% is covered by private health insurance, 2% via free state health care (e.g. soldiers) and 0.1% is without insurance coverage[447]. GKV is financed by income-related contributions. There are several co-payments at all levels of health care.

The most relevant players in the German pharmaceutical system are:

- The Ministry of Health (Bundesministerium für Gesundheit, BMG) is the regulatory body for pharmaceuticals. The Ministry of Health is responsible for the legal framework of manufacturing, authorisation, monitoring and distribution of pharmaceuticals. The Ministry of Health also decides in cooperation with the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) on the reimbursement of pharmaceuticals.
- The Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) decides if a new pharmaceutical is categorised as innovative (patent-protected pharmaceutical with a significant therapeutic advantage) and is responsible for the grouping of all other reimbursable pharmaceuticals in reference groups.
- The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) is responsible for the authorisation and registration of pharmaceuticals.
- The Head Association of Health Insurance Funds (Spitzenverbände der Krankenkassen) is responsible for the setting of reference prices.

Due to the German Medicines Act (Arzneimittelgesetz, AMG)[448] the BfArM is the relevant institution for the market authorisation of most pharmaceuticals for human use and the registration of homeopathic medicines. The BfArM acts as medicines agency like in many other European Member States. For some pharmaceuticals (i.e. vaccines and sera) the Paul-Ehrlich Institute (PEI) is responsible for licencing.[449] The BfArM also monitors the risk of pharmaceuticals, which are brought on the market[450].

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447 Tilson 2005

448 AMG §77 (1), http://www.rechtliches.de/info_AMG.html

449 AMG §77 (2), http://www.rechtliches.de/info_AMG.html

450 http://www.bfarm.de

The BMG decides on reimbursement eligibility in cooperation with the G-BA[451] on basis of provisions stated in SGB V (cf. 10.3)[452].

The G-BA is also in charge of the categorisation of reimbursable pharmaceuticals as innovative or not. The G-BA decides on the basis of benefits assessment provided by the Institute for Quality and Efficiency in Health Care (Institut für Qualtität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG) if a pharmaceutical is considered to be "innovative" (cf. 10.3.2).

All other reimbursable pharmaceuticals are grouped in reference groups by the G-BA[453]. The G-BA has 21 members (nine representatives of the Statutory Sickness Fund, nine representatives of health service providers and 3 independent members). Furthermore, up to nine patient representatives are allowed to participate in G-BA discussions, but without voting rights[454].

Following the grouping of pharmaceuticals the Head Association of Sickness Funds (representatives of all statutory Sickness Funds) sets the reference prices according to SGB V.[455]

Table 10.1: Germany - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Bundesministerium für Gesundheit (BMG) / Minstry of Health	Ministry of Health (regulatory body for pharmaceuticals, involved in reimbursment decisions)	Bundesministerium für Gesundheit und soziale Sicherheit Am Probsthof 78a D-53105 Bonn Germany Tel.: +49 18 8844 10 Fax: +49 18 8844 122 54 info@bmg.bund.de www.bmgs.bund.de	Mr. Ulrich Dietz Am Probsthof 78a D-53105 Bonn Germany Tel.: +49 18 8844 120 15 Fax: +49 18 8844 149 11 ulrich.dietz@bmgs.bund.de
Spitzenverbände der Krankenkassen (SK) / Head Association of Sickness Funds	Third Party Payer (setting reference prices)	Spitzenverbände der Krankenkassen Friedrich-Ebert-Straße Technologiepark 51429 Bergisch Gladbach Tel.: +49 22 0444 303 Fax: +49 22 0444 315 info@g-k-v.com www.g-k-v.com	Spitzenverbände der Krankenkassen Friedrich-Ebert-Straße Technologiepark 51429 Bergisch Gladbach Tel.: +49 22 0444 303 Fax: +49 22 0444 315 info@g-k-v.com www.g-k-v.com

451 SGB V § 91

452 SGB V § 31 and § 34

453 SGB V §35 (1)

454 http://www.g-ba.de

455 SGB V §35 (5)

Institution	Task	Contact details/URL	Responsible person
Gemeinsamer Bundesausschuss (G-BA) / Federal Joint Commitee	Grouping of pharmaceuticals in reference groups	G-BA Auf dem Seidenberg 3a D-53721 Siegburg Germany Tel.: +49 22 4193 880 Fax: +49 22 4938 8573 www.g-ba.de	Mr. Rainer Hess Chairman Auf dem Seidenberg 3a D-53721 Siegburg Germany Tel.: +49 22 4193 880 Fax: +49 22 4193 88573
Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) / Federal Institute for Drugs and Medical Devices	Authorisation and registration of pharmaceuticals	BfArM Kurt-Georg-Kiesinger-Allee 3 D-53175 Bonn Germany Tel.: +49 22 8207 30 Fax: +49 22 8207 www.bfarm.de	Mr. Reinhard Kurth Director Kurt-Georg-Kiesinger-Allee 3 D-53175 Bonn Germany Tel.: +49 1888 3073 203 Fax: +49 1888 3075 514 kurth@bfarm.de
Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWIG) / Institute for Quality and Efficiency in Health Care)	Assessment of the benefit of new pharmaceuticals	IQWIG Dillenburger Straße 27 D-51105 Köln Germany Tel.: +49 22 1356 850 Fax: +49 22 1356 851 www.iqwig.de	Mr. Stefan Lange Representative director of the institute Dillenburger Straße 27 D-51105 Köln Germany Tel.: +49 22 1356 850 Fax: +49 22 1356 851 Stefan.lange@iqwig.de
Bundesfachverband der Arzneimittel- Hersteller (BAH)/ Association of Pharmaceutical Industry	Association of pharmaceutical Industry	Bundesfachverband d. Arzneimittel-Hersteller Ubierstraße 73 D-53173 Bonn Germany Tel.: +49 22 8957 450 Fax: +49 22 89574590 bah@bah-bonn.de www.bah-bonn.de/	Bundesfachverband d. Arzneimittel-Hersteller Ubierstraße 73 D-53173 Bonn Germany Tel.: +49 22 8957 450 Fax: +49 22 89574590 bah@bah-bonn.de www.bah-bonn.de/
Deutscher Generikaverband (DGV)/ German Association of Generic Industry	Association of generic industry	Deutscher Generikaverband Littenstraße 10 D-10179 Berlin Germany Tel.: +49 30 2809 3030 Fax: +49 30 2809 30390 berlin@generika.de www.generika.de	Mr. Dietmar Buchberger Executive Director Littenstraße 10 D-10179 Berlin Germany Tel.: +49 30 2809 3030 Fax: +49 30 2809 30390 berlin@generika.de

Institution	Task	Contact details/URL	Responsible person
Bundesverband des pharmazeutischen Grosshandels (PHAGRO) / Association of the German Pharmaceutical Wholesalers	Wholesaler association	PHAGRO Savignystr. 55 D-60325 Frankfurt Germany Tel.: +49 69 9758 760 Fax: +49 69 9758 7633 phagro@t-online.de www.phagro.de/	Mr. Hermann Ringenaldus Savignystr. 55 D-60325 Frankfurt Germany Tel.: +49 69 9758 760 Fax: +49 69 9758 7633 phagro@t-online.de
Verband der Arz-Neimittelimporteure Deutschland (VAD) / Association of German Pharmaceutical Parallel Traders	Parallel traders organisation	VAD Im Holzhau 8 D-66663 Merzig Germany kontakt@vad-news.org http://www.vad-news.de/	Mr. Edwin Kohl Im Holzhau 8 D-66663 Merzig Germany Tel: +49 6867 920-0 Fax: +49 6867 920 1018
Arzneimittelkommission der Deutschen Ärzteschaft / Commission of Pharmaceuticals of German Doctors	Information of doctors about pharmaceuticals	Arzneimittelkommission der Deutschen Ärzteschaft Herbert-Lewin-Platz 1 D-10623 Berlin Germany Tel.: +49 30 4004 565 00 Fax: +49 30 4004 565 55 info@akdae.de www.akdae.de	Mr. Heiner Berthold Executive Director Herbert-Lewin-Platz 1 D-10623 Berlin Germany Tel.: +49 30 4004 565 00 Fax: +49 30 4004 565 55 info@akdae.de

Source: ÖBIG 2006

10.1.2 Market Players

10.1.2.1 Pharmaceutical Industry

There are 50 research-based international pharmaceutical companies and, in addition, 350 small and medium sized companies in Germany[456]. In 2004 there were 114,200 employees in the pharmaceutical industry and the pharmaceutical production amounted to € 23.7 billion.

Germany is rather an export than an import country. In 2004, pharmaceutical exports amounted in € 13.1 billion. This corresponds to an export quota of 55%. In 2004 35 pharmaceuticals with new active ingredients were authorised, which is the highest number since the year 1998[457].

456 PHAGRO 2006

457 PHAGRO 2006

10.1.2.2 Distribution

In Germany there are 16 full-line wholesalers, which are all members of the Association of German Pharmaceutical Wholesalers PHAGRO (Bundesverband des Pharmazeutischen Großhandels). Four of the sixteen wholesalers are acting nationwide and 12 are regional wholesalers. Altogether there are 106 warehouses and 12,262 employees in this sector[458]. About 90% of all deliveries to pharmacies are supplied by wholesalers.

Pharmaceuticals are mainly sold through pharmacies. In 2004, there were 21,392 pharmacies in Germany, which corresponds to one pharmacy per 3,858 inhabitants[459].

In total there were 8,933 pharmaceuticals (including homeopathic pharmaceuticals) authorised or registered in Germany (counting: excluding different package sizes, pharmaceutical forms and strength)[460].

10.1.2.3 Patients

If a pharmaceutical price is higher than the reference price the prescribing doctor has to inform the patient that s/he has to pay the difference out-of-pocket.[461]

In the G-BA up to nine patient representatives have the right to participate in the discussions, but have no voting right.[462]

The EU patient information provisions (Title V of the Community Code relating to medicinal products) were implemented by the 5th Amendment to the AMG published in the Bundesgesetzblatt of 16 August 1994. Patient information leaflets are compulsory for newly authorised pharmaceuticals. So-called old medicines should have a leaflet within one year of re-authorisation[463].

10.1.3 Overview of the Pharmaceutical System

Figure 10.1 shows an overview of the pharmaceutical system in Germany.

458 PHAGRO 2006

459 PHAGRO 2006

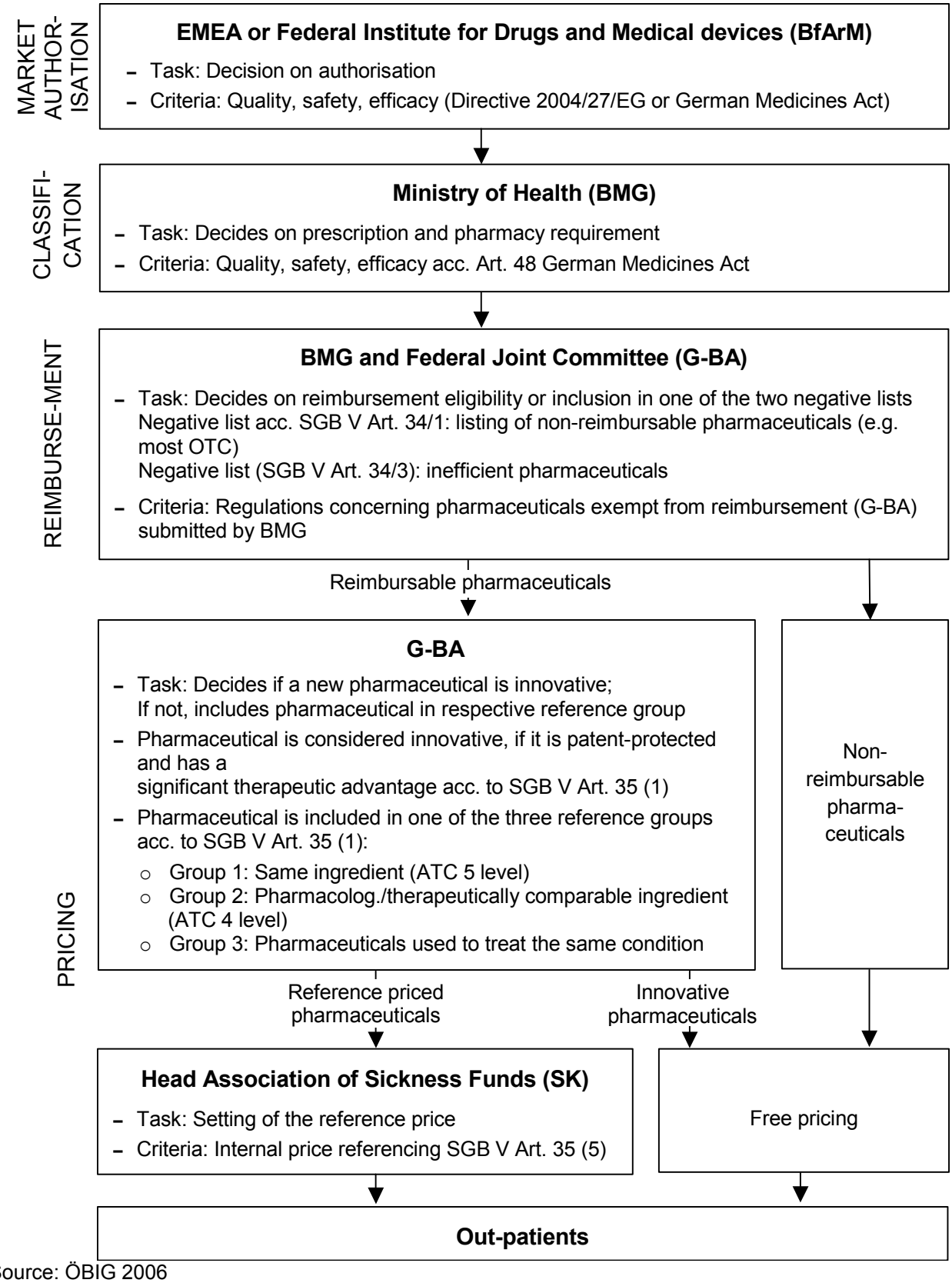
460 VFA 2005

461 SGB V § 73 (5)

462 SGB V §140f (2)

463 AESGP 2004

Figure 10.1: Germany - Pharmaceutical System, 2006



Source: ÖBIG 2006

10.2 Pricing

10.2.1 Scope of Price Control

In Germany, pricing of pharmaceuticals is officially unregulated even though the authorities influence pharmaceutical prices through the reference price system. The reference price system covers approximately 75 to 80%[464] of the market. However the notification of the manufacturer price of a pharmaceutical is obligatory. Hospital prices in Germany can be freely set.

Table 10.2: Germany - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing (but notification necessary)	Non reimbursable OTC, innovative pharmaceuticals, HOM	Non reimbursable OTC	Non reimbursable OTC
Indirect statutory pricing (via reference price system)	POM under the reference price system, OTC in reference group 3	All reference priced pharmaceuticals regulated via a regressive mark-up scheme	All reference priced pharmaceuticals regulated via a regressive mark-up scheme
Institutions in charge of pricing	G-BA Ministry of Health Reference prices are set by the sickness funds		
Legal basis	Drug Price Ordinance / Arzneimittelpreisverordnung Social Code Book No. 5 / Sozialversicherungsgesetz V (SGB V)		

G-BA = Gemeinsamer Bundesausschuss, HOM = Hospital-only medicines, OTC = Over-the-Counter, POM = Prescription-only medicines

Source: ÖBIG 2006

10.2.1.1 Manufacturer Price

In general, there is free pricing in Germany. The pricing at manufacturer level is indirectly regulated for groups of pharmaceuticals which are part of the reference price system (c.f. 10.3.2).

10.2.1.2 Wholesale Price

Wholesale mark-ups in Germany are regulated by law[465]. There are regressive mark-up schemes which are different for POM (cf. Table 10.3) and reimbursable OTC (cf. Table 10.4). With the enactment of the Arzneimittelpreisverordnung on 1 January 2004 mark-ups for non-reimbursable OTC were freed. For rebates on wholesale prices cf. section 10.2.2.4.

[464] Tilson 2005

[465] Drug price Ordinance(Arzneimittelpreisverordnung) §2 (2-5)

Table 10.3. Germany - Wholesale Mark-up Scheme for Prescription-only Medicines (POM, 2006)

Manufacturer price in €	Maximum mark-up in % of manufacturer price	Maximum wholesale mark-up in €
0,00 - 3,00	15.0%	-
3.01 - 3.74	-	0.45
3.75 - 5.00	12.0%	-
5.01 - 6.66	-	0.60
6.67 - 9.00	9.0%	-
9.01 - 11.56	-	0.81
11.57 - 23.00	7.0%	-
23.01 - 26.82	-	1.61
26.83 - 1.200	6.0%	-
From 1.200		72.00

Source: Drug Price Ordinance (Arzneimittelpreisverordnung) 2004[466]

Table 10.4: Germany - Wholesale Mark-up Scheme for Reimbursable OTC

Manufacturer price in €	Maximum mark-up in % of manufacturer price	Maximum wholesale mark-up in €
0.00 - 0.84	21.0%	-
0.85 - 0.88	-	0.18
0.89 - 1,70	20.0%	-
1.71 - 1.74	-	0.34
1.75 - 2.56	19.5%	-
2.57 - 2.63	-	0.5
2.64 - 3.65	19.0%	-
3.66 - 3.75	-	0.7
3.76 - 6.03	18.5%	-
6.04 - 6.20	-	1.12
6.21 - 9.10	18.0%	-
9.11 - 10.92	-	1.64
10.93 - 44.46	15.0%	-
44.47 - 55.58	-	6.67
55.59 - 684.76	12%	-
From 684.77	3%	+61.63

Source: Drug Price Ordinance (Arzneimittelpreisverordnung)[467]

466 Drug price Ordinance (Arzneimittelpreisverordnung) §2 (2,3)

467 Drug Price Ordinance (Arzneimittelpreisverordnung) §2 (4,5)

10.2.1.3 Pharmacy Retail Price

Since the implementation of the healthcare reform 2004 pharmacists receive for POM a fixed fee of € 8.10 for each dispensed pharmaceutical pack plus an additional 3% on the wholesale price (cf. Table10.5). One of the measures of the healthcare reform 2004 was the exclusion of non-reimbursable OTC products from the "Arzneimittelpreisverordnung" regulations governing distribution mark-ups with the effect that mark-ups for these products are free[468]. For those OTC that can still reimbursed cf. Table10.6). For discounts to the sickness funds refer to section 10.2.2.4

Table10.5: Germany - Pharmacy Mark-up Scheme for Prescription only Medicines, 2006

Flat Pharmacy fee in €	Mark-up in % of wholesale price
8.10	3%

Source: Drug Price Ordinance (Arzneimittelpreisverordnung)[469]

Table10.6: Germany- Pharmacy Mark-up Scheme for Reimbursed OTC Products, 2006

Wholesale Price in €	Pharmacy Mark-up in % of Wholesale price	Manufacturer Mark-up in €
0.0 - 1.22	68.0%	-
1.23 - 1.34	-	0.83
1.35 - 3.88	62.0%	-
3.89 - 4.22	-	2.41
4.23 - 7.30	57.0%	-
7.31 - 8.67	-	4.16
8.68 - 12.14	48.0%	-
12.15 - 13.55	-	5.83
13.56 - 19.42	43.0%	-
19.43 - 22.57	-	8.35
22.58 - 29.14	37.0%	-
29.15 - 35.94	-	10.78
35.95 - 543.91	30%	-
From 543.92	8.263%	+118.24

Source: Drug Price Ordinance (Arzneimittelpreisverordnung)[470]

468 PPR 2005 Germany

469 Drug Price Ordinance (Arzneimittelpreisverordnung) § 3 (1)

470 Drug Price Ordinance (Arzneimittelpreisverordnung) § 3 (3,4)

10.2.1.4 Value Added Tax (VAT)

VAT for pharmaceuticals is 16%, like for other products.[471] An increase of the VAT to 19% is planned to be implemented from 1 January 2007 on, which will also affect pharmaceuticals.[472]

10.2.2 Price Related Cost-containment Measures

10.2.2.1 Internal Price Referencing

The reference prices of all three reference groups (cf. 10.3.2) are determined through internal price referencing. The pharmaceutical prices of all pharmaceuticals in a reference group are compared. For the detailed calculation of reference prices cf. section Reimbursement Price 10.3.1.1

10.2.2.2 External Price Referencing

Germany is - together with the United Kingdom - one of the few EU member states not applying any kind of external price referencing, i.e. international price comparisons. Germany is a reference country for most EU Member States using external price comparisons. This explains why pharmaceutical companies ask for a premium price, i.e. a rather high one, in Germany.

10.2.2.3 Price Freezes / Stops

There was a price freeze from 1 January 1993 to 1 January 1995 for pharmaceuticals not included in the reference price system[473].

There was another price freeze on reimbursable non-reference priced pharmaceuticals from 1 January 2003 to 31 December 2004 (at the level of manufacturer price as of 1 October 2002)[474]

According to the Act on Economic Provision with Pharmaceuticals (Arzneimittelversorgungs-Wirtschaftlichkeitsgesetz, AVWG), which became effective on 1 May 2006, a price freeze on all pharmaceuticals (at the level of manufacturer price as of 1 November 2005) from 1 May 2006 to 31 March 2008 is applied.

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471 Tilson 2005

472 PPR 1/2006

473 ÖBIG, 1998

474 SGB V §130a (2)

10.2.2.4 Discounts and Rebates

Sickness funds get statutory rebates by pharmacists. Table 10.7 displays their development in the last years.

Table 10.7: Germany - Development of Pharmacy Rebates to the Sickness Funds for Prescription-only Medicines, 2000 - 2006

Year	Rebate/Discount per pack
till 2001	5%
2002	6%
2003	6%-10% depending on the pharmaceutical price
Since 2004 (healthcare reform)	€ 2.-

Source: BMGS 2006, www.die-gesundheitsreform.de

For reimbursable OTC products the rebate to the sickness funds is 5%[475].

Since the 1 January 2003 there has been a statutory 6% rebate on reimbursable non-reference priced pharmaceuticals by manufacturers to the sickness funds[476]. In 2004, this rebate was increased to 16% and then reduced to the original level[477].

According to the AVWG, a mandatory manufacturer discount of 10% on the manufacturer price to the sickness funds for off-patent pharmaceuticals with identical active ingredients (except pharmaceuticals priced 30% below the corresponding applicable reference price) came into force in May 2006[478].

10.2.2.5 Parallel Trade

Parallel trade plays an important role in the German pharmaceutical market. Parallel trade has grown since the passing of a law in 2000 requiring pharmacists to replace branded pharmaceuticals with re-imported products when the latter are at least 10% cheaper. Between 1998 and 2001 the parallel trade more than trebled, from € 260.- to € 800.- million. The market share of imported pharmaceuticals increased from 1.8% 1998 to 5.8% in 2001[479].

In the year 2004 the law changed again: So from 1 January 2004 on the imported pharmaceutical has to be at least 15% or € 15.- cheaper[480] than the original product to get substituted by the pharmacist. This changing in law has led to a decrease in parallel trade cf. 10.3.4.2

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475 SGB V § 130 (1)

476 SGB V §130a (1)

477 SGB V §130a (1a)

478 AVWG § 130a (3b)

479 Arfwedson 2003

480 SGB V §129 (1)

10.2.3 Co-Payments

One of the most important aims of the GKV Modernisation Act[481] (GKV-Modernisierungsgesetz) was to reduce pharmaceutical expenditure. Since the entering in force of the GKV Modernisation Act in 2004 co-payments of pharmaceuticals have increased to 10% of pharmacy retail price with a minimum fee of € 5.- and a maximum fee of € 10.-[482] (in 2003 it was between € 4.- and € 5.-). There is an out of pocket maximum of 2% of gross income per year.[483] This co-payment is charged supplementary to any amount payable above the reference price.

10.2.4 Information Transparency and Marketing

There is a pharmaceutical list, the so-called "Rote Liste"[484]. Besides prices it also contains information on the ATC code, the pharmaceutical form, the reference price, package size and on the manufacturer, but it is only available for health professionals.

OTC advertising to the general public in Germany is allowed for all OTC pharmaceuticals (including reimbursable OTC) in all media. Certain indications specified in the Community Code[485] cannot be advertised in General Public.

EU provisions on pharmaceutical advertising laid down in Title Eight of the Community Code Advertising Requirements have been implemented in the Pharmaceutical Advertising Law (Gesetz über die Werbung auf dem Gebiet des Heilwesens in Deutschland, HWG) as follows:

- For television advertising: see HWG §4[486]
- For print advertising: see HWG §4[487]

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481 GKV-Modernisierungsgesetz

482 SGB V §61

483 SGB V § 62 (1)

484 http://www.rote-liste.de

485 Community Code, Title eight, Article 88

486 HWG §4 (5), http://www.transpatent.com/gesetze/hwg.html

487 HWG §4 (3) http://www.transpatent.com/gesetze/hwg.html

10.3 Reimbursement

10.3.1 Pharmaceutical Lists and Reimbursement Categories

There is a negative list but no positive list in Germany although there have been a couple of attempts to establish a positive list.

10.3.1.1 Reimbursement Price

The reimbursement price of patent protected innovative pharmaceuticals (cf. 10.3.2) is the market price of the pharmaceutical. For products which are part of the reference price system the reference price is the reimbursement price.

The legal basis for the calculation of the reference prices is the SGB V[488].The reference prices for the three reference groups (cf. 10.3.2) are calculated by the Head Association of Sickness Funds as follows:

- Reference group 1: The reference price of a standard pack must not exceed the highest price in the lowest third of the reference group. (for definition of group 1 cf. 10.3.2)
- Reference group 2 and 3: For the determination of the reference prices there are no legislative requirements (for definition of groups cf. 10.3.2).

10.3.1.2 Reimbursable Pharmaceuticals

There is no positive list in Germany. With some exemptions (cf. 10.3.1.4) all POM are fully or partly reimbursed. Pharmaceuticals which are part of the reference price system are reimbursed the reference price. If the price exceeds the reference price the patient has to pay the difference out-of-pocket. Patent-protected innovative pharmaceuticals (for definition cf. 10.3.2) are fully reimbursed and not part of the reference price system.

OTC are reimbursed for children under the age of twelve. Some OTC which are used for the treatment of serious conditions are included in the reference price system (for group 3 cf. 10.3.2).

10.3.1.3 Generics

All reimbursable generics are included in the reference price system.

For generic substitution was previously the permission of the prescribing doctor necessary. In February 2002 a new substitution legislation[489], which did no longer require the authorisation of the prescriber, was introduced. Under this legislation the pharmacist is obliged to substitute with an equivalent generic pharmaceutical with a price below a certain threshold (the

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488 SGB V § 35 (5)

489 SGB V §129 (1)

upper ceiling of the lowest third of price range). This price range is defined by the average price of the three cheapest and the three most expensive pharmaceuticals of a group with the same active ingredient (reference group 1). If the prescriber has already chosen a product from the lowest third of price band or indicates on the prescription that the product must be dispensed as written the pharmacist is not allowed to substitute the pharmaceutical[490].

10.3.1.4 Non-reimbursable Pharmaceuticals

Pharmaceuticals on the negative list are excluded from reimbursement. According to SGB V, [491] the following product categories are included in the negative list:

- Inefficient pharmaceuticals[492]
- OTC products with some exemptions (cf. 10.3.1.2)
- Products which focus on the improvement of the quality of life (so called lifestyle products) like pharmaceuticals to stimulate or increase the sexual drive, appetite suppressants or hair restorer[493]
- Pharmaceuticals which are used for “minor disturbance of health” (e.g. pharmaceuticals for curing a cold)

10.3.1.5 Delisting

In line with the health care reform of January 2004 the delisting of most OTC pharmaceuticals (OTC had been reimbursed in Germany before) and the so-called lifestyle products (for definition cf. 10.3.1.4) was decided. On 16 March 2004 the G-BA published a list[494] of 36 OTC active ingredients remaining eligible for (statutory) reimbursement[495].

10.3.2 Reference Price System

The German reference price system was introduced in 1989. Since the introduction there where several reforms concerning the reference price system. According to SGB V the GB-A is responsible for the grouping of pharmaceuticals in reference groups and acquires the necessary mean daily and single doses[496]. In these groups there should be pharmaceuticals with:

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490 Tilson 2005; SGB V §84

491 SGB V § 34

492 SGB V §34 (3)

493 SGB V §34 (1)

494 http://www.g-ba.de

495 PPR 2005

496 SGB V §35 (1)

- Reference group 1: The same active ingredient (generics) ATC 5 level
- Reference group 2: Pharmacologically/therapeutically comparable active ingredients (e.g. pharmaceuticals in the same pharmacological class, such as statins) ATC 4 level
- Reference group 3: Pharmaceuticals in all pharmacological classes used to treat the same condition (e.g. hypertension)

All patent protected drugs have been reimbursed 100% (and were not part of the reference price system) until 2004. In course of the Healthcare reform 2004 patent protected drugs "without significant therapeutic advantage"[497] were included into the reference price system. Exemption criteria have been suggested by the G-BA, which was set up as part of the healthcare reform. Pharmaceuticals with a new active ingredient must be truly innovative (with a novel mode of action) and representing a therapeutic advantage to get fully reimbursed.

According to SGB V the Head association of Sickness funds are setting the reference prices on the basis of the acquired daily and single doses[498].

10.3.3 Pharmaceutical Budgets

The budget of contract doctors (of the sickness funds) is controlled through individual spending targets (Richtgrößen) as well as through regional agreements on target spending limits and cost-control measures (Zielvereinbarungen). Both measures are negotiated between the Association of contract doctors (Kassenärztliche Vereinigung) and the National Associations of Sickness Funds (Landesverbände der Krankenkassen).[499] The "Richhtgrößen and "Zielvereinbarungen" differ between the german federal countries.. The two mechanisms are outlined below:

- "Richtgrößen": a value is set for the average prescribing costs per patient per year for each physician at the regional level. Individual doctors exceeding their budget are subject to audits by a committee of doctors and sickness funds. If the doctor overspends his budget of more than 25% he may have to either full or partly re-pay the excess. Some diseases/treatment are exempt from this regulation, like pharmaceutical therapy for cystic fibrosis, insulin therapy for insulin-dependent diabetes and anti-retroviral pharmaceuticals for HIV treatment[500].
- "Zielvereinbarungen": these arrangements set regional limits for pharmaceutical expenditures and outline cost-containment measures including the use of generics and parallel imported pharmaceuticals and information policy. Provision can also be made for a bonus to be paid if set targets are met. At the time of the negotiations a decision is to be taken as

[497] SGB V §35 (1)

[498] SGB V §35 (3)

[499] SGB V §84 (1)

[500] SGB V §84

to whether the bonus money should be shared across-the-board between all doctors, or whether to break down to regional targets. In the latter case, targets are set at the individual doctor level, such as an agreement to reduce spending by 10%[501]. The bonus money, then only distributed to those doctors achieving their targets[502].

10.3.4 Other Volume Control Oriented Measures

10.3.4.1 Prescription Monitoring and Other Doctors-related Measures´

Doctors are obliged to follow prescribing guidelines (Arzneimittel-Richtlinien, AMR)[503] determined by the G-BA. These guidelines recommend either complete exclusion from reimbursement or restrictions on the usage of certain groups of pharmaceuticals. The guidelines are published on the website of the G-BA[504].

10.3.4.2 Generics and Parallel Trade

Germany is the largest generic market in Europe. Generics accounted for 50.6% by volume of prescriptions reimbursed by the sickness funds in 2002. In 2003 generic growth exceeded growth of branded pharmaceuticals (+ 13% compared to + 8%).[505]

In the total pharmaceutical market the proportion of generic packages rose from 10.9% in the year 1981 to 55.2% in 2004[506].

Like mentioned before the change in the law (cf. 10.2.2.5) concerning parallel trade has led to a certain decrease in parallel trade. For the development of the expansion rates of parallel imports and the total pharmaceutical market cf. 10.2.2.5.

501

502 PPR 2005

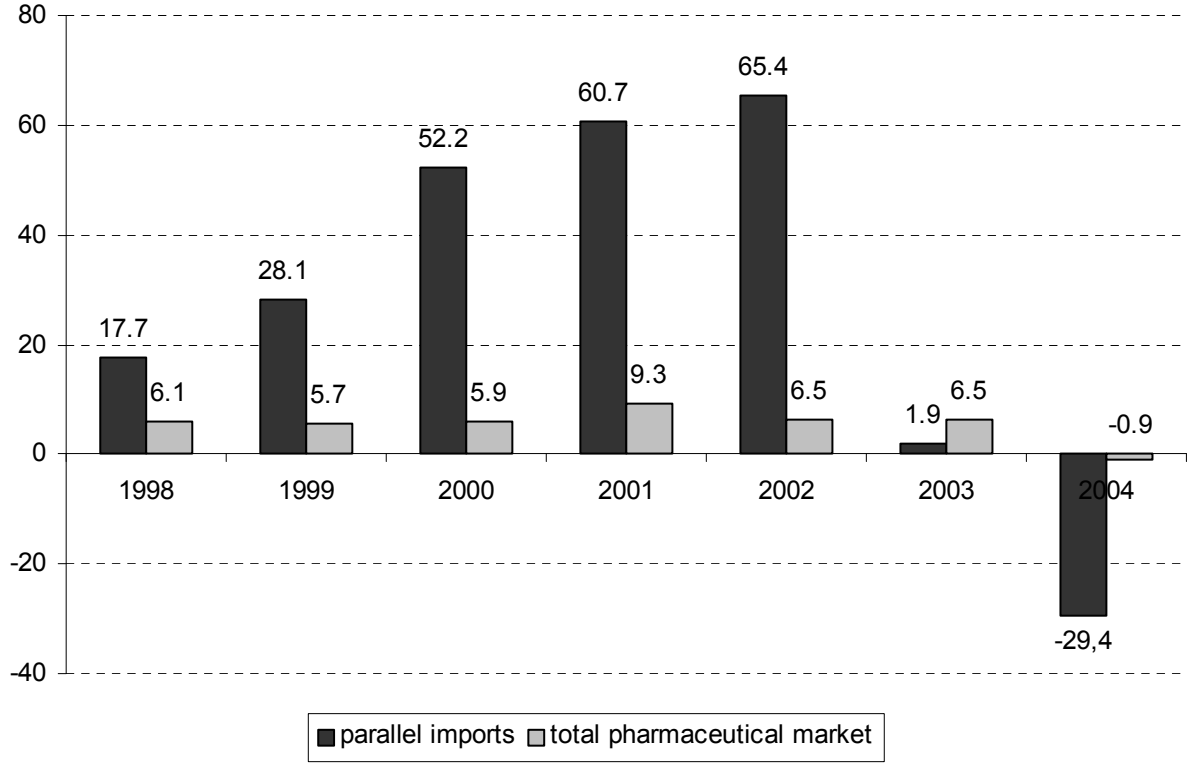
503 SGB V §92 (1)

504 http://www.g-ba.de

505 Tilson/Barry 2005

506 Schwabe 2006

Figure 10.2: Germany - Growth Rate of Parallel Imports and the Total Pharmaceutical Market, 1998 - 2004



Source: Verband Forschender Arzneimittelhersteller (VFA) / German Association of Research-BasedPharmaceutical Companies, 2005

This figure shows that in 2004 the parallel imports decrease by 29.4%, which is high in comparison to a decrease of 0.9% of the total pharmaceutical market.

Most parallel imports are in the sector of patent protected innovative pharmaceuticals (e.g. pharmaceuticals, which are fully reimbursed by the sickness funds)[507]. A measure to increase the use of parallel imported pharmaceuticals is the so called “Zielvereinbarungsmodell”. Further information on this measure is provided in section 10.3.3.

[507] VFA 2005

10.4 Overview of the Pharmaceutical Market in Germany

Tasks / Duties	Yes	No	Comment	Legal basis
Public Authorities				
Decide on prescription status	X		The BMG decides about the prescription status	AMG
Decide on manufacturer price		X	Public Authorities only indirectly influence pricing (via reference price system)	SGB V
Agree on manufacturer price		X		
Fix wholesale margin	X		Regressive maximum margins for all reimbursable Pharmaceuticals.	Arzneimittelpreisverordnung
Fix pharmacy retail price	X		Flat fee (€ 8.1) + 3% for POM, regressive margin scheme for reimbursed.	Arzneimittelpreisverordnung
Decide on reimbursement status	X		Decision if a pharmaceutical is reimbursed or if it comes to the negative list	SGB V
Agrees on reimbursement price		X		
Decide on reimbursement price	X		The G-BA sets the reference prices (=maximum reimbursement price)	SGB V
Use Pharmaco-economic guidelines	X		Guidelines about reimbursement	SGB V
Use Internal reference pricing	X		Reimbursement decision: for setting the reference prices	SGB V
Use External reference pricing		X		
Price freezes	X		Several price freezes, latest from 1 Mayl 2006	
Margin cuts	X		Indirect via the statutory rebates to the sickness funds	SGB V
Discounts and Rebates	X		Manufacturers and Pharmacies to the Sickness funds	SGB V
Company profit control		X		
Country specific:			No external price referencing	
Pharmaceutical Industry				
Sets manufacturer price freely	X		For non-reimbursable OTC , innovative pharmaceuticals and HOM	SGB V
Notifies manufacturer price	X		A notification is compulsory	AMG

Tasks / Duties	Yes	No	Comment	Legal basis
Negotiates manufacturer price		X		
Is free to set price below fixed manufacturer price		X	Manufacturer price is not fixed in Germany	
Decides on application for re-imbursement		X		
Negotiates reimbursement price		X		
Free to keep manu-facturer price above reimbursement price	X		It is allowed to set the manu-facturer price above the ref-erence price, but patients have to pay the difference if they want the pharmaceutical	SGB V
Free to grant rebates / discounts to wholesalers	X			Arzneimittelpreisverordnung
Free to grant rebates / discounts to pharmacies	X		Since 1 May 2006 only cash rebates for OTC products are allowed	SGB V
Can engage in marketing towards doctors	X		They can provide samples to doctors	AMG
Can engage in public advertising	X		Only for OTC	HWG
Can provide information toward patients	X		Only for OTC	HWG
Applies for switches and de-listing		X		
Promotional control		X		
Country specific:				
Distribution Chain				
Wholesaler				
Margins are fixed by legisla-tion/statutory	X		Based on (max) manufac-turer price	Arzneimittelpreisverordnung
Margins are subject to statutory dis-counts / rebates		X		SGB V
Free to grant dis-counts / rebates to pharmacies	X			Arzneimittelpreisverordnung
Pharmacists				

Tasks / Duties	Yes	No	Comment	Legal basis
Margins are fixed by statute	X		Based on wholesaler maximum price (for reimbursed pharmaceuticals)	Arzneimittelpreisverordnung
Free to set retail price	X		For self medication only (non-reimbursable OTC)	
Obliged to inform patient on cheaper product	X		Generic substitution is obligatory for reference priced pharmaceuticals	SGB V
Obliged to substitute by a generic	X		Generic substitution is obligatory for reference priced pharmaceuticals	SGB V
Allowed to substitute by a generic	X			SGB V
Obliged to substitute by a parallel import	X		If the parallel traded pharmaceutical is at least 15% or € 15 cheaper than the branded product.	SGB V
Allowed to substitute by a parallel import	X			SGB V
Therapeutic / analogous substitution is allowed		X		
Are subject to statutory discounts / rebates	X		€ 2.- for every dispensed pack for POM, 5% for reimbursable OTC to the Sickness Funds	SGB V
Claw back system exists		X		
May grant rebates to customers		X		
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			SGB V
Are obliged to inform on co-payment / deductibles	X		If a pharmaceutical price is higher than the reference price the prescribing doctor has to inform the patient that he has to pay the difference out-of-pocket.	SGB V
Prescription habits are monitored	X		Only contract doctors of the sickness funds	SGB V
Are subject to prescription guidelines	X		Compulsory for contracting doctors	SGB V

Tasks / Duties	Yes	No	Comment	Legal basis
Budgets are controlled	X		Compulsory for contracting doctors	SGB V
Allowed to prescribe INN	X			SGB V
Obliged to prescribe INN		X		
Can oppose generic substitution	X			SGB V
Can oppose therapeutic substitution			N. app.	
Can oppose substitution by parallel import		X		
Country specific:				
Patients				
Can shop for cheapest price of the product			For selfmedication	AVWG
Pay a flat rate per prescription / pack		X	10% of pharmaceutical retail price with a min of € 5.- and max. of € 10.-	SGB V
Pay a certain percentage per prescription / pack or a deductible	X		10% of the pharmaceutical price (min. € 5.- max. € 10.-) per pack	SGB V
Annual minimum co-payment		X	N. app.	
Annual maximum co-payment	X		2% of annual gross income and 1% for chronically ill	SGB V
May ask for substitution by a generic	X			SGB V
May oppose substitution by a generic	X		Yes, if they pay the difference between the reference price and original product.	
May ask for substitution by a parallel import	X			SGB V
Can oppose substitution by a parallel import	X		Yes, if they the difference between the reference price and original product	
Can oppose substitution only on payment of price difference	X		Yes, if the difference between the reference price and original product	SGB V

Tasks / Duties	Yes	No	Comment	Legal basis
Has to pay the difference between reimbursement price and retail price	X		Difference between reference price and the retail price	SGB V
Has access to full public information on prices and products		X		
Country specifics:				

N. app. = Not applicable, N. a. = Not available, HOM = Hopital-only medicines, POM = Perscription-only Medicine, AMG = Arzneimittelgesetz, SGB V = Sozialgesetzbuch V, HVG = Gesetz über die Werbung auf dem Gebiet des Heilwesens

Source: ÖBIG 2006

GREECE

11 Greece

11.1 Pharmaceutical System

11.1.1 Regulatory Framework and Authorities

The national health care service in Greece is organised on the basis of a National Health System (ESY). It was established in 1983[508] with the aim to provide free, equitable and comprehensive health care coverage. ESY is mainly funded through general taxation, the numerous state sickness funds (employer and employee contributions) and private insurance schemes. Around 99% of the population is compulsorily insured by one of the about 40 occupation-based sickness funds. The most important sickness funds are the National Social Insurance Institute (IKA) covering approximately 50% of the population (mainly salaried workers); the Organisation on Agricultural Insurance (OGA) covering around 20% mainly agricultural workers; and the Fund for Merchants, Manufacturers and Small Industries (OAEE) covering around 13% of the population[509].

The most relevant players in the pharmaceutical system in Greece are:

- the Ministry of Health and Social Solidarity (MoH), which is at central level responsible for the provision of health care and the development of a national health policy an strategy
- the Ministry of Development (YPAN) advised by the Pricing Committee, which is responsible for setting the prices of pharmaceuticals[510]
- the National Organisation for Medicines (EOF) supervised by the MOH, which is responsible for issuing market authorisations and the classification of pharmaceuticals according to their prescription status, as well as for pharmacovigilance
- the 40 occupation-based sickness funds with their umbrella organisation, the General Secretariat of Social Security (GGKA), being responsible for the reimbursement of pharmaceuticals, with IKA building the largest sickness fund
- the newly established (in May 2006) Committee of First Degree for the Transparency of the compensation of Medicinal Products (EDAF) within the EOF, being responsible for the determination and the formation of therapeutic groups[511]

The responsibility of granting market authorisation lays with EOF[512]. In general, EOF procedures are harmonised to EU legislation, meaning that pharmaceuticals can either be author-

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508 Law 1397/1983

509 PPR 2005

510 Market Decree 14/89; http://www.sfee.gr/category/english/47/0/3/1/index.htm

511 Law 3457/2006; www.sfee.gr/download/english/1720/index.html

512 Ministerial Decree Y6a/3221, published in the Government's Gazette # 782 of 1995

ised through the mutual recognition provision, or through a centralised authorisation by the European Medicines Agency (EMEA), or through a national authorisation by EOF. Marketing licences are valid for 5 years.

In line with the EU classification provisions, in Greece, pharmaceuticals are classified into POM and pharmaceuticals available without prescription, which are, in fact, OTC products. POM can further be classified as[513]:

- pharmaceuticals with renewable or non-renewable medical prescription
- pharmaceuticals subject to special medical prescription (narcotics with 4 different levels of classification, psychotropics)
- pharmaceuticals on restricted medical prescription, revised for use in certain areas such as hospitals

As far as OTC products are concerned, the Greek Proprietary Association (EFEX) and the Pan Hellenic Pharmacist's Association (PAPW) have reached a common position on the classification of OTC products according to a list based on active ingredients, pharmaceutical form, strength and dosage[514]. OTC products are only made available in pharmacies (cf. 11.1.2.2).

It is common practice in Greece that the majority of POM can also be purchased without a prescription. This constitutes one of the main reasons why the development of the OTC market as a separate category has not progressed.

EOF is also responsible for switching pharmaceuticals from POM to OTC products. The requirements are based on the confirmation of at least 5 other EU Member States that the pharmaceutical is available without prescription, as well as a statement regarding the high safety standard of the pharmaceutical. Each manufacturer has to apply separately for switching its pharmaceutical.

513 Ministerial Decree Y6a/776, published in the Government's Gazette #536 of 1993

514 9 February 2004, a decision signed by the Deputy Minister of Health published in the Government's Gazette (Issue # 284)

Table 11.1 gives an overview of the relevant stakeholders in Greece introduced in section 11.1.1 and 11.1.2.

Table 11.1: Greece - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Ministry of Health and Social Solidarity	Ministry of Health (Regulatory Body for Pharmaceuticals), Pricing	Ministry of Health 17, Aristotelous Street GR-10187 Athens Greece Tel.: +30 2105 2328 209 webmaster@mohaw.gr www.mohaw.gr/	Mr. Athanasios Giannopoulos Deputy Minister Directorate of Medical and Paramedical Resources 17, Aristotelous Street GR-10187 Athens Greece Tel.: +30 2105 2328 209
General Secretariat of Social Security	Third Party Payer, Reimbursement	General Secretariat of Social Security 20 Stadiou, GR-1010 10 Athens Greece Tel.: +30 3368 000 Fax: +30 3368 012 www.ggka.gr	General Secretariat of Social Security 20 Stadiou, GR-1010 10 Athens Greece Tel.: +30 3368 000 Fax: +30 3368 012 www.ggka.gr
National Organisation for Medicines (EOF)	Medicines Agency (Market authorisation, Classification)	EOF Messogion Avenue 284 Cholargos 15562 GR-15562 Athens Greece Tel.: +30 2106 5072 05 Fax: +30 2106 5495 85 relation@eof.gr www.eof.gr/eof_en/enhome.html	Ms. Siouti Director of the Division of Pharmaceutical Studies and Research Messogion Avenue 284 Cholargos 15562 GR-15562 Athens Greece Tel.: +30 2106 5072 05 Fax: +30 2106 5495 85
Social Insurance Institute (IKA)	Sickness Fund, Reimbursement	IKA Ag. Konstantinou GR-10241 Athens Greece Tel.: +30 1523 6061 Fax: +30 1522 9757 www.ika.gr/en/home.cfm	Ms. Irene Antonopoulou General Director Ag. Konstantinou GR-10241 Athens Greece Tel.: +30 1522 0008 Fax: +30 1522 9757
Organismos Georgikon Asphaliseor / Organisation on Agricultural Insurance (OGA)	Sickness Fund, Reimbursement	OGA Patision 30 GR-10170 Athens Greece http://www.oga.gr/default.asp	OGA Patision 30 GR-10170 Athens Greece http://www.oga.gr/default.asp

Institution	Task	Contact details/URL	Responsible person
Fund for Merchants, Manufacturers and Small Industries (OAEE)	Sickness Fund, Reimbursement	OAEE Satovriandou Street 18 GR-10432 Athens http://www.tebe.gr/	OAEE Satovriandou Street 18 GR-10432 Athens http://www.tebe.gr/
Institute of Pharmaceutical Research and Technology (IFET)	Institute of Pharmaceutical Research and Technology	IFET 18th km Marathonos Ave. GR-153 51 Pallini Attiki Greece Tel :+ 30 2106 6034 10 www.ifet.gr/english_site/company.htm	Ms. Vardica Areti 18th km Marathonos Ave. GR-153 51 Pallini Attiki Greece Tel : +30 2106 6034 10 areti@ifet.gr
Association of Pharmaceutical Manufacturers (SFEE)	Association of Pharmaceutical Manufacturers	SFEE Vas Georgiou 30 & M Asias Str. GR-15233 Chalandri Greece Tel.: +30 2106 8911 01 Fax: +30 2106 8910 60 sfee@otenet.gr www.sfee.gr	Mr. Niadas Secretary General Vas Georgiou 30 & M Asias Str. GR-15233 Chalandri Greece Tel.: +30 2106 8911 01 Fax: +30 2106 8910 60
Panhellenic Association of Pharmaceutical (PAPW) Wholesalers and Qualified Pharmacists	Wholesaler Association and Association of Pharmacists	PAPW 34 Beranzerou Street GR-104 32 Athens Greece Tel.: +30 2105 2275 19 Fax: +30 2105 2217 62 papw-gr@otenet.gr	Mr. Euripides Adamou 34 Beranzerou Street GR-104 32 Athens Greece Tel.: +30 2105 2275 19 Fax: +30 2105 2217 62 papw-gr@otenet.gr
Panhellenic Medical Association	Medical Doctors' Association	Medical Doctors´ Association Ploutarchou 3 GR-10675 Athens Greece Tel.: +30 1725 8660/661/662 Fax: +30 1725 8663 pis@pis.gr	Mr. George Karantanas Secretary General Ploutarchou 3 GR-10675 Athens Greece Tel.: +30 1725 8660/661/662 Fax: +30 1725 8663
Greek Proprietary Association (EFEX)	OTC Industry Association	EFEX Commercial Centre Aithrion, Office A 53 Aghiou Constantinou GR-15124 Marousi Greece Tel.: +30 2106 1975 60 Fax: +30 2106 1971 41 efex2004@otenet.gr	Mr. George Dokios Director General Commercial Centre Aithrion, Office A 53 Aghiou Constantinou GR-15124 Marousi Greece Tel.: +30 2106 1975 60 Fax: +30 2106 1971 41

Source: ÖBIG 2006

11.1.2 Market Players

11.1.2.1 Pharmaceutical Industry

Greece is rather an import country (€ 1,886 million in 2005) than an export country (€ 530 million in 2005)[515]. According to EFPIA, the pharmaceutical production in Greece amounted to € 437 million in 2005. In 2005, there were 11,200 people employed in the pharmaceutical industry.

Domestic demand for pharmaceuticals is satisfied by both imports and local production, part of which is also exported.

11.1.2.2 Distribution

The distribution market is highly fragmented, owing to the country's geography. In 2005, there were around 150 private wholesalers and 30 pharmacy-owned co-operatives, each group holding approximately half the market. The leading private wholesalers are Lavipharm Alliance Santé, Strumsas and Marinopoulos.

Distribution of all pharmaceuticals (prescription and non-prescription) can only take place in pharmacies[516]. In remote areas, local doctors or health centres may distribute pharmaceuticals, having obtained a special permission from the MoH.

In 2005, there were approximately 9,500 pharmacies representing one pharmacy per 1,162 inhabitants. Additionally, there are 144 hospital pharmacies and 7 military pharmacies[517].

The licences for opening a pharmacy are granted by the various prefectures across Greece. Establishment criteria (e.g. distance between pharmacies, number of inhabitants) are regulated by legislation[518]. After 1997 new pharmacies can only be opened where an established pharmacy already exists. Pharmacies must be owned by pharmacists. Distance selling and teleshopping of pharmaceuticals are not allowed.

11.1.2.3 Patients

Patients do not play a role in the pricing and reimbursement decisions of pharmaceuticals. There are no Patient's Associations.

Pharmaceutical consumption is considered as high (in 1998 28,2 packages/inhabitant and year). Patients tend not to be price sensitive since the prices of pharmaceuticals are the lowest among the EU (cf. 11.3.4.2).

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515 EFPIA, Pharmaceutical Industry in Figures, 2005

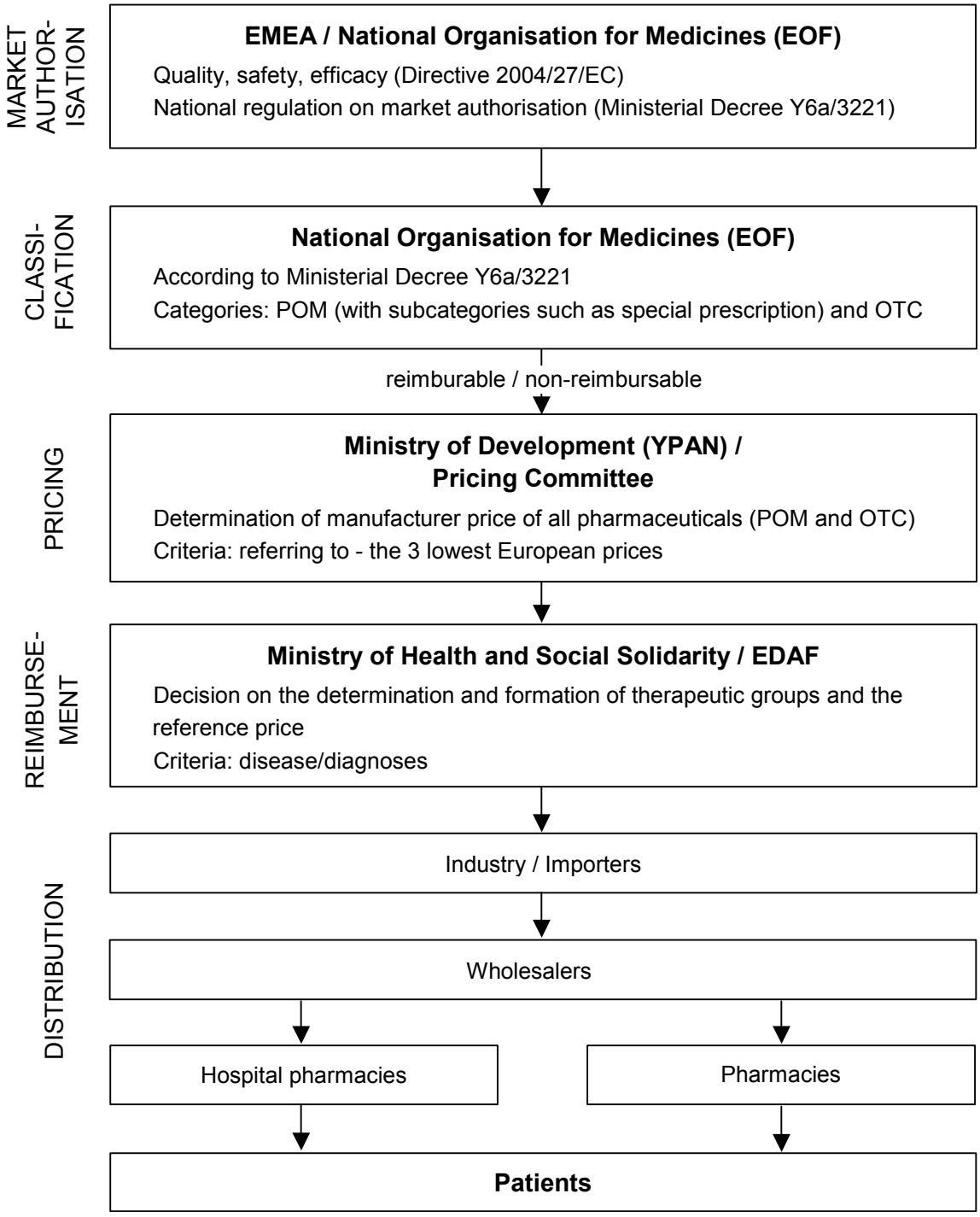
516 Law 1963/91, Government's Gazette #138; and Law 96/73

517 AESGP, 2005

518 Law 1963/91, Government's Gazette #138

11.1.3 Overview of the Pharmaceutical System

Figure 11.1: Greece - Pharmaceutical System, 2006



POM = Prescription-only Medicines, OTC = Over-the-Counter
Source: ÖBIG 2006

11.2 Pricing

11.2.1 Scope of Price Control

The Directorate of Prices and Medicinal Products within the YPAN is responsible for determining the manufacturer price of all pharmaceuticals (including also OTC products). When deciding on manufacturer prices, the Directorate is advised by the Pricing Committee[519] operating under the General Secretariat of Commerce under the YPAN. Prices are then published in the Price Bulletin by the YPAN with the consent of the MoH.

After a new government had come in place in March 2004, the pricing and reimbursement system (cf. 11.3) underwent major changes, which came into force in December 2005. The former pricing system had been in act since 1997. It was based on the lowest EU manufacturer price for imported pharmaceuticals. Manufacturer prices for locally produced pharmaceuticals were calculated on the basis of the production costs and distribution expenses to which a fixed profit margin of 8.5% was added. In order to calculate the manufacturer price, it was compared to the lowest wholesale price of the same product in other European countries. If the price was lower than in the other EU countries where the pharmaceutical is marketed, the Greek price was accordingly reduced. Under this pricing system, locally manufactured pharmaceuticals have generally been priced lower than imported brands. This has resulted in product withdrawals and an even more dominant position for imported pharmaceuticals. In May 2004 the Greek Supreme Court ratified that the formally current pricing system was unconstitutional[520].

The new pricing system[521], the so called “2+1” system, takes the 3 lowest European prices into account (cf. 11.2.1.1).

It is expected that this new pricing system will result in slightly higher prices than under the old system[522].

Table 11.2 gives an overview of the pricing system in Greece.

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519 The Pricing Committee has 9 members from the General Secretariat of Commerce, EOF, the Ministry of Finance, the pharmaceutical industry and pharmacists.

520 Market Decree 14/89, which has been updated on the 8 May 2006 Law 3457/2006, http://www.sfee.gr/category/english/47/0/3/1/index.htm

521 Market Decree 14/89, which has been updated on the 8 May 2006 Law 3457/2006, http://www.sfee.gr/category/english/47/0/3/1/index.htm

522 http://www.sfee.gr/category/english/47/0/3/1/index.htm (new method for the determination of prices)

Table 11.2: Greece - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Not applied	Not applied	Not applied
Statutory Pricing	All pharmaceuticals on the basis of the 3 lowest European prices. In case of locally produced pharmaceuticals with no equivalent in other EU countries, pricing on the basis of production costs and a profit margin of 8.5%	All pharmaceuticals regulated via a margin of 8.43% on the manufacturer price	All pharmaceuticals regulated via a margin of 35% on the wholesale price
Price Negotiations	Not applied	Not applied	Not applied
Discounts/rebates	Not applied	Mandatory 4% discounts to provincial pharmacies	Not applied
Institution in charge of pricing	Ministry of Development (YPAN), advised by the Pricing Committee		
Legal Basis	Market Decree 14/89; http://www.sfee.gr/category/english/47/0/3/1/index.htm		

Source: ÖBIG 2006

11.2.1.1 Manufacturer Price

According to the new legislation[523], which entered into force in December 2005, the manufacturer prices of new pharmaceuticals (imported as well as locally produced) are calculated on the basis of the average of the 3 lowest European manufacturer prices. 2 reference prices must be from the former EU-15 and Switzerland and 1 price must be from a new Member State that joined the EU in May 2004. The first new pharmaceuticals to be priced under the new system will be published in the Price Bulletin, which is expected to be published in the course of the summer 2006. Applications for these pharmaceuticals had to be filed by January 2006. However, pharmaceutical companies may apply for price increases of existing pharmaceuticals in subsequent Price Bulletins.

In case of locally manufactured pharmaceuticals with no equivalent pharmaceutical in another country the manufacturer prices are determined on the basis of a cost-plus system. The expenses are calculated the ground of the average costs of this sector, taking into account the following costs: production and packaging costs, administration, distribution costs, and research and development costs. On the overall costs a profit mark-ups of 8.5% is added.

Prices of off-patent pharmaceuticals shall be reduced by 20%.

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523 Market Decree 14/89; Market Decree 14/89, which has been updated on the 8 May 2006 Law 3457/2006, http://www.sfee.gr/category/english/47/0/3/1/index.htm

11.2.1.2 Wholesale Price

The wholesale mark-up is 8.43% upon the manufacturer price for all pharmaceuticals. To support provincial pharmacies (in communities with less than 5,000 inhabitants) it is mandatory for manufacturers, packagers, importers and wholesalers to grant a compulsory 4% discount to provincial pharmacies (cf. 11.2.2.6)[524].

11.2.1.3 Pharmacy Retail Price

The pharmacy margin is 35% upon the wholesale price for all pharmaceuticals.

11.2.1.4 Value Added Tax (VAT)

On 1 April 2005, the VAT rate for both POM and OTC products augmented from 8% to 9%, applied at the wholesale level. There are exceptions for some pharmaceuticals where a lower VAT rate is applied. The standard VAT rate of 18%[525].

11.2.2 Price related Cost-containment Measures

11.2.2.1 Pharmaco-economic Evaluation

In January 2002, the MoH released a draft document with guidelines for the preparation and presentation of pharmaco-economic studies for innovative pharmaceuticals. The following data should be demonstrated:

- New pharmaceuticals with a new active ingredient and a new mechanism of pharmacological action should have a documented higher efficacy and tolerance compared to older treatments
- New pharmaceuticals with a new active ingredient but with similar mechanism of action should have a proven therapeutic and /or economic advantage
- New pharmaceutical forms, strengths or pack sizes of pharmaceuticals should prove a benefit compared to the treatment and the expenditure of the active ingredients already listed.

Since May 2006, when the reform of the health care system came into force[526], pharmaco-economic evaluation became very relevant in the reimbursement process. The reform foresees the implementation of a reference price system (cf. 11.3.2). The newly established Committee EDAF is responsible for the formation of therapeutic groups. Requirements for the inclusion into the therapeutic groups are criteria such as therapeutic and pharmaco-effectiveness are .

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524 Market Decree 14/89; Market Decree 14/89, which has been updated on the 8 May 2006 Law 3457/2006, http://www.sfee.gr/category/english/47/0/3/1/index.htm

525 http://www.sfee.gr/category/english/68/0/100/1/index.html

526 Law 3457/2006; www.sfee.gr/download/english/1720/index.html

11.2.2.2 Internal Price Referencing

Since May 2006, a reference price system is in force (cf. 11.3.2), which foresees internal price referencing, meaning that the reimbursement price of a pharmaceutical is the price of the cheapest pharmaceutical in one substitution/reimbursement group[527].

11.2.2.3 External Price Referencing / Cross Country Referencing

As it was already mentioned in section 11.2.1.1, manufacturer prices of all pharmaceuticals are calculated on the average of the 3 lowest European prices.

11.2.2.4 Price Freezes / Cuts

Price freezing has been a feature of the Greek pricing system since 1997, when the previous pricing system was in place. The prices either remained frozen or were reduced in line with other European reference country prices.

In February 2004, there were price cuts ranging from 0.5% to 53.2% for 221 pharmaceuticals. The price reductions resulted from the annual monitoring carried out by YPAN by checking the price of the pharmaceuticals against reference countries to ensure that the Greek price was indeed the lowest in Europe.

With the implementation of the new pricing system (cf. 11.2.1), these price freezes will be individually evaluated, followed by an application of the pharmaceutical company to readjust the prices to the maximum limit of the average of the 3 lowest European prices.

11.2.2.5 Margin Cuts

In 1997, the wholesale mark-up on the manufacturer price was cut from 12% to 8.43%. There have been no margin cuts on the pharmacy level in the last year.

11.2.2.6 Discounts and Rebates

As it was already mentioned in section 11.2.1.2, manufacturers, packagers, importers and wholesalers have to offer a compulsory discount of 4% to provincial pharmacies. In order to enable wholesalers to offer this discount, the producer, packager and importer has to grant wholesalers an additional compulsory discount of 0.4%.

Furthermore, wholesalers may grant a 5% discount on the wholesale price to pharmacies provided that the discount is recorded in the invoice[528].

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527 Law 3457/2006; www.sfee.gr/download/english/1720/index.html

528 Market Decree 14/89; http://www.sfee.gr/category/english/47/0/3/1/index.htm

The newly implemented (May 2006) reimbursement system foresees mandatory volume discounts for pharmaceutical companies (cf. 11.3.1.1). The pharmaceutical company shall annually pay an amount to the Social Health Insurance which is calculated on a so called "recovery price" and the turnover[529].

11.2.2.7 Promotional Control

In 2002, controls over companies' promotional spending on POM were introduced by legislation. Each company's expenditure is limited to a percentage of its turnover in the previous year, as listed in Table 11.3. The following expenses are covered:

- Medical books and literature
- Journal advertisements
- Conference attendance expenses
- Financial support for doctors participating in scientific events approved by EOF
- Travel and accommodation expenses for scientists participating in scientific events

Table 11.3: Greece - Permitted Level of Promotional Spending, 2005

Turnover in million €	Promotional spending limit (% of turnover)
< 6	16%
< 15	13%
< 30	10%
< 45	6%
> 45	4%

Source: PPR 2005

11.2.2.8 Parallel Trade

Due to a low pricing level, Greece is a key source for parallel export in the European Union. According to IMS, parallel exports accounted for 21% of total pharmaceutical sales by value in May 2004. Although higher prices are expected from the forthcoming price changes, they are considered as unlikely to be radical enough to reduce the flow of parallel exports.

11.2.3 Co-Payments

The co-payment rate is set at 25% of the pharmacy retail price. In some cases, the co-payment rate is reduced to 10% or even to 0% depending on the disease and population group (e.g. income-pensioners, cf. 11.3.1).

[529] Law 3457/2006, Article 4; www.sfee.gr/download/english/1720/index.html

Additionally the patient has to pay the difference between the reimbursement price and the reference price.

11.2.4 Information Transparency and Marketing

Prices of pharmaceuticals are relatively easy to access. They are regularly published in the Price Bulletin by the YPAN[530].

The dominant legislative instruments governing advertising of pharmaceuticals are:

- the Ministerial Decision Y6a/776/23.6.1993 “on the harmonisation of the Greek legislation to the relevant legislation of the European Community regarding the classification of medicinal products for human use, their labelling and package leaflets, as well as of their advertising”[531],
- Ministerial Decision Number A6/1098/84 “on medicinal information about medicines by pharmaceutical companies”[532],
- Ministerial Decision Y6a/22261/8.3.2002 “on the advertising of medicinal products that may be given without prescription”[533],
- Ministerial Decision DYC3(a)/127858/2004[534], Presidential Decree Number 100/2000 (which includes dispositions regarding the sponsorship of television programs by pharmaceutical companies), in combination with Legislative Decree 96/1973 “on trading of pharmaceuticals and cosmetic products”[535].

In general, all pharmaceuticals may be advertised to the general public. Advertising through mass media should comply with the standards of the patients information leaflet regarding safety, quality and efficacy.

Free sampling follows the EU provision according to which free samples may only be supplied by doctors following written request of patients. In practice, there is no free sampling, as EOF is not willing to grant the relevant permissions.

In general, doctors, pharmacies and pharmaceutical companies are allowed to inform patients about special characteristics of pharmaceuticals and the prices of pharmaceuticals.

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530 www.gge.gr

531 published in the Official Gazette B 536/1993

532 published in Official Gazette B 37/1985

533 published in Official Gazette B 284/2002

534 published in Official Gazette B 284/2004

535 published in Official Gazette B 172/1973

The information on patient information leaflets entered in act in 1993[536]. Patient information leaflets are mandatory unless all required information is included on the outer and inner packaging.

11.3 Reimbursement

In the course of the changes in the pricing system in December 2005 (cf. 11.2.1), the reimbursement system has also undergone a lot of changes. The positive list was abolished and a so-called "insurance price", which is the reimbursement price, was introduced[537]. Furthermore, all pharmaceuticals (with the exception of OTC products and lifestyle pharmaceuticals) are now reimbursable as soon as they receive a price.

In May 2006, the new reimbursement system came into force[538]. It is based on based on diseases/indications. In the course of the new reimbursement system two new Committees have been established:

- the Committee of First Degree for Transparency of the Compensation of Medicinal Products (EDAF) within the EOF. It is responsible for the determination and formation of therapeutic groups within the reference price system[539]
- the Committee of Second Degree for Transparency of Medicinal Products' Compensation (DEDAF) within the MOH[540].

11.3.1 Pharmaceutical Lists and Reimbursement Categories

As it was mentioned, the positive list was abolished December 2005. All pharmaceuticals (except OTC products and lifestyle pharmaceuticals) are now reimbursable as soon as they receive the price by YPAN.

The former pricing system was based on a positive list. The principle criterion for inclusion on the positive list was the therapeutic efficacy, and it was evaluated based on 4 criteria: severity of disease, effectiveness (safety ratio), target population and alternative treatments.

There are 3 reimbursement categories (cf. 11.2.3):

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536 Ministerial Decree Y6a/776, published in the Government's Gazette #536 of 1993

537 Market Decree 14/89; Market Decree 14/89, which has been updated on the 8 May 2006 Law 3457/2006, http://www.sfee.gr/category/english/47/0/3/1/index.htm

538 Law 3457/2006; www.sfee.gr/download/english/1720/index.html

539 the committee consists of 7 members from the MoH, the Ministry of Finance, and the Ministry of Employment and Social Protection and the Merchant Marine

540 the committee consists of 5 members from the MoH, the Ministry of Finance, and the Ministry of Employment and Social Protection

100%: applies to pharmaceuticals treating cancer, epilepsy, depression, multiple sclerosis, growth hormone deficiency, insulin for diabetics and pharmaceuticals used in pregnancy

90%: pharmaceuticals for chronic conditions such as osteoporosis, Parkinson's disease, coronary heart diseases, hepatic cirrhosis and Crohn's disease; this category also applies to pharmaceuticals used by low-income pensioners

75%: this is the standard level of reimbursement, applying to the majority of the population

In the course of the changes in the reimbursement system (cf. 11.3), the MoH is planning to create a negative list instead of the positive list. The negative list would include OTC and some lifestyle products[541].

11.3.1.1 Reimbursement Price

The reimbursement price, is 96% of the manufacturer price reduced by the respective percentage of the patient co-payment (cf. 11.2.3). This system includes a mandatory volume discount for pharmaceutical companies (cf. 11.2.2.6).

11.3.1.2 Selection Criteria

All pharmaceuticals with pricing approval, (except OTC and lifestyle products), are eligible for reimbursement.

11.3.1.3 Generics

The manufacturer prices for generics are set at a maximum of 80% of the price of the original pharmaceutical. However, once a patent of an original pharmaceutical expires, it will face a mandatory 20% decrease 1 year after the marketing of one or more pharmaceuticals with the same active ingredient[542].

11.3.1.4 Non-reimbursable Pharmaceuticals

There are plans to implement a negative list (cf. 11.3.1). Currently, OTC and lifestyle products are excluded from eligibility from reimbursement.

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541 IOBE, written information, April 2006

542 http://www.sfee.gr/category/english/47/0/3/1/index.htm

11.3.1.5 Delisting

Greece legalised OTC products for sale by pharmacies in 1993, in line with the EU recommendations that there should be two legal classes of pharmaceuticals (cf. 11.1.1). This was followed by delisting from reimbursement of around 2,000 pharmaceuticals in 1998. The OTC market was expected to develop significantly. In practice, the move had little impact and the OTC market remains undeveloped, partly because the pharmacists' association has lobbied against the sale of OTC products in non-pharmacy outlets.

11.3.2 Reference Price System

In May 2006, a reference price system has been introduced[543]. The EDAF is responsible for the formation of the therapeutic groups, which are being approved under the decision of the MoH. The pharmaceuticals have to be classified in therapeutic groups within a time limit of 30 days after the issue of market authorisation. Criteria for the classification are such as therapeutic and pharmaco-economic effectiveness, the cost of the daily treatment, the safety of the pharmaceutical and the effect on health expenditure.

From all the original pharmaceuticals which constitute every therapeutic group, a reference price is formed. The therapeutic groups and the reference prices can be revised every 2 years, under a decision of the EDAF.

11.3.3 Pharmaceutical Budgets

In Greece, there are no pharmaceutical budgets being applied for doctors or other health care providers, meaning there is no fixed prescribing budgets in terms of money for health care professionals.

11.3.4 Other Volume Control Oriented Measures

11.3.4.1 Prescription Monitoring and Other Doctors-related Measures

By now, there has been limited focus on the prescribing habits of doctors but the healthcare reform advocates the use of prescribing monitoring systems for more effective prescribing control. IKA has developed a central prescription processing unit (KME), in order to computerise prescriptions. KME will also provide automate control of central records with databases on patients, pharmaceuticals prescribed, diagnosis, prescribing doctors and pharmacies. This is generally regarded as a move in the direction of greater monitoring and control over prescription patterns.

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543 Law 3457/2006; www.sfee.gr/download/english/1720/index.html

11.3.4.2 Generics and Parallel Trade

According to SFEE, generics account for around 10% of the market by value.

Since prices of original products are among the lowest in the EU and price differences between originals and generics are low, the environment for generics is less attractive than in other markets.

Generic substitution of generics is not permitted. Doctors are not allowed to prescribe by INN. However, they can prescribe by generic brand name. Patients are generally not price sensitive and tend to be suspicious of the quality of generics (cf. 11.1.2.3).

11.4 Overview of the Reimbursement Market in Greece

Tasks / Duties	Yes	No	Comment	Legal bases
Public authorities				
Decide on prescription status	X		EOF	Market Decree 14/89; http://www.sfee.gr/category/english/47/0/3/1/index.htm
Decide on manufacturer price	X		On the basis of the 3 lowest European prices	Market Decree 14/89; http://www.sfee.gr/category/english/47/0/3/1/index.htm
Agree on manufacturer price		X	N.app.	
Fix wholesale margin	X		Regulated via a mark-up of 8.43% on the manufacturer price	Market Decree 14/89; http://www.sfee.gr/category/english/47/0/3/1/index.htm
Fix pharmacy retail price	X		Regulated via a markup of 35% on the wholesale price	Market Decree 14/89; http://www.sfee.gr/category/english/47/0/3/1/index.htm
Decide on reimbursement status	X		MoH	Market Decree 14/89; http://www.sfee.gr/category/english/47/0/3/1/index.htm
Agrees on reimbursement price		X	N.app.	
Decide on reimbursement price	X		MoH, 96% of the manufacturer price reduced by the percentage of the patient co-payment	Market Decree 14/89; http://www.sfee.gr/category/english/47/0/3/1/index.htm
Use Pharmaco-economic guidelines	X		For the reference price system	
Use Internal reference pricing	X		In the reference price system	

Tasks / Duties	Yes	No	Comment	Legal bases
Use External reference pricing	X		Decide on the manufacturer price on the basis of the 3 lowest European prices	Market Decree 14/89; http://www.sfee.gr/category/english/47/0/3/1/index.htm
Price freezes		X	N.app.	
Margin cuts	X		Profit margin	
Discounts and Rebates	X		A discount of 4% to provincial pharmacies	Market Decree 14/89; http://www.sfee.gr/category/english/47/0/3/1/index.htm
Company profit control		X	N.app.	
Country specific:				
Pharmaceutical Industry				
Sets manufacturer price freely		X	N.app.	
Notifies manufacturer price		X	N.app.	
Negotiates manufacturer price		X	N.app.	
Is free to set price below fixed manufacturer price		X		
Decides on application for reimbursement	X			
Negotiates reimbursement price		X	N.app.	
Free to keep manufacturer price above reimbursement price		X	Usually adapts manufacturer price to reimbursement price	
Free to grant rebates / discounts to wholesalers	X			
Free to grant rebates / discounts to pharmacies	X			
Can engage in marketing towards doctors	X		Promotional control	Market Decree 14/89; http://www.sfee.gr/category/english/47/0/3/1/index.htm
Can engage in public advertising	X			
Can provide information toward patients	X			
Applies for switches and de-listing	X			
Promotional control	X			

Tasks / Duties	Yes	No	Comment	Legal bases
Country specific:				
Distribution chain				
Wholesaler				
Margins are fixed by statute	X		Regulated via a mark-up of 8.43% on the manufacturer price	Market Decree 14/89; http://www.sfee.gr/category/english/47/0/3/1/index.htm
Margins are subject to statutory discounts / rebates	X			Market Decree 14/89; http://www.sfee.gr/category/english/47/0/3/1/index.htm
Free to grant discounts / rebates to pharmacies	X			
Pharmacists				
Margins are fixed by statute	X		Regulated via a mark-up of 35% on the wholesale price	Market Decree 14/89; http://www.sfee.gr/category/english/47/0/3/1/index.htm
Free to set retail price		X	N.app.	
Obliged to inform patient on cheaper product		X	N.app.	
Obliged to substitute by a generic		X	N.app.	
Allowed to substitute by a generic		X	N.app.	
Obliged to substitute by a parallel import		X	N.a.	
Allowed to substitute by a parallel import		X	N.a.	
Therapeutic / analogous substitution is allowed		X	N.app.	
Are subject to statutory discounts / rebates		X	N.a.	
Claw back system exists		X	N.app.	
May grant rebates to customers	X			
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			

Tasks / Duties	Yes	No	Comment	Legal bases
Are obliged to inform on co-payment / deductibles	X			
Prescription habits are monitored	X		Implementation of central prescription processing unit (KME) by IKA	
Are subject to prescription guidelines		X		
Budgets are controlled		X	N.app.	
Allowed to prescribe INN		X		
Obliged to prescribe INN		X		
Can oppose generic substitution		X	N.app.	
Can oppose therapeutic substitution		X	N.a.	
Can oppose substitution by parallel import		X	N.a.	
Country specific:				
Patients				
Can shop for cheapest price of the product		X	N.app.	
Pay a flat rate per prescription / pack	X		Of 25% of the pharmacy retail price	
Pay a certain percentage per prescription / pack or a deductible		X	N.app.	
Annual minimum co-payment		X	N.app.	
Annual maximum co-payment		X	N.app.	
May ask for substitution by a generic		X	N.app.	
May oppose substitution by a generic		X	N.app.	
May ask for substitution by a parallel import		X	N.a.	
Can oppose substitution by a parallel import		X	N.a.	

Tasks / Duties	Yes	No	Comment	Legal bases
Can oppose substitution only on payment of price difference		X	N.a.	
Has to pay the difference between reimbursement price and retail price		X	N.app.	
Has access to full public information on prices and products	X			
Country specifics:				

N. app. = Not applicable, N. a. = Not available

Source: ÖBIG 2006

HUNGARY

12 Hungary

12.1 Pharmaceutical System

12.1.1 Regulatory Framework and Authorities

In Hungary health care is organised on the basis of a Bismarckian social insurance system. The National Health Fund (Országos Egészségbiztosítási Pénztár, OEP) is financed by income-related contributions of employers, employees and self-employed persons – as well as by earmarked taxes and general budget allocations, and covers mainly the recurrent costs of the health care system. Besides the OEP, the state (and the local governments) plays an important role in the organisation and financing of the Hungarian health care system, especially by bearing capital costs. The compulsory health insurance in Hungary is strongly based on the principle of solidarity and is characterized by benefits in kind and unrestricted access to primary, secondary and tertiary care.

In the family doctor system primary care physicians have contracts with the regional branches of the OEP and usually work in publicly owned practices The scope of medical coverage is regulated by the state. General Practitioners (GP) act as gatekeepers to specialists services and are remunerated primarily on a capitation basis. Specialist services are provided in publicly owned polyclinics and out-patient departments. The in-patient sector is mainly in public hands, with only a few hospitals being operated by churches and private institutions. Services of the in-patients sector are financed on the basis of a DRG system.

The most relevant players in the Hungarian pharmaceutical system are

- the Hungarian Ministry of Health (Egészségügyi Minisztérium, EüM), which is responsible for the regulatory framework in terms of pharmaceuticals,
- the National Health Fund (OEP) advised by the Technology Evaluation Committee (Technológia Értékelő Bizottság, TÉB), which is responsible for the reimbursement of pharmaceuticals and
- the National Institute of Pharmacy (Országos Gyógyszerészeti Intézet, OGYI), acting as a Medicines Agency.

The responsibility of granting market authorisation for pharmaceuticals bears with the OGYI, which is also in charge of the classification of pharmaceuticals according to their prescription status into non-prescription medicines (OTC) and prescription-only medicines (POM) with sub-categories (e.g. prescription on hospital or specialists advise or for use under supervi-

sion; pharmaceuticals with risk of abuse).[544, 545] The category of "preparations having therapeutic effect but not classified as pharmaceuticals" will wane on 1 April 2011. By this date all these products shall be reclassified as pharmaceuticals or other products. Hungarian law incorporates the provisions of the Community Code with regard to market authorisation and classification. The duration of the market authorisation procedure has been limited to 210 days from submission of the application; newly issued market authorisations are valid for 5 years and shall then be renewed. Further responsibilities of the OGYI are amongst others quality inspections, authorisations of clinical trials and vigilance agenda. Also the responsibility for issuing manufacturing licences (which includes the licence for wholesale of the manufactured pharmaceuticals) and wholesaling licences bears with OGYI in agreement with the Hungarian Trade Licensing Office (Magyar Kereskedelmi Engedélyezési Hivatal, MKEH).[546]

Manufacturer prices for pharmaceuticals can be set freely[547]. Prices have to be notified to the EüM, the OEP and the Hungarian Chamber of Pharmacists (Magyar Gyógyszerész Kamara, MGYK), which are in turn obliged to make the information publicly accessible. Distribution margins are statutory regulated by the EüM and are the same for all registered pharmaceuticals. The EüM, as the supervising body of the OEP, is also involved in negotiations with the pharmaceutical industry on rebates, price-volume agreements etc.

The OEP is in charge of reimbursement decisions, which are made on the basis of recommendations of the Technology Evaluation Committee (TÉB), a body consisting of members of the OEP, representatives of the Hungarian Chamber of Doctors (Magyar Orvosi Kamara, MOK), the Special Board of Doctors and the Hungarian Chamber of Pharmacists (MGYK). Parameters considered by the TÉB are among others the proposed manufacturer price and reimbursement category, benefits compared to already reimbursed pharmaceuticals and prices in other countries as well as analyses prepared by the National Institute for Strategic Health Research (Egészségügyi Stratégiai Kutatóintézet, ESKI).

For opposing the decision of the OEP the pharmaceutical manufacturer can turn to the Head of the OEP, in this case the Appeal Committee (Fellebbviteli Bizottság, FB), consisting of representatives of the Ministry of Health (EüM), the Ministry of Finance (Pénzügyminisztérium, PM), the Ministry of Economy and Transport (GKM), the Prime Minister Office and Economic Competition Office, deals with the case. Against the decision of the Appeal Committee the manufacturer can turn to the judicial branch.

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544 Law 95/2005 on medicinal products for human use and on the amendment of other laws regulating the pharmaceutical market [2005 évi XCV. törvény az emberi alkalmazásra kerülő gyógyszerekről és egyéb, a gyógyszerpiacot szabályozó törvények módosításáról]

545 Decree of the Ministry of Health 52/2005 on the market authorisation of medicines for human use [52/2005. (XI. 18.) EüM rendelet az emberi alkalmazásra kerülő gyógyszerek forgalomba hozataláról] - reclassification of all pharmaceuticals according to Art. 18 of this Decree shall be finished by 1 April 2006

546 Art. 4.2 and Art. 11.2 Law 95/2005 on medicinal products for human use and on the amendment of other laws regulating the pharmaceutical market

547 Price Act 87/1990 [1990. évi LXXXVII. Törvény az árak megállapításáról]; Decree of the Ministry of Health 25/1997 on medicines marketed without social security reimbursement [25/1997. (VIII. 22.) NM rendelet a társadalombiztosítási támogatás nélkül forgalmazott gyógyszerekről]

Table 12.1 contains an overview of relevant Hungarian stakeholders introduced in sections 12.1.1 and 12.1.2.

Table 12.1 Hungary - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Egészségügyi Minisztérium (EüM) / Ministry of Health	Ministry of Health (Regulatory Body for Pharmaceuticals)	EüM Arany Janos utca 6-8 H-1051 Budapest Hungary Tel.: +36 1 3017 800 Fax: +36 1 3020 925 webmester@eum.hu www.eum.hu/eum/eum.main.page	Mr. József Hamvas Head of Pharmaceutical Department Arany Janos utca 6-8 H-1051 Budapest Hungary Tel.: +36 1 3017 923 Fax: +36 1 3020 925 Hamvas.jozsef@eum.hu
Országos Egészégbiztositasi Pénztár (OEP) / National Health Insurance Fund	Third Party Payer, Pricing and Reimbursement	OEP Vaci ut 73 A H-1139 Budapest Hungary Tel.: +36 1 3502 001 Fax: +36 1 3596 654 sajto@oep.hu www.oep.hu	Mr. Gabor Lengyel Head of Pharmaceutical Department Vaci ut 73 A H-1139 Budapest Hungary Tel.: +36 1 3503 061 lengyel.g@oep.hu
Országos Gyógyszerészeti Intézet (OGYI) / National Institute of Pharmacy	Medicines Agency (Market Authorisation, Vigilance, etc.)	OGYI Zrinyi u. 3 H-1051 Budapest Hungary Tel.: +36 1 3171 488 Fax: +36 1 3181 167 ogyi@ogyi.hu www.ogyi.hu	Ms. Eva Csekey Deputy-Director-General Zrinyi u. 3 H-1051 Budapest Hungary Tel.: +36 1 3171 488 Fax: +36 1 3181 167 csekey@ogyi.hu
Magyarországi Gyógyszergyártók (és Nagykereskedök) Országos Szövetsége (MAGYOSZ) / Hungarian Pharmaceutical Manufacturers Association	Association of Hungarian Pharmaceutical Industry	MAGYOSZ P.O. Box 970 H-1386 Budapest 62 Hungary Tel.: +36 1 2709 101 Fax: +36 1 2880 266 info@magyosz.org www.magyosz.org	Mr. László Buzás Director Lehel út 11 H-1134 Budapest 62 Hungary Tel: +36 1 2709 101 Fax: +36 1 2880 266 info@magyosz.org

Institution	Task	Contact details/URL	Responsible person
Innovativ Gyógyszergyártók Egyesülete (AIPM) / Association of Innovative Pharmaceutical Companies	Association of International Pharmaceutical Industry	AIPM Csörsz u. 45, MOM Park H-1124 Budapest Hungary Tel.: +36 1 2504 876 Fax: +36 1 2504 877 igy@aipm.hu www.igy.hu	Ms. Krisztina Székely Chairperson of the Association Csörsz u. 45, MOM Park H-1124 Budapest Hungary Tel.: +36 1 2504 876 Fax: +36 1 2504 877 igy@aipm.hu
Gyógyszernagykereskedok Szövetsége (HAPW) / Association of Pharmaceutical Wholesalers	Wholesaler Association	HAPW Radvány u. 20/A. H-1118 Budapest Hungary Tel.: +36 1 3090 249 Fax: +36 1 3090 248 php-gynsz@nextramail.hu www.php-gynsz.hu/	Mr. István Fáczányi Director Radvány u. 20/A. H-1118 Budapest Hungary Tel.: +36 1 3090 249 Fax: +36 1 3090 248 Php-gynsz@nextramail.hu
Magyar Gyógyszerész Kamara (MGYK) / Hungarian Chamber of Pharmacists	Association of Pharmacists	MGYK Dózsa Görgy út 86/B H-1068 Budapest Hungary Tel.: +36 1 3519 483 Fax: +36 1 3519 485 hivatal@mgyk.hu www.mgyk.hu/	Mrs. Katalin Hável President Mr. Attila Horváth-Sziklai Dózsa Görgy út 86/B H-1068 Budapest Hungary Tel.: +36 1 3519 483 Fax: +36 1 3519 485 Hsza@mgyk.hu
Magyar Orvosi Kamara (MOK) / Chamber of Physicians	Medical Doctors' Association	MOK Szondi u. 100 H-1068 Budapest Hungary Tel.: +36 1 2694 391 Fax: +36 1 2694 392 Mok@mok.hu www.mok.hu	Mr. István Éger President Szondi u. 100 H-1068 Budapest Hungary Tel.: +36 1 2694 391 Fax: +36 1 2694 392 Mok@mok.hu Www.mok.hu
Egészségügyi Stratégiai Kutatóintézet (ESKI) / National Institute for Strategic Health Research	Research Institute (HTA, Pharmaco-economic Evaluation)	ESKI Szentkirályi ut 21 H-1088 Budapest Hungary Tel.: +36 1 3384 133 Fax: +36 1 2669 710 eski@eski.hu www.eski.hu	Mr. Gyula Kincses General Director Szentkirályi ut 21 H-1088 Budapest Hungary Tel.: +36 1 3384 133 Fax: +36 1 2669 710 gardosi@eski.hu

Source: ÖBIG 2006

12.1.2 Market Players

12.1.2.1 Pharmaceutical Industry

In Hungary the pharmaceutical industry was an important branch of industry in the past decades. In the 1990s the Hungarian pharmaceutical industry was privatized and is nowadays mainly in the hands of foreign investors. The biggest local producer is Richter Gedeon which also dominates the pharmaceutical market in terms of sales, followed by EGIS Gyógyszergyár. Pharmaceutical production in Hungary amounted to HUF 356,820 million / € 1,407.46 million in 2003. The local pharmaceutical industry covers approximately one third of the Hungarian market in value, and more than half of the pharmaceutical market in volume. The domestic share of pharmaceutical sales has constantly declined since 1990.[548] About one third of the turnover is made on the local market, main export markets are besides the CEE Countries Germany, the UK, France and Italy. More than 40 pharmaceutical companies possess a manufacturing licence; the products of approximately 20 local producers are available in Hungarian pharmacies. The number of employees in the pharmaceutical industry has dropped in the last decade from approximately 23,000 in 1990 to an estimated 12,000 in the year 2002.

12.1.2.2 Distribution

In Hungary pharmaceutical wholesale is organized in a multi-channel system. In 2005, there were about 80 companies holding a wholesale license.[549] Quite a few pharmaceutical companies hold wholesale licenses but do not deliver to pharmacies mainly due to distribution costs. Since 2005 the license to manufacture pharmaceuticals on Hungarian territory incorporates a wholesale license if certain conditions are met. In fact, only four wholesalers (Phoenix Pharma, Hungaropharma, Medimpex and Pannonmedicina) dominate the market with an estimated total 85% market share. These four wholesalers are members of the Hungarian Association of Pharmaceutical Wholesalers (Gyógyszer-Nagykereskedõk Szövetsége, HAPW). Besides these companies, there are approximately 6 to 8 small wholesale companies, most of them are not full-line wholesalers.[550]

In general, pharmaceuticals are dispensed to patients in pharmacies. In 2005 there were 2,030 pharmacies and 155 hospital pharmacies in Hungary. Geographic and demographic criteria for setting up a pharmacy are applied; the service population of a new pharmacy has to be at least 5,000 people and the minimum distance to an existing pharmacy has to be 250 to 300 meters. Furthermore the ownership of a pharmacy is only allowed for a trained pharmacist, who has to hold the majority (51%) on the pharmacy. Up to 49% of the pharmacy may be owned by any natural or legal person.[551] Although multiple ownership of pharmacies

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548 MAGYOSZ 2005

549 OGYI 2006

550 HAPW, personal communication, June 2005

551 Law 54/1994 on establishment and operation of pharmacies [1994.évi LIV. Törvény a gyógyszertárak létesítéséről és működésük egyes szabályairól]

is not permitted, approximately 250 pharmacies are organized in form of chains, via the possibility for anyone to hold 49% of a pharmacy.

Besides pharmacies self-dispensing doctors are allowed and do exist in rural areas; they dispense without profit margin pharmaceuticals delivered by pharmacies. This form of pharmaceutical distribution is of minor importance; wholesalers do not to hold pharmacy licenses to directly supply self-dispensing doctors.[552,553] Additionally some hospitals are entitled to dispense pharmaceuticals to out-patients.[554]

Self-service of OTC is not allowed, nor is distance selling of pharmaceuticals, e.g. via internet, legitimized.[555]

12.1.2.3 Patients

The role of the as a “market player” is characterised by a reference price system setting incentives to opt for cheaper pharmaceuticals; patients may only opt for pharmaceuticals above the reference price at their own expense.

As the reference price system has gradually been moved from INN based ATC 5 level groups to ATC 4 level (therapeutic groups) (cf. 12.3.2), patients may not only have the choice between a branded product and its bioequivalent generic products but might be confronted with a choice between a innovative product and a selection of older brands and their generics representing the therapeutic alternative. This is due to the fact that within one reference price group pharmaceuticals with different mechanisms of action and levels of effectiveness are clustered. As patients usually lack information on pharmaceuticals and effectiveness of therapeutic alternatives, they have to rely on the advice of doctors and pharmacists concerning their treatment.

Hospital doctors have to prescribe by INN when dismissing a patient; general practitioners (GP) have the possibility to do so. There are plans to introduce compulsory INN prescribing for GP as well, though this has not happened yet.[556] Pharmacists are obliged to offer generic substitution in all cases, thus the role of the pharmacist was strengthened.

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552 MGYK, personal communication, June 2005

553 HAPW, personal communication, April 2006

554 MGYK, personal communication, June 2005

555 AESGP, 2005

556 PPR 09/2005; OEP, personal communication, March 2006

12.1.3 Overview of the Pharmaceutical System

Hungary comes place 15 in the ranking of all pharmaceutical retail markets in Europe, and place 3 in the ranking of the CEE pharmaceutical retail markets.[557] The generic market share is quite high with approximately 50% of the market, both in terms of value and in terms of volume in the year 2004.[558]

Approximately 60% of the total pharmacy turnover is made in the social health insurance market; the remainder of 40% in the private market. Table 12.2 gives an overview of the pharmaceutical market and authorised pharmaceuticals.

Table 12.2: Hungary - Pharmaceutical Market

Pharmaceutical Market	Year
No. of authorised pharmaceuticals	*Per May.2005*
authorised [1, 2]	5.118
POM and hospital-only products[2]	4.426
OTC[2]	777
Pharmaceutical - turnover (in millions)[3]	*2004*
Total	HUF 407,800 / € 1,620.4
Non-prescription market (OTC)	HUF 59,800 / € 237.6

OTC = Over-the-Counter, POM = prescription-only medicines

[1] Without centralized registered pharmaceuticals

[2] The total sum of OTC products, POM (all categories) and hospital-only pharmaceuticals exceeds the number of authorised products due to double assignment in different categories according to pack size.

[3] At pharmacy retail prices (excl. hospital sales)

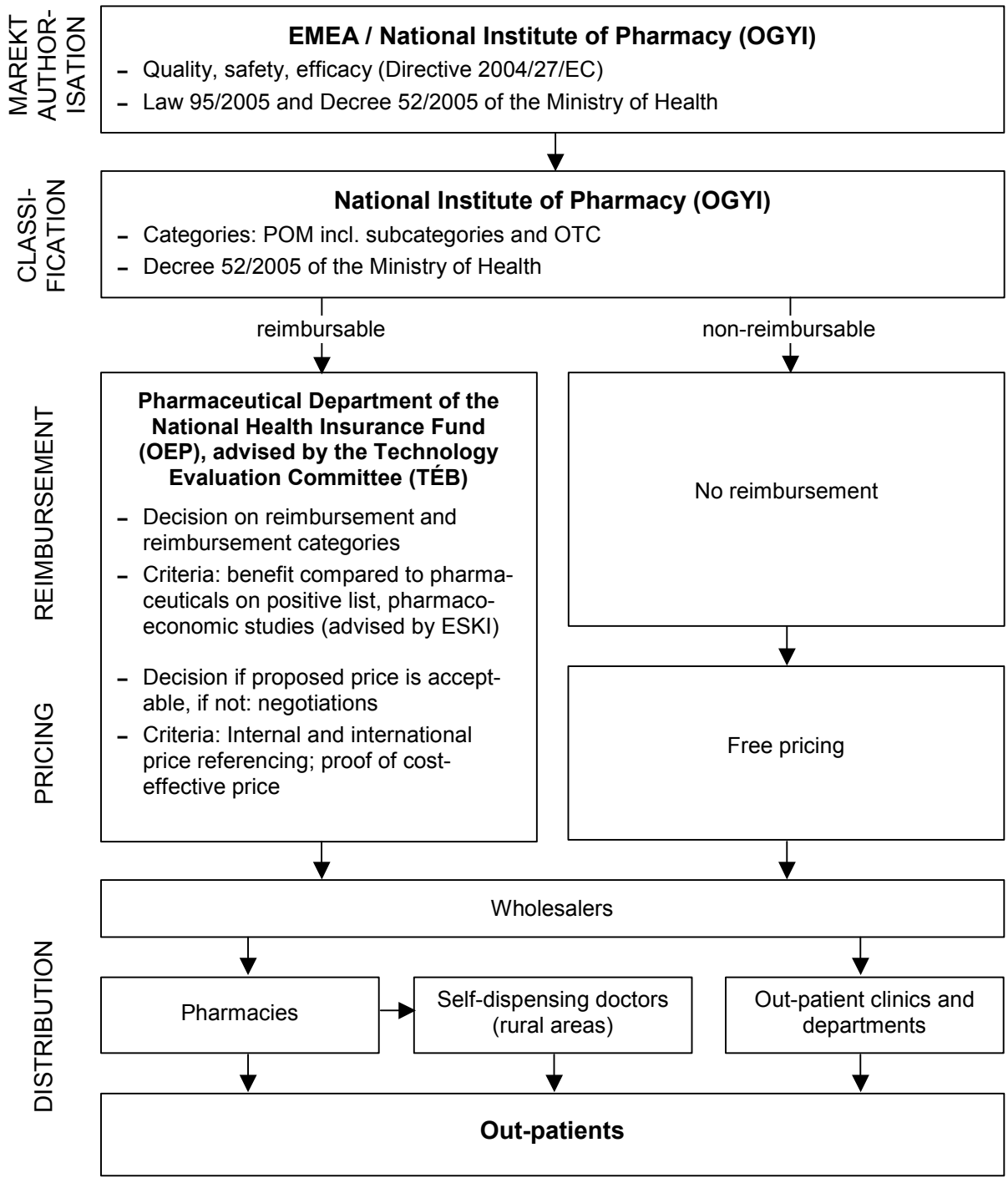
Source: AESGP 2005; OGYI; data gathering by ÖBIG

Figure 12.1 shows an overview of the pharmaceutical system in Hungary.

557 IMS 2005

558 EGA 2005

Figure 12.1: Hungary - Pharmaceutical System, 2006



Source: ÖBIG 2006

12.2 Pricing

12.2.1 Scope of Price Control

In Hungary, there is a system of free pricing for all pharmaceuticals regardless of their prescription status (POM or OTC) at manufacturer level. Thus pharmaceutical companies are free to set prices of non-reimbursable pharmaceuticals at their will.[559] There is no separate price setting procedure.

If a product shall be included in the positive list, the manufacturer has to apply for reimbursement to the OEP. However, the application has to include the proposed manufacturer price. The OEP may accept or reject reimbursement at the proposed price; negotiations between the OEP and the pharmaceutical companies may take place if a pharmaceutical shall be included into reimbursement but the proposed price is deemed to high. Still the OEP does not set prices; rather the pharmaceutical companies may adjust their prices so that the OEP accepts the product for reimbursement.

As stated above, OTC prices are free. For OTC products which are included in the list for the socially disadvantaged (cf. 12.3.1), which applies to about 100 OTC products, prices are negotiated with the OEP.

Prices for hospital products are agreed in the same way as prices for reimbursable pharmaceuticals (cf. 12.3) but are of maximum nature, thus leaving hospitals and manufacturers or wholesalers the possibility to negotiations.

The statutory margin schemes for wholesalers (cf. Table 12.3) and for pharmacies (cf. Table 12.4) are applicable for all pharmaceuticals regardless of their prescription or reimbursement status.

559 Price Act 87/1990 [1990. évi LXXXVII. Törvény az árak megállapításáról]; Decree of the Ministry of Health 25/1997 [25/1997. (VIII. 22.) NM rendelet a társadalombiztosítási támogatás nélkül forgalmazott gyógyszerekről]

Table 12.3: Hungary - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	All pharmaceuticals regardless of their prescription status	Not applied	Not applied
Statutory Pricing	Not applied	All pharmaceuticals regulated via a regressive mark-up scheme	All pharmaceuticals regulated via a regressive mark-up scheme
Price Negotiations	Prices for pharmaceuticals applying for inclusion to reimbursement lists may be negotiated with the OEP	Not applied	Not applied
Price/volume agreements, discounts/rebates	Yes (Price Freezes 2004-2006 and Industry payback arrangement for 2005 and 2006)	No	No
Institution in charge of pricing	- Manufacturers - EüM sets the legislative framework - Price of reimbursable pharmaceuticals is agreed between OEP and the pharmaceutical companies		
Legal Basis	- Price Act 87/1990 - Decree of the Ministry of Health 25/1997; - Decree of the Ministry of Health 19/2001 on the commercial price mark-up of medicinal products; - Decree of the Ministry of Health 70/2003 on the commercial price mark-up of medicinal products; - Decree 32/2004 of the Minister of Health, Family and Social Affaires - Contract between the government and the pharmaceutical industry		

EüM = Egészségügyi Minisztérium, OEP = Országos Egészségbiztosítási Pénztár

Source: ÖBIG 2005

12.2.1.1 Manufacturer Price

Manufacturer prices may be set freely.[560] The manufacturers have to notify their prices – both for reimbursable and for non-reimbursable products to the Ministry of Health (EüM) and the Chamber of Pharmacists (MGYK). Prices of non-reimbursable pharmaceuticals may be altered quarterly. Since June 2004 due to a provision in an agreement between the manufacturer associations and the EüM / OEP prices of reimbursable pharmaceutical have not been allowed to change unless the exchange rate drops by more than 6.25% (cf. 12.2.2.4).[561]

For pharmaceuticals which shall be included in the positive list, manufacturers have to apply for reimbursement to the OEP - the application has to include amongst others the proposed

[560] Price Act 87/1990 [1990. évi LXXXVII. Törvény az árak megállapításáról]; Decree of the Ministry of Health 25/1997 [25/1997. (VIII. 22.) NM rendelet a társadalombiztosítási támogatás nélkül forgalmazott gyógyszerekröl

[561] OEP, personal communication, April 2006

manufacturer price (cf. 12.3). The proposed price is either approved by the OEP or negotiations take place and the pharmaceutical company may then reduce the proposed price. Thus the OEP does not set any prices, but accepts or rejects price proposals of pharmaceutical companies.

For innovative pharmaceuticals companies have to indicate amongst other information, the manufacturer prices in other EU Member States and pharmaco-economic studies in their application form (cf. 12.2.2.3 and 12.2.2.1).

For the first generic product the proposed price needs to be at least 30% lower than the price of the original product in Hungary. The manufacturer price of pharmaceuticals entering an already established reference price group may at the maximum be the same as the manufacturer price of the reference product. (cf. 12.2.2.2)

12.2.1.2 Wholesale Price

Since 1993, wholesale mark-ups have been regulated as regressive staggered mark-up schemes, valid for all authorised pharmaceuticals. The wholesale mark-up scheme was last modified in 2001 and is applied to all pharmaceuticals regardless of their reimbursement status.[562] The wholesale mark-up is regulated as a maximum mark-up.

The average wholesale margin amounted to 6.36% in 2004.[563]

Wholesalers are not obliged to grant any rebates or discounts to the OEP or any other public body.[564]

However, wholesalers may grant discounts to pharmacies; discounts in the range from 1% to 3% are common. [565]

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562 Decree of the Ministry of Health 19/2001 on the commercial price mark-up of medicinal products [19/2001.(V.23.) EüM rendelet A gyógyszerek kereskedelmi árréséről]

563 AESGP 2005

564 HAPW, personal communication, April 2006

565 PPR 2005

Table 12.4: Hungary - Wholesale Mark-up Scheme, 2006

Manufacturer price / CIP from...to...in HUF / €	Wholesale mark-up in % of the manufacturer price / CIP in HUF / €
up to HUF 150.- / € 0.59	12%
from HUF 150.01 / € 0.60 to HUF 180.- / € 0.71	HUF 18.- / € 0.07
from HUF 180.01 / € 0.72 to HUF 300.- / € 1.19	10%
from HUF 300.01 / € 1.20 to HUF 333.- / € 1.32	HUF 30.- / € 0.12
from HUF 333.01 / € 1.33 to HUF 500.- / € 1.98	9%
from HUF 500.01 / € 1.99 to HUF 600.- / € 2.38	HUF 45.- / € 0.18
from HUF 600.01 / € 2.39 to HUF 1,000.- / € 3.97	7.5%
from HUF 1,000.01 / € 3.98 to HUF 1,154.- / € 4.58	HUF 75.- / € 0.30
from HUF 1,155.01 / € 4.59 to HUF 2,000.- / € 7.94	6.5%
from HUF 2,000.01 / € 7.95 to HUF 2,600.- / € 10.33	HUF 130.- / € 0.52
from HUF 2,600.01 / € 10.33 on	5%

CIP = Cost, Insurance and Packaging

Source: Decree of the Ministry of Health 19/2001

12.2.1.3 Pharmacy Retail Price

Pharmacy mark-ups are also regulated in a regressive staggered mark-up scheme and were last modified in 2004.[566] Before, a change of the pharmacy mark-up scheme in 2001 had replaced a percentage mark-up for expensive pharmaceuticals by fixed sum compensation. Like for wholesalers, the pharmacy mark-up scheme is applicable to all pharmaceuticals regardless of their reimbursement and prescription status.

[566] Decree of the Ministry of Health 70/2003 on the commercial price mark-up of medicinal products [70/2003. (XII. 18.) ESZCSM rendelet a gyógyszerek kereskedelmi árrésérõl szóló 19/2001. (V. 23.) EüM rendelet módosításáról]

Table 12.5: Hungary - Pharmacy Mark-up Scheme, 2006

PPP from...to...in HUF / €	Pharmacy mark-up in % of the PPP in HUF / €
up to HUF 500.- / € 1.98	26%
from HUF 501,- / € 1.99 to 590.- / € 2.34	HUF 130.- / € 0.52
from HUF 591,- / € 2.35 to 1,500.- / € 5.96	22%
from HUF 1,501,- / € 5.97 to 1,737.- / € 6.90	HUF 330.- / € 1.31
from HUF 1,738,- / € 6.91 to 3,500.- / € 13.90	19%
from HUF 3,501,- / € 13.91 to 3,911.- / € 15.54	HUF 665.- / € 2.64
from HUF 3,912,- / € 15.55 to 5,000.- / € 19.86	17%
from HUF 5,001.- / € 19.87 on	HUF 850.- / € 3.38

PPP = Pharmacy Purchase Price

Source: Decree of the Ministry of Health 70/2003

The average pharmacy margin declined from 20.47% in 2000 to 15.42% in 2003; in 2004 the average pharmacy margin amounted to 16.64%.[567]

The PRP for reimbursable pharmaceuticals is uniform throughout the country; pharmacies are not allowed to deviate from the co-payment charge of any reimbursable pharmaceutical.

With regard to non-reimbursable pharmaceuticals: since summer 2005 pharmacies have to pass on discounts received during procurement on to the patients, thus calculating PRP according to the pharmacy mark-up scheme based on the discounted wholesale price.[568] The PRP of non-reimbursable pharmaceuticals therefore might slightly vary between pharmacies according to the negotiated wholesale discounts they receive. Therefore the PRP published is of informative nature, but according to the MGYK[569] in practice the PRP of non-reimbursable pharmaceuticals is uniform throughout the country as well, as the law does not specify according to which method wholesale discounts shall be broken down to a product basis and then be passed on to the customers.

The PRP of all pharmaceuticals are published quarterly by the MGYK.

Besides the pharmacies, self-dispensing doctors supply patients with pharmaceuticals in rural areas. They have to procure the pharmaceuticals through a pharmacy, without being granted a margin (cf. 12.1.2.2).

567 AESGP 2005

568 Art. 31.b Law 95/2005 on medicinal products for human use and on the amendment of other laws regulating the pharmaceutical market

569 MGYK, personal communication, May 2006

12.2.1.4 Value Added Tax (VAT)

VAT on pharmaceuticals was introduced in 2004. The standard VAT is 25%, the reduced VAT on pharmaceuticals is 5%. Furthermore, there is a VAT rate of 15% for para-pharmaceutical products.[570]

12.2.2 Price related Cost-containment Measures

Most of the cost-containment measures apply to reimbursable pharmaceuticals only. Hospital products are also included in the positive list (0% reimbursement category), thus being evaluated by the TÉB. Price agreements apply to hospital pharmaceuticals as well.

12.2.2.1 Pharmaco-economic Evaluation

Pharmaceutical companies have to provide the OEP with pharmaco-economic evaluations for new pharmaceuticals when submitting the reimbursement application. Furthermore economic evaluations are requested for already reimbursable INN e.g. with new indications or in case of a request for a price increase.[571]

There are pharmaco-economic guidelines in place for Hungary which have to be used with economic evaluations submitted with the reimbursement application.[572]

Besides the pharmaco-economic studies provided by companies the evaluation of the TÉB regarding the inclusion of a pharmaceutical onto the positive list may comprise a health economic evaluation, prepared by the ESKI. Since May 2004 ESKI has been in charge of advising the TÉB with regard to cost-effectiveness but also with regard to medicinal effectiveness.

12.2.2.2 Internal Price Referencing

With application for reimbursement pharmaceutical companies have to submit, amongst others, information on the proposed manufacturer price, information on prices and market shares of the product in other EU Member States and information on daily treatment costs in comparison with therapeutic alternatives at ATC 4 level (cf. 12.3). The TÉB considers the treatment costs compared to alternative therapies in its analysis - also with regard of therapeutic reference price groups.

Besides, internal price referencing is relevant for the prices of off-patent products. According to the OEP, the manufacturer price of the first generic product needs to be at least 30% lower than the manufacturer price of the original product. The manufacturer price of a generic

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570 Europäische Kommission 2005

571 ESKI, personal communication, May 2006

572 Pharmaco-economic guidelines were published in the official gazette of the EüM (Egészségügyi Közlöny) 2002, Vol. LII, No. 11, p. 1314-1334; an english translation is available Szende, A. et al. 2002

entering an existing reference price group may at the maximum be the same as the price of the reference product.

12.2.2.3 External Price Referencing / Cross Country Referencing

For innovative pharmaceuticals companies have to indicate prices in other EU Member States. Usually, the prices in Austria, Belgium, the Czech Republic, France, Germany, Greece, Ireland, Italy, Poland, Portugal, Slovakia, Slovenia and Spain are taken into account. Prices of other countries may be filed as well. As a general rule, the price in Hungary must be lower than the price of the product in all reference countries.

The price information is provided by pharmaceutical industry, and price comparison are not reviewed on a regular basis.

Besides the prices, information on the market share of pharmaceutical on the ATC 4 level in the referenced countries has to be indicated.

12.2.2.4 Price Stops / Cuts

Hungary has been struggling with its publicly funded pharmaceutical expenditure for quite some years. Pharmaceutical expenditure ranks second place on the list of expenditure categories and accounts for over 30% of OEP's budget. As the OEP's pharmaceutical budget has been overspent in the past years, the Ministry of Health and the OEP have been looking for ways to curtail public pharmaceutical expenditure. Both price related and volume related cost containment measures were set; these include price stops/freezes; price-volume-agreements and manufacturer paybacks/rebates (cf. 12.2.2.6) and agreements binding prices of imported pharmaceuticals to exchange rate fluctuations.

A price stop was introduced by the political decision makers in the year 2000; in succession to this prize stop, pharmaceutical prices were only allowed to be raised below the inflation rate between 2000 and 2003. Under this agreement between the government and the pharmaceutical industry associations, the prices of all pharmaceuticals were only allowed to rise at three occasions. After the elections, the new government introduced again a price stop until the end of 2002. Prices of non-reimbursable pharmaceuticals were allowed to be changed quarterly from January 2003 onwards, whilst for reimbursable pharmaceuticals only a modest price increase was made on 1 February 2003. Prices went up by an average of 4.5%, whereas more expensive pharmaceuticals were raised by a smaller percentage than pharmaceuticals priced HUF 550.- / € 2.17 (2003) or below. The price hike of 1 July 2003 under this agreement failed to materialize and prices of reimbursable pharmaceuticals remained frozen until February 2004.

In addition a payback scheme (price-volume agreement) was introduced from September to December 2003 to control pharmaceutical expenditure (cf. 12.2.2.6).

A further industry payback arrangement was proposed for the first half of 2004. According to an agreement, from January to June 2004 manufacturers should payback 15% of the revenues of pharmaceutical sales to the OEP. As only a small part of the manufacturers signed

the agreement (whilst 138 manufacturers representing 85% of the Hungarian market opposed it); the government imposed a price cut of 15% from 1 April 2004 for a period of 6 months on all pharmaceuticals (reimbursable and non-reimbursable) with a PRP above HUF 600.- / € 2.38 (2004) by manufacturers not signing the contract. After legal complaints filed by the pharmaceutical industry associations the price cut was ruled unconstitutional and lost its validity, as did the agreement signed by some manufacturers, on 30 June 2004.

A new agreement between the pharmaceutical industry associations and the government came into force from July 2004 and is valid until July 2006. Under this agreement both local and multinational manufacturers set wholesale prices in € at a fixed exchange rate of HUF 251.24 to the € and signed to refrain from raising HUF prices, unless HUF dropped more than 6.25% against the €. Any resulting price increase has to be reported by 30 April before coming into force on 1 July each year. In return the government promised to increase OEP's pharmaceutical budget. In January 2005, as agreed in the above mentioned contract, prices of pharmaceuticals below HUF 600.- / € 2.42 (2005) were raised by HUF 45.- / € 0.18; pharmaceuticals priced between HUF 600.- / € 2.42 and HUF 1,000.- / € 4.03 were increased by HUF 70.- / € 0.28. Again in July 2005 prices of 1,200 reimbursable pharmaceuticals were raised.

Besides, payback arrangements were signed for 2005 and 2006 (cf. 12.2.2.6).

12.2.2.5 Margin Cuts

Since 1993 wholesale and pharmacy margins on pharmaceuticals have been regulated through a regressive mark-up scheme (cf. Table 12.4 and Table 12.5).

The pharmacy mark-up scheme was last modified with effect from 1 January 2004 which resulted in an increase of the average pharmacy margin from 15.42% in 2003 to 16.64% in 2004, after a decrease in the average pharmacy margins since the year 2000.

Wholesale mark-ups remained practically unchanged from 1993 to 1999. In 1999, the wholesale mark-ups were lowered (an average decrease of 1.5%), and again in 2002. In 2004, the aggregate wholesale margin amounted to 6.36% (cf. 12.2.1.2).

12.2.2.6 Discounts and Rebates

There are no direct rebates or claw-backs to be paid by pharmacists or wholesalers to the OEP.

But there is a history of payback agreements between the pharmaceutical industry and the OEP which provided for the pharmaceutical industry to grant ex-post discounts to the OEP in case of budget excess.

- A general payback scheme (price-volume agreement) was introduced from September to December 2003 to control pharmaceutical expenditure. Manufacturers could decide on one of three payback options; one general scheme or 2 individual contract options based on the manufacturers' sales with the OEP. A manufacturer rebate of 20% had to be paid to the OEP, if targeted monthly sales were exceeded.

- Besides the general payback scheme for the pharmaceutical industry, there are individual price-volume agreements with manufacturers for certain pharmaceuticals. Depending on the contract there are yearly paybacks based on the monetary yearly sales volume; above defined limits the manufacturer has to payback a increasing percentage share up to 100% of the exceeded volume to the OEP. Also monthly paybacks may be agreed on in individual contracts, with the payback sum depending on the monthly sales volume.
- The government imposed a price cut of 15% in spring 2004, which was declared unconstitutional, after legal steps had been taken by the industry against this measure (cf. 12.2.2.4).
- A payback arrangement, originally signed between the government and the pharmaceutical industry associations in July 2004, was modified in September 2005, provided that pharmaceutical industry would allocate a lump sum of HUF 20,000 million / € 80.6 million to the pharmaceutical budget, which was set at HUF 284,000 million / € 1,145 million for 2005. As it was exceeded by roughly 23%, the industry has to cover roughly 6% of the total expenditure for reimbursable pharmaceuticals. For the year 2006 a payback sum of HUF 22,500 million / € 90.7 million was agreed. The payback is shared amongst the pharmaceutical industry according to the market share of sales with reimbursed pharmaceuticals and the growth of these sales, whereas pharmaceuticals under the reference prices system are not considered in the calculation of the share.

12.2.2.7 Company Profit Controls

The profits of pharmaceutical companies are indirectly influenced by the above mentioned cost containment measures and most directly by the price stops and the general payback arrangements and individual price-volume agreements.

However, there are no direct company profit controls like e.g. in the UK.

12.2.2.8 Parallel Trade

According to information of the Chamber of Pharmacists (MGYK) parallel imported products are of no relevance in Hungary.[573] In general there are very few parallel traded pharmaceuticals in Hungry, the marketing authorisation process of such pharmaceuticals is regulated by decree.[574] Parallel trade is not taken into account with the decision on the reimbursement status.

Product patents have been in place in Hungary since 1994, before that date process patents had been granted to pharmaceutical companies. Under the process patent system, only the process is protected, not the “molecule” itself; therefore copies could be manufactured if a different process was used. An agreement between the Hungarian and the multinational (“in-

573 MGYK, personal communication, May 2006

574 Decree of the Ministry of Health 53/2004 on the marketing authorization of parallel traded pharmaceuticals [53/2005. (XI. 18.) EüM rendelet a gyógyszernek nem minősülő gyógyhatású anyag vagy termék emberi alkalmazásra kerülő gyógyszerré történő átminősítésének feltételeiről]

novative") industry was found, granting local manufacturers the right to further sell their copies as well as to finish started research on alternative processes.[575]

Because of concerns of the pharmaceutical industry, the Accession Treaty includes a derogation to limit exports from the new EU Member States, when intellectual property rights differed at the time of the market launch of a pharmaceutical. The G10 High Level Group also recommended governing parallel imports between EU Member States. The derogation provides, that holders of Supplementary Protection Certificates (SPC), which had been granted in the EU-15 before product patents were available in the new EU Member States, may prevent exports from the new Member States. Furthermore, parallel importers have to notify patent holders of their intention to import a pharmaceutical 30 days prior to their application for a parallel import product licence, thus pharmaceutical companies have the chance to take legal action if they feel that the derogation of the EU Accession Treaty is violated.

12.2.3 Co-Payments

There is a proportional (percentage) co-payment for pharmaceuticals in the out-patient sector, while pharmaceuticals used for in-patient treatment are covered through the DRG system without any extra charge for the patient. There is no additional prescription fee (fixed fee) due for the patient. Besides the percentage co-payment for pharmaceuticals in the out-patient sector, within the reference price system additional private expenditure might arise to patients.

Pharmaceuticals on the positive list are generally reimbursed at 90%, 70% and 50% (so-called normative reimbursement) - thus leaving patients with co-payment rates between 10% and 50% of the PRP (or reimbursement price; cf. 12.3.1.1). Furthermore, expensive pharmaceuticals with approved special indications are reimbursed at 100% or 90% if prescribed by a specialist or on behalf of the recommendation of a specialist for a defined indication. Thus co-payment for these pharmaceuticals in the category of reimbursement for special diseases (cf. 12.3.1) is lower (0% or 10%), under the condition that the pharmaceutical is prescribed by a specialist or a GP acting on advice of a specialist; otherwise they fall in the category of normative reimbursement at a higher co-payment rate.

The difference between the reimbursement sum, calculated from the reimbursement level and the reimbursement price (which is the basis for calculation of the reimbursement amount, cf. 12.3.1.1), and the PRP has to be paid by the patient in the pharmacy.

In addition, there are special reimbursement rules for people with low income. Socially disadvantaged persons, qualifying for this kind of reimbursement, are granted pharmaceuticals from a special list - containing about 600 POM and 100 OTC for the treatment of the most

[575] ICEG EC 2003

common chronic conditions - for free (threshold co-payment).[576] The list was last amended on 1 October 2005.[577]

Furthermore, pharmaceuticals may be reimbursed on behalf of individual applications. Such applications may be filed because of the social situation or a disease that needs special, expensive treatment. Individual applications are considered on a case to case basis, although there are trends in what kind of pharmaceuticals are reimbursed.[578]

Besides these forms of co-payment, Hungary operates a reference price system (cf. 12.3.2) thus offering the patient a choice between a variety of products at different co-payments. The patient is reimbursed a fixed sum, calculated from the reference price and the reimbursement level for a pharmaceutical, for one reference price group. The reference price system, both for groups based on INN and therapeutic reference price groups, applies to pharmaceuticals under normative reimbursement (co-payment of 50%, 30% or 10%), as well as to pharmaceuticals which are reimbursed due to special diseases at a co-payment rate of 10% or 0%. The difference between the reimbursement sum and the actual PRP of the chosen product has to be borne by the patient (cf. 12.3.2).

Thus there are strong incentives for patients to opt for cheaper pharmaceuticals or treatment alternatives.

With regard to reimbursable pharmaceuticals, Hungarian law holds that pharmacies are not allowed to deviate from the co-payment charge (cf. 12.2.1.3).

12.2.4 Information Transparency and Marketing

The EüM publishes the Health Bulletin (Egészségügyi Közlönyök), which is the “official gazette” for the Health Sector containing information on new legislation or decrees edited by the EüM, information on prices and market authorisation data. The gazette is available on the internet.[579] Information on the list of authorised pharmaceuticals is available in a practical form on the OGYI website[580], OGYI also publishes the list of para-pharmaceuticals holding a market authorisation. The Medicines Compendium including information on Summary of Product Characteristics (SmPC) of all national and centralised authorised pharmaceuticals is edited by the OGYI, but this information is not for free. Besides the above-mentioned publications other private information resources are available with information directed to different target groups (e.g. Pharmindex, pharmachip).

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576 Law on social provision 3/1993 and Decree 28/1993

577 OEP, personal communication, October 2005

578 OEP, personal communication, April 2006

579 http://www.kozlonykiado.hu/kozlonyok/index.php?m=2&p=0220&k=6

580 http://www.ogyi.hu/index.php?menu=menu&main=main/tkmain&lang=en

In Hungary prices and information on reimbursement status of reimbursable pharmaceuticals are published on the internet by the OEP. [581, 582] Also the MGYK publishes the PRP of pharmaceuticals, including prices of non-reimbursable pharmaceuticals. The PRP of non-reimbursable pharmaceuticals are recommended prices and are of informative nature.[583]

Prices of reimbursable pharmaceuticals are uniform throughout the country, so there is no need for patients to shop around. With regard to non-reimbursable pharmaceuticals prices may slightly vary, as pharmacies were obliged last summer to pass on discounts from wholesalers to customers, thus the PRP is calculated on the basis of the discounted wholesale price (cf. 12.2.1.3). According to information of the MGYK in practice PRP of non-reimbursable pharmaceuticals are uniform as well, as the method how discounts have to be passed on is not clearly specified.

The EüM also publishes a guide for health care professionals, which gives information on the price, reimbursement status and co-payment under specific conditions (e.g. special reimbursement for socially disadvantaged or special reimbursement with certain diseases) of pharmaceuticals.[584]

Pharmaceutical advertisement is regulated by the Law on commercial advertising activity both for POM (Art. 9) and OTC products (Art. 10)[585] and the Decree on advertisement of medical products with therapeutic effect but not qualified as pharmaceuticals[586]. General provisions are held in the Medicines Law[587], which also regulates the packaging of pharmaceuticals and information to customers and is in line with the Directive 2001/83/EC. According to Hungarian regulations it is allowed to advertise for OTC via broadcast media and print media.[588] Besides persons allowed prescribing or dispensing pharmaceuticals, information on pharmaceuticals may also be given by other persons with health qualifications registered with OGYI, as long as the EU provisions on pharmaceutical advertising are fulfilled. The Law on medicinal products for human use, the Law on commercial advertising activity and the Decree provide amongst others for provisions on the work of pharmaceutical representatives including the information they may give to health professionals; and contain rules on the warning notices which have to appear in pharmaceutical advertisements.

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581 http://www.oep.hu/portal/page?_pageid=35,34923&_dad=portal&_schema=PORTAL

582 Art. 26.4 Law 95/2005 on medicinal products for human use and on the amendment of other laws regulating the pharmaceutical market

583 http://www.mgyk.hu/szolg/gyogyszerar_kihirdetes

584 http://www.eum.hu/eum/eum.news.page?pid=DA_163361

585 Law 58/1997 on commercial advertising activity [1997. évi LVIII. törvény a gazdasági reklámtevékenységről], amended on 1 March 2001

586 Decree of the Ministry of Health 64/2003 [64/2003. (X. 31.) ESZCS rendelet az emberi felhasználásra kerülő gyógyszerek, gyógyszernek nem minősülő gyógyhatású készítmények reklámozásáról és ismertetéséről]

587 Law 95/2005 on medicinal products for human use and on the amendement of other laws regulating the pharmaceutical market [2005 évi XCV. törvény az emberi alkalmazásra kerülő gyógyszerekről és egyéb, a gyógyszerpiacot szabályozó törvények módosításáról]; Decree on the labelling and package leaflet of medicinal products for human use of the Minister of Health 30/2005; [30/2005. (VIII. 2.) EüM rendelet az emberi alkalmazásra kerülő gyógyszerek címkéjéről és betegtájékoztatójáról]

588 Law on TV and Radio Broadcasting 1/1996 [1996. évi I. Törvény a rádiózásról és televíziózásról]

Besides these regulations there is a code of ethics[589], which was first issued by Hungarian Pharmaceutical Manufacturers Association (MAGYORSZ) and the Association of Innovative Pharmaceutical Companies in Hungary (AIPM) in 1995 and last amended in 2005. The code is in line with Hungarian Legislation and EU regulations and complies with the Requirements of the European Federation of Pharmaceutical Industry Associations (EFPIA). This self regulatory industry code, which is binding on members of both associations, lays down detailed regulations for promotional activities and information provided to health professionals by the pharmaceutical industry.

A Communication Ethics Committee (Kommunikációs Etikai Bizottságot, KEB) was established by MAGYOSZ and AIPM, which shall deal with the enforcement and cases of breach of the code of conduct. Complaints can be filed by companies, the OEP or the OGYI or any health professional. The decisions of the KEB are published twice a year in official journals of the Hungarian Chamber of Doctors and Chamber of Pharmacists to generate adverse publicity. The severest sanction for the breach of the code is the termination of membership of MAGYOSZ and AIPM.

From a legal point of view the Directorate for Consumer Protection (Fogyasztóvédelmi Főfelügyelőség, FVF) and on first instance the county consumer protection directorates supported by the OGYI are the competent institutions for controlling the advertising of pharmaceuticals, thus may put sanctions for violation of advertising rules.[590]

However, the pharmaceutical industry is still the main source of pharmaceutical information for physicians who are in turn primarily deciding on which medical treatment a patient will receive.

Besides, pharmacists take an active role with regard to selection of pharmaceuticals. With regard to self-medication pharmaceuticals, pharmacists are obliged by law to inform patients on therapeutic and side effects of the pharmaceutical and on interactions with other pharmaceuticals taken; furthermore pharmacists have to inform patients on the possibility to substitute the prescribed product and on the prices of pharmaceuticals.

The patients´ choice on medicines is characterised by the reference price system, which has been expanded over the last years (cf. 12.3.2). A list of interchangeable pharmaceuticals is published on the internet by the OGYI and is updated on a monthly basis.[591] The OEP tries to influence on the prescribing habits of doctors by feed-back on prescribing habits but there are no formal prescribing controls in place. There are plans to introduce compulsory INN prescribing for GP; hospital doctors already have to prescribe by INN, when dismissing a patient (cf. 12.3.4.1).

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589 AIPM, 2005; http://www.igy.hu/index.php3?sid=11455281311403684889&tract=2&mod=etikkod

590 Art. 27.1 Law 95/2005 on medicinal products for human use and on the amendment of other laws regulating the pharmaceutical market

591 http://www.ogyi.hu/download/helyett060215.pdf

12.3 Reimbursement

The OEP is responsible for the reimbursement of pharmaceuticals in the out-patient sector, while in the in-patient sector pharmaceutical expenditure is covered through the DRG system. Private insurance only plays a minor role in reimbursement of pharmaceuticals.

The manufacturer has to submit an application for inclusion into reimbursement to the OEP, which has to contain, among others,

- the proposed manufacturer price,
- the proposed reimbursement category and level of reimbursement,
- benefits compared to already reimbursed pharmaceuticals,
- prices of the pharmaceutical and market share in other countries, mostly EU Member States (external price referencing, cf. 12.2.2.3)
- daily treatment costs in comparison to treatment alternatives at ATC 4 level (internal price referencing, cf. 12.2.2.2)
- proposed number of patients treated annually
- medical effectiveness studies and
- pharmaco-economic studies.[592]

After the application has been checked by the Pharmaceutical Department of the OEP with regard to formal correctness it is forwarded to the TÉB. The pharmaceutical Technology Evaluation Committee (TÉB) consists of a chairperson nominated by the OEP and 10 members; 5 persons having voting rights and 5 consultants. Members of the TÉB are representatives of the OEP (5), the Ministry of Health (EüM;1), the Ministry of Economy and Transport (Gazdasági és Közlekedési Minisztérium, GKM; 1), the Hungarian Chamber of Pharmacists (1), the Hungarian Chamber of Doctors (MOK; 1), and a member nominated by the Association of Hungarian Medical Societies (Magyar Orvostársaságok és Egyesületek Szövetségének, MOTESZ; 1).[593] The TÉB considers the reimbursement application; among the criteria taken into account are the proof of medical efficacy, submitted price proposal (affordability), public interest; pharmaco-economic analysis provided by the manufacturer or made by the National Institute for Strategic Health Research (ESKI) and the analyses prepared by the pharmaceutical department.

The reimbursement decision is taken by the Head of the Pharmaceutical Department of the OEP on basis of the recommendation of the TÉB. The reimbursement level may be negotiated with the manufacturers; the decision on reimbursement is based on the price proposed

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592 http://www.oep.hu/pls/portal/docs/PAGE/SZAKMA/OEPHUSZAK EUSZOLG/GYOGYSZER/KERELMEZES/KERELEM_GYOGYSZERTBTAM.PDF

593 http://www.oep.hu/pls/portal/docs/PAGE/SZAKMA/OEPHUSZAK_ EUSZOLG/GYOGYSZER/TEBUGYREND.PDF

by the manufacturer. Prices are not set by the OEP but may be negotiated in the reimbursement decision process - though officially the OEP only may accept or reject a reimbursement application; there is no separate pricing procedure.

Decisions on inclusion to the positive list and the reimbursement level are published in the Journal of the Health Insurance (Egészségbiztosítási Közlöny). In addition, the OEP publishes a list of pharmaceuticals and their reimbursement category on the internet, furthermore the EüM publishes the guide for health care professionals guide for health care professionals (Segédlet a gyógyszerkészítmények rendeléséhez és kiadásához).

12.3.1 Pharmaceutical Lists and Reimbursement Categories

In Hungary there is a positive list in use. Pharmaceuticals in this list are categorised in accordance with the World Health Organization's (WHO) ATC code (anatomical, therapeutic and chemical classification). The positive list includes pharmaceuticals at different reimbursement levels (normative reimbursement, preferential reimbursement, reimbursement due to social reasons, hospital pharmaceuticals). There is no negative list.

The OEP operates a reference price system, clustering pharmaceuticals on ATC 5 level (INN), but also clustering pharmaceuticals in therapeutic reference price groups at ATC 4 level (cf. 12.3.2 and 12.2.3).

Different reimbursement categories are applied:

- Pharmaceuticals on the positive list are generally reimbursed in kind, at rates of 90%, 70% and 50% (so-called normative reimbursement) of the pharmacy retail price (PRP). Normative reimbursement accounts for approximately one quarter of OEP´s pharmaceutical expenditure.[594]
- Furthermore, expensive pharmaceuticals with approved special indications are reimbursed at 100% or 90% if prescribed by a specialist or on behalf of the recommendation of a specialist, otherwise they fall under the lower reimbursement levels of normative reimbursement (preferential reimbursement category). These maximum reimbursement categories apply to individuals suffering from severe chronic diseases like cancer, multiple sclerosis or diabetes (100%), or epilepsy, rheumatoid arthritis or asthma (90%) and are only applicable with treatment of these diseases. The list of disease conditions is defined by EüM.[595]

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[594] Ministerial and the Self-Government of the Health Insurance Fund Statement, 1996; published in Welfare Gazetta 25/1996 and Law 83/1997 on compulsory health services in the framework of social security and Decree 217/1997 on compulsory health service provision [1997. évi LXXXIII. törvény a kötelező egészségbiztosítás ellátásairól, egységes szerkezetben a végrehajtásáról szóló 217/1997. (XII. 1.) Korm. Rendelettel]

[595] Decree of the Ministry of Health 1/2003 [1/2003. (I. 21.) ESzCsM rendelet a társadalombiztosítási támogatással rendelhető gyógyszerekről és a támogatás összegéről]

A decree by the EüM defines which ATC Groups qualify for which category of normative and/or preferential reimbursement.[596]

- In addition, there is special reimbursement for people with low income (reimbursement for socially disadvantaged persons). Approximatly 5% of the population are eligible to pharmaceuticals reimbursed at 100% according to a separate list, revised each year by a committee with representatives of the OEP, the EüM, the MOK and the MGYK. This list also comprises about 100 OTC products.
- Furthermore, pharmaceuticals can be reimbursed on behalf of individual applications. Individual applications may be filed because of the social situation or medical condition that needs special treatment.
- Besides the OEP provides very expensive pharmaceuticals through a special budget; these pharmaceuticals are purchased centrally by the OEP via tenders (e.g. for haemophilia).[597]

12.3.1.1 Reimbursement Price

Manufacturer prices of all pharmaceuticals are free, with exception of reimbursable pharmaceuticals, where the price has to be accepted by the OEP (cf. 12.2.1.1). Wholesale prices and PRP are calculated via mark-up schemes applicable to all pharmaceuticals regardless of their reimbursement status (cf. Table 12.4 and Table 12.5). Prices of all pharmaceuticals are notified to the EüM and the MGYK and are applicable to the whole pharmaceutical market, regardless of the payer (third party payer vs. private).

Out-patient pharmaceutical reimbursement by the OEP for pharmaceuticals which are not included in a reference price group is based on the PRP, which is the basis for calculating the reimbursement sum. Within the reference price system the reference price of the INN based reference price cluster or the therapeutic reference price cluster is the reimbursement price, i.e. the basis for calculation of the reimbursement sum.

Due to the a series of cost containment measures the current PRP is not always the basis for calculation of the reimbursement sum, because of e.g. previously frozen prices and/or individual agreements between manufacturers and government.

The reimbursement sum with different reimbursement categories and the current PRP are published by the OEP and the EüM (cf. 12.2.4).

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596 Decree 69/2005 of the Ministry of Health. [69/2005 (XII. 28.) EüM rendelet a törzskönyvezett gyógyszerek és a különleges táplálkozási igényt kielégítő tápszerek társadalombiztosítási támogatásba való befogadásának szempontjairól és a befogadás vagy a támogatás megváltoztatásáról szóló 32/2004. (IV. 26.) ESzCsM rendelet módosításáról]

597 OEP, personal communication, May 2006

12.3.1.2 Selection Criteria

Reimbursement of pharmaceuticals hinges either on the pharmaceutical category as classified by ATC and on the underlying disease for selected ATC groups. A decree has been published by the EüM allocating each ATC group to a normative reimbursement category, and if applicable to a preferential reimbursement category (this is 90% or 100% reimbursement according to clearly specified indications and restrictions).

The TÉB assesses reimbursement applications taking into account the seriousness of the disease (chronic or acute, long-term or short-term, reversible or irreversible), the proof of clinical efficacy and the cost-effectiveness of the treatment (budget impact). Sub rules apply to reimbursement applications for generic pharmaceuticals and variations of a pharmaceutical already reimbursed (e.g. new pharmaceutical form, strengths or pack size).

Criteria for inclusion to the positive list are held in a decree, which should comply with the Transparency Directive (Council Directive 89/105/EEC), and has been amended twice since.[598]

12.3.1.3 Pharmaceuticals on Positive List

There are approximately 6,200 pharmaceuticals on the positive list (counted including different pharmaceuticals forms, strengths and pack sizes). The positive list also includes the 0% reimbursement category comprising pharmaceuticals used in in-patient care; by integrating them to the reimbursement list they are evaluated by the TÉB, and the OEP has control over the price, which may be thus negotiated.

Approximately 1,500 of these pharmaceuticals fall under normative reimbursement categories; 1,500 pharmaceuticals are clustered in INN based reference price groups and more than 200 in therapeutic reference price groups.

Besides the general positive list, there is a list for patients with low income. In this category (Közgyógyellátottak) some OTC are as well reimbursable. To benefit from this list an authorisation by the local government (special card) is necessary. This list comprises approximately 700 products (including all strengths and pack sizes).

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598 Decree 10/2004 of the Ministry of Health [10/2004. (XII. 15.) EüM rendelet a törzskönyvezett gyógyszerek és a különleges táplálkozási igényt kielégítő tápszerek társadalombiztosítási támogatásba való befogadásának szempontjairól és a befogadás vagy a támogatás megváltoztatásáról szóló 32/2004. (IV. 26.) ESzCsM rendelet módosításáról] and Decree 69/2005 of the Ministry of Health [69/2005. (XII. 28.) EüM rendelet
a törzskönyvezett gyógyszerek és a különleges táplálkozási igényt kielégítő tápszerek társadalombiztosítási támogatásba való befogadásának szempontjairól és a befogadás vagy a támogatás megváltoztatásáról szóló 32/2004. (IV. 26.) ESzCsM rendelet módosításáról]

12.3.1.4 Generics

The generic market share is quite high with approximately 50% of the market in terms of volume in the year 2004.[599]

For generics the same procedure rules apply for reimbursement as for original products. The pricing of generic pharmaceuticals is based on internal price referencing. The first generic pharmaceutical applying for reimbursement should be priced 30% below the originator product (cf. 12.3).

All generics are included in the reference price system, which has been expanded in July 2005 (cf. 12.3.2).

12.3.1.5 Non-reimbursable Pharmaceuticals

OTC products and pharmaceuticals used in hospital settings are in general excluded from reimbursement. However, pharmaceuticals excluded from general reimbursement, may be reimbursed under certain circumstances, e.g. OTC products on the list for socially disadvantaged persons or in general pharmaceuticals on individual application.

There is no explicit negative list.

12.3.1.6 Appeal Procedure

The Head of the Pharmaceutical Department of the OEP decides in the first instance, based on the recommendation of the TÈB, on the inclusion to the positive list. In the case of a negative decision, the manufacturer may appeal to the Head of the OEP. In this case an appeal committee (Fellebbviteli Bizottság, FB) consisting of representatives of the Ministry of Health (EüM); the Ministry of Finance (Pénzügyminisztérium, PM), the Ministry of Economy and Transport (GKM), the Prime Minister Office and the Economic Competition Office deals with the case. Against the decision of this committee the producer can turn to the judicial branch.

The procedure rules for the Appeal Committee are set by the Director of the OEP.

12.3.1.7 Delisting

According the agreement between the government and the pharmaceutical industry associations (cf. 12.2.2.4) it is agreed not to exclude any pharmaceuticals from the positive list until 1 July 2006. Theoretically and legally the OEP may de-list pharmaceuticals whose efficacy is seriously doubted, the cost-efficiency is not proved or there was no market volume at all within the last six month; furthermore pharmaceuticals may be de-listed because the marketing rules were violated by the manufacturer, or the manufacturer does not comply with the agreements between the pharmaceutical industry and government. .

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[599] EGA 2005

12.3.2 Reference Price System

In 1997, a reference price system (fix reimbursement system) on the basis of the same active ingredient (INN) was introduced for 75 substance groups.[600] In 2005 there were nearly 100 reference price clusters in the normative reimbursement category and further 40 reference price groups reimbursed on the basis of special indications. The reference price groups are further subdivided according to strength and pharmaceutical form. The reference price for each cluster is set on the basis of the cheapest product (reference product) available on the market. The OEP selects the reference price products and publishes the list of reference price products. This list may be changed once a year, which last happened on 1 July 2005.

In 2003, the first therapeutic reference price group (covering therapeutically similar pharmaceuticals on ATC 4 level) was introduced for cholesterol lowering agents. In 2005, there were about 20 therapeutic reference price clusters either in normative or preferential reimbursement category. For this category reference prices are set on the basis of daily treatment costs and days of treatment.

Information on reference price groups and daily treatment cost are published by the OEP.[601]

Pharmacists are obliged to inform patients on the possibility of substitution and the cheapest pharmaceutical with the reference price system.[602]

The patient has to pay the difference between reference price and the PRP in the pharmacy, thus the OEP may only reimburse part of the PRP.

12.3.3 Pharmaceutical Budgets

In Hungary there are no pharmaceutical budgets being applied for doctors, meaning there is no fixed prescribing budgets in terms of money for health care professionals.

Still the prescription volume or prescription habits of general practitioners and specialists are monitored by the OEP (cf. 12.3.4.1).

600 Decree No. 217/1997 on the compulsory health service provision

601 http://www.oep.hu/pls/portal/docs/PAGE/SZAKMA/OEPHUSZAK_EUSZOLG/GYOGYSZER/GYOGYSZERREN DELESHEZ.ZIP

602 Law on Medicines of Human Use and Modifications of other Laws Regulating the Pharmaceutical Market 95/2005 [2005. évi XCV. Törvény az emberi alkalmazásra kerülő gyógyszerekről és egyéb, a gyógyszerpiacot szabályozó törvények módosításáról]

12.3.4 Other Volume Control Oriented Measures

12.3.4.1 Prescription Monitoring and other Doctors-related Measures

The OEP monitors the prescription patterns of their contracted general practitioners and specialists and compares the individual prescription habit in comparison to the average of all contract doctors. Doctors are provided with this information, which benchmarks the prescription volume classified by e.g. patient age, gender or therapeutic drug group at local and national level. The prescription habits of doctors who are markedly above the average is analysed more closely.

A system giving bonuses to doctors based on their prescription habits is under discussion. The introduction of electronic patient prescription cards is planned on a nationwide basis for the year 2007; currently these cards are tested in three regions. The cards will also allow identifying fraudulent prescriptions.

12.3.4.2 Generics and Parallel Trade

As in other new EU Member States like Slovenia or Poland the generic market share is quite high compared to market shares in the old Member States. Generics account for approximately 50% of the market in terms of volume in the year 2004.[603] In terms of value the generic market accounted for slightly above one quarter of pharmaceutical sales according to IMS Health.[604]

Prescribing by INN is obligatory for hospital doctors with dismissal of patients; in the outpatient sector INN prescribing is allowed, though not obligatory. However, pharmacists are obliged to offer generic substitution in all cases as there might be a significant difference in co-payment for the patients.[605] The existence of a reference price system and the co-payment system provides an incentive to the patient to opt for cheaper generics, though there are no incentives for pharmacists to substitute generic.

There is no active information policy on generics provided to the patients by the OEP.

Parallel imports to Hungary are of no importance to the market[606] and are not taken into consideration when deciding on the reimbursement status (cf. 12.3.1.2).

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603 EGA 2005

604 PPR 2005

605 MGYK, personal communication, June 2005

606 MGYK, personal communication, May 2006

12.4 Overview of the Reimbursement Market in Hungary

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Public Authorities				
Decide on prescription status	X		OGYI	
Decide on manufacturer price		X	Free for all pharmaceuticals	Price Act of 1990; Decree of the Ministry of Health 25/1997 on medicines marketed without social security reimbursement
Agree on manufacturer price	X		Negotiations for reimbursable pharmaceuticals - OEP might accept or reject a price proposal by the manufacturer	
Fix wholesale margin	X		Maximum margin for all pharmaceuticals	Decree of the Ministry of Health 19/2001 on the commercial price mark-up of medicinal products
Fix pharmacy retail price	X		Via margin for all pharmaceuticals	Decree of the Ministry of Health 70/2003 on the commercial price mark-up of medicinal products
Decide on reimbursement status	X		OEP	Law 83/1997 and Decree 217/1997 on compulsory health services in the framework of social security; Decree of the Ministry of Health 69/2005.
Decide on reimbursement price	X		OEP - decide on reimbursement level and reference price group; accept or reject price proposed by manufacturer	Decree 32/2004 of the Minister of Health Family and Social Affaires
Use pharmaco-economic guidelines	X		With reimbursement decision; studies are evaluated by ESKI	Guideline of the Ministry of Health on conducting pharmaco-economic studies
Use Internal reference pricing	X		For generics	Decree 32/2004 of the Minister of Health Family and Social Affaires
Use External reference pricing	X		OEP uses external price referencing for new active substances	Decree 32/2004 of the Minister of Health Family and Social Affaires
Price freezes	X		Currently prices can only be increased in special cases regulated by a contract between the government and the pharmaceutical manufacturers and a ministerial decree	- Decree 32/2004 of the Minister of Health Family and Social Affaires - contract between government and pharmaceutical industry

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Margin cuts	X		Wholesale margins for all pharmaceuticals are set by the EüM, 1999 and 2001 they have been statutorily reduced. Also pharmacy margins for all pharmaceuticals are set by EüM; they have been last modified in January 2004 which resulted in an increase of the average pharmacy margin. Before they were statutorily reduced in 2001.	
Discounts and Rebates	X		Neither wholesale nor pharmacies have to grant any rebates or claw-backs to OEP or any other public body. There are payback arrangements etc. for the industry. (2003, 2005, 2006)	
Company profit control		X	Company profits are not directly controlled - but company profits are influenced by payback mechanisms and price freezes	
Country specific:				
Pharmaceutical Industry				
Sets manufacturer price freely	X		For all pharmaceuticals; free to change each quarter for non-reimbursable; negotiations for price of reimbursable pharmaceuticals	
Notifies manufacturer price	X		Notifies price to EüM and MGYK; for reimbursable pharmaceuticals prior agreement with OEP has to be found	
Negotiates manufacturer price	X		For reimbursable pharmaceuticals with OEP - officially companies propose a price, which may be accepted or rejected by OEP	
Is free to set price below fixed manufacturer price	X		Free to reduce price of non-reimbursable and reimbursable pharmaceuticals every quarter; has to notify EüM, OEP and MGYK of price decrease	Decree 32/2004 of the Minister of Health Family and Social Affaires
Decides on application for reimbursement	X			

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Negotiates reimbursement price	X		Proposes price to the OEP with reimbursement application, may alter the price if deemed to high by OEP.	
Free to keep manufacturer price above reimbursement price	X		Within the reference price system: maximum by 20% higher then the reference daily therapeutic cost of the active ingredient based fixed group	Decree 32/2004 of the Minister of Health Family and Social Affaires
Free to grant rebates/discounts to wholesalers	X			
Free to grant rebates/discounts to pharmacies	X		Usually wholesale acts in between manufacturers and pharmacies.	
Can engage in marketing towards doctors	X		In line with code of conduct	- Law on commercial advertising activity 1997 amended on 1 March 2001 - Decree of the Ministry of Health 64/2003 - Law on Medicines of Human Use and Modifications of other Laws Regulating the Pharmaceutical Market 95/2005 - Code of Conduct
Can engage in public advertising	X		Only for authorised OTC products	- Law on commercial advertising activity 1997, amended on 1 March 2001 - Law on Medicines of Human Use and Modifications of other Laws Regulating the Pharmaceutical Market 95/2005 - Decree of the Ministry of Health 64/2003

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Can provide information toward patients	X		For OTC pharmaceuticals	- Law on TV and Radio Broadcasting 1/1996 - Law on commercial advertising activity 1997, amended on 1 March 2001 - Decree of the Ministry of Health 64/2003 - Law on Medicines of Human Use and Modifications of other Laws Regulating the Pharmaceutical Market 95/2005
Applies for switches and de-listing	X		Have to file application to OGYI	
Country specific:				
Distribution Chain				
Wholesaler				
Margins are fixed by statute	X		Mark-up scheme for all pharmaceuticals regardless of reimbursement or prescription status	Decree of the Ministry of Health 19/2001 on the commercial price mark-up of medicinal products
Margins are subject to statutory discounts/rebates		X		
Free to grant discounts/rebates to pharmacies	X			
Pharmacists				
Margins are fixed by statute	X		Mark-up scheme for all pharmaceuticals regardless of reimbursement or prescription status	Decree of the Ministry of Health 70/2003 on the commercial price mark-up of medicinal products
Free to set retail price		X		
Obliged to inform patient on cheaper product	X			Law on Medicines of Human Use and Modifications of other Laws Regulating the Pharmaceutical Market 95/2005
Obliged to substitute by a generic		X	Obliged to inform patient on the possibility of substitution	Law on Medicines of Human Use and Modifications of other Laws Regulating the Pharmaceutical Market 95/2005
Allowed to substitute by a generic	X			
Obliged to substitute by a parallel traded product		X		

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Allowed to substitute by a parallel traded product	X			
Therapeutic/ analogous substitution is allowed		X		
Are subject to statutory discounts/ rebates		X		
Claw back system exists		X		
May grant rebates to customers		X	Not for reimbursable pharmaceuticals. For non-reimbursable pharmaceuticals: Are obliged by law to pass on discounts negotiated with wholesalers by applying the mark-up scheme to the reduced wholesale price; not applied in practice. May grant discounts for privately purchased pharmaceuticals on an individual basis.	Law on Medicines of Human Use and Modifications of other Laws Regulating the Pharmaceutical Market 95/2005
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			
Are obliged to inform on co-payment/ deductibles	X			
Prescription habits are monitored	X		Doctors receive a reimbursement allocation list, which pits the prescription habits of the GP against the average at local, county and national level.	
Are subject to prescription guidelines		X		
Budgets are controlled		X		
Allowed to prescribe INN	X			

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Obliged to prescribe INN		X	GP are allowed to prescribe by INN, not obliged; however hospital doctors have to prescribe by INN when dismissing a patient.	
Can oppose generic substitution	X		By writing a remark on the prescription.	
Can oppose therapeutic substitution			Not applicable.	
Can oppose substitution by parallel traded product			Not applicable.	
Country specific:				
Patients				
Can shop for cheapest price of the product		X	PRP are uniform throughout the country for reimbursable pharmaceuticals. PRP may slightly vary for non-reimbursable pharmaceuticals, as pharmacists are obliged to pass on discounts negotiated with wholesalers; in practice they are uniform throughout the country. May ask for a discount for privately purchased pharmaceuticals.	Law on Medicines of Human Use and Modifications of other Laws Regulating the Pharmaceutical Market 95/2005
Pay a flat rate per prescription/pack		X		
Pay a certain percentage per prescription/pack or a deductible	X		Certain percentage according to reimbursement class (normative reimbursement), underlying disease and prescribing doctor (preferential reimbursement)	
Annual minimum co-payment		X		
Annual maximum co-payment		X	No, but exemptions for low income patients	
May ask for substitution by a generic	X		May ask the doctor or the pharmacist, if not ruled out by prescribing doctor.	
May oppose substitution by a generic	X		Only at own expense	
May ask for substitution by a parallel traded product			Not applicable	

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Can oppose substitution by a parallel traded product			Not applicable	
Can oppose substitution only on payment of price difference			Not applicable	
Has to pay the difference between reimbursement price and PRP	X		Has to pay the difference between the reimbursement sum, calculated from the reimbursement price or the reference price and the reimbursement category and the PRP at the pharmacy.	
Has access to full public information on prices and products	X		Has access to full information on PRP and reimbursement levels.	
Country specifics:				

Source: ÖBIG 2006

IRELAND

13 Ireland

13.1 Pharmaceutical System

13.1.1 Regulatory Framework and Authorities

In Ireland the healthcare system is mainly funded from general taxation (75%), private funding via voluntary health insurance[607] (accounting for 11%) and patient co-payments (the remainder).

Overall responsibility lies within the Department of Health and Children (DoHC) which governs healthcare policy and expenditure in Ireland. While many other European countries have moved towards more decentralisation of the health system, Ireland is heading in the other direction. Until 2004, healthcare was administered through ten regional health boards. At the beginning of 2005, this competence was shifted from the regional health boards to the newly founded Health Service Executive (HSE) that, as a single entity, now manages the health service (Health Act 2004, No 42 of 2004)[608].

The entire population is entitled to a core publicly funded service. Access to public health service is based on a means-tested system of eligibility comprising two categories:

- Category I:

  People with an income below a certain threshold and their dependants fall into category I. They are entitled to a wide range of free services (in-patient and out-patient services including pharmaceutical therapy) under the so-called General Medical Services (GMS) scheme. The GMS scheme is also known as the medical card scheme and covers approximately 30 percent of the Irish population.

- Category II:

  The rest of the population receives free in-patient treatment with a co-payment, and pharmaceutical expenditure above a threshold is reimbursed under the Drug Payments (DP) scheme.

This eligibility structure forms the key feature of the Irish healthcare system. In addition, there is also a well developed private sector which can be accessed through voluntary health insurance cover and/or direct payment. Even in the public health system there is, however, a mixture of public and private care.

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607 Health Insurance (Amendment) Act 2003, Number 11 of 2003, http://www.oireachtas.ie/documents/bills28/acts/2003/a1103.pdf

608 S.I. No. 797 of 2005; Health Act 2004, No. 42 of 2004 http://www.dohc.ie/legislation/statutory_instruments/pdf/si20050797.pdf?direct=1

The DoHC is in charge of the overall pharmaceutical policy, whereas other statutory bodies such as the Irish Medicines Board (IMB), the HSE Primary Care Reimbursement Service (PCRS), the Pharmaceutical Society of Ireland (PSI) and the Irish Pharmaceutical Healthcare Association (IPHA) fulfil concrete tasks in the field of authorisation of pharmaceuticals (IMB) reimbursement (PCRS and Product Committee of DoHC), the authorisation of pharmacists (PSI) and pricing (IPHA). All relevant stakeholders are displayed in Table 13.1

Besides the EMEA (European Medicines Agency) being the competent authority for the centralised and decentralised market authorisation of pharmaceuticals, the IMB is the relevant authority on national level for the authorisation of pharmaceuticals. Legal basis is the Irish Medicines Board Act 1995[609]. The IMB regulates the licensing and sale of pharmaceuticals for human use in Ireland by means of the Medicinal Products (Licensing and Sale) Regulations (S.I. No.142 of 1998)[610], Prescription and Control of Supply (S.I. No. 540 of 2003)[611] and relevant EC Directives, in particular Council Directive 2004/27/EC (Definition of Medicine products and Registration) and Directive 2004/24/EC (Herbal Medicine Products). Before a pharmaceutical can be authorised for use, an application has to be made to the IMB that has to contain all of the necessary data supporting its quality, safety and efficacy.

Pricing activities are covered by an agreement between the IPHA and the DoHC. The current agreement between IPHA and the DoHC started in 1993, it was renewed in 1997 and extended in 2001 until 2005. At the moment there are negotiations concerning another renewal of this agreement.

On behalf of the HSE, the PCRS makes payments to general practitioners, pharmacists, dentists and optometrists/ophthalmologists with whom agreements have been signed.

Table 13.1 contains an overview of relevant stakeholders in Ireland.

609 Irish Medicines Board Act 1995, http://www.irishstatutebook.ie/ZZA29Y1995.html

610 S.I. No. 142 of 1998, Medicinal Products (Licensing and Sale) Regulations 1998, http://www.irishstatutebook.ie/ZZSI142Y1998.html

611 S.I. No. 540 of 2003, Medicinal Products (Prescription an Control of Supply) Regulations 2003 http://www.irishstatutebook.ie/ZZSI540Y2003.html

Table 13.1: Ireland - Relevant Authorities and Market Player in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Department of Health and Children (DoHC), Product Committee	Ministry of Health (Regulatory Body for Pharmaceuticals), Reimbursement Decisions	DoHCGeneral Medical Services Division Hawkins House IRL-Dublin 4 Ireland Tel.: +353 1 6354 113 Fax: +353 1 6711 947 http://www.doh.ie	MS. Bernadette Ryan Hawkins House IRL-Dublin 4 Ireland Tel.: +353 1 6354 113 Fax: +353 1 6711 947 Bernadette_Ryan@health.irlgov.ie
HSE National Shared Services - Primary Care Reimbursement Service (PCRS)	General Medical Services Board (Payments and Reimbursement)	HSE Exit 5 M50, North Road Finglas IRL-Dublin 11 Ireland Tel.: +353 1 8343 644 Fax: +353 1 8343 589 http://www.gmspb.ie	Ms. Deirdre Elliot Exit 5 M50 North Road IRL-Dublin 11 Ireland Tel.: +353 1 8647100 Fax: +35 1 8343 589 deirdre.elliott@mailv.hse.ie
Irish Medicines Board (IMB)	Medicines Agency (Authorisation of pharmaceuticals, Registration of medical devices)	IMB Earlsford Center, Earlsford Terrace IRL-Dublin 2 Ireland Tel.: +353 1 6764 9717 Fax: +353 1 6767 836 http://www.imb.ie	Ms. Suzanne Mc Donald Earlsford Center, Earlsford Terrace IRL-Dublin 2 Ireland Tel.: +353 1 6764 9717 Fax: +353 1 6767 836 imb@imb.ie
Irish Pharmaceutical Healthcare Association (IPHA)	Association of Pharmaceutical Industry - (Pricing Agreement)	IPHA Franklin House 140 Pembroke Road IRL-Dublin 4 Ireland Tel.: +353 1 6603 350 Fax: +353 1 6686 672 http://www.ipha.ie	Ms. Bridget Cunningham Franklin House 140 Pembroke Road IRL-Dublin 4 Ireland Tel.: +353 1 6603 350 Fax: +353 1 6686 672 info@ipha.ie
Pharmaceutical Distributors Federation (PDF)	Wholesalers' Association	PDF Glandore House, 33 Fitzwilliam Place IRL-Dublin 2 Ireland Tel.: +353 1 2024 855 Fax: +353 1 2024 855	Mr. Kieran Obroin Glandore House, 33 Fitzwilliam Place IRL-Dublin 2 Ireland Tel.: +353 1 2024 855 Mcpal@iol.ie

Institution	Task	Contact details/URL	Responsible person
Pharmaceutical Society of Ireland (PSI)	Statutory Board for Licensing Pharmacists	PSI 18 Shrewbury Road, Ballsbridge IRL-Dublin 4 Ireland Tel.: +353 1 283 7294 Fax: +353 1 283 7678 http://www.pharmaceuticalsociety.ie	Ms. Cecily Roche 18 Shrewbury Road, Ballsbridge IRL-Dublin 4 Ireland Tel.: +353 1 283 7294 pharm-soc@pharmaceutical.society.ie
Irish Pharmaceutical Union (IPU)	Association of Pharmacists	Butterfield House - Butterfield Avenue, Rathfarnham IRL-Dublin 14 Ireland Tel.: +353 1493 6401 Fax: +353 1493 6407 info@ipu.ie www.ipu.ie/	Ms. Pamela Logan Butterfield House - Butterfield Avenue, Rathfarnham IRL-Dublin 14 Ireland Tel.: +353 1493 6401 Fax: +353 1493 6407 info@ipu.ie
Irish Medical Organisation (IMO)	Medical Doctors' Association	IMO Fitzwilliam Place, 10 IRL-Dublin 2 Ireland Tel.: +353 1 6767 273 Fax: +353 1 6612 758 http://www.imo.ie	Mr. Asam Ishtiaq Fitzwilliam Place, 10 IRL-Dublin 2 Ireland Tel.: +353 1 6767 273 Fax: +353 1 661 2758 imopresident@imo.ie
Irish Patients Association	Association of Patients	Irish Patients Association 24 Church Road IRL-Ballybrack, Co Dublin Ireland Tel.: +353 1 2722 555 Fax: +353 1 2722 506 info@irishpatients.ie	Mr. Stephen McMahon 24 Church Road IRL-Ballybrack, Co Dublin Ireland Tel.: +353 1 2722 555 Fax: +353 1 2722 506 www.irishpatients.ie/
Irish National Centre for Pharmacoeconomics St. James's Hospital (NCPE)	Research Institution	NCPE James's Street IRL-Dublin 8 Ireland Tel.: +353 1 4103 427 Fax: +353 1 4730 596 www.ncpe.ie/	Mr. Michael Barry James's Street IRL-Dublin 8 Ireland Tel.: +353 1 4103 427 Fax: +353 1 4730 596 mbarry@stjames.ie

Source: ÖBIG 2006

13.1.2 Market Players

13.1.2.1 Pharmaceutical Industry

Ireland's pharmaceutical sector now hosts 14 of the world's top 15 pharmaceutical companies[612]. At the end of 2005 there were 120 pharmaceutical companies active in Ireland, thereof 83 non-Irish ones. The growth of the pharmaceutical industry in Ireland is remarkable. Employment in the sector has grown from 5,200 persons in 1988 to 24,000 at the beginning of 2006. In the year 2005 Ireland's pharmaceutical industry became the world's biggest net exporter of pharmaceuticals.

With exports amounting to more than € 37.5[613] billion in 2004, equalling 44% of the total export volume of Ireland, the pharmaceutical sector has became a very important part of the Irish economy and its continuous development has contributed significantly to the Irish economic prosperity. Recent figures indicate that the sector is still rising with pharmaceutical exports growing by 7.3% to € 17.02 billion for the first five months 2005.

In general, Ireland is more an export country than an import country; in terms of parallel trade, Ireland is more a source for parallel export than the other way round.

13.1.2.2 Distribution

In Ireland, there is a multi-channel distribution of pharmaceuticals, which means that there are no exclusive sales contracts for pharmaceuticals with single wholesalers in place.

Pharmaceuticals are, in general, dispensed by pharmacies. Furthermore they can be distributed by

- Self-dispensing doctors in case the nearest pharmacy is more than 5 kilometres away,
- Drugstores and several other retail outlets (e.g. corner shops, petrol stations, supermarkets) for a very limited number of OTC pharmaceuticals.

There were 1,333 pharmacies in 2005, which corresponds to nearly 3,000 inhabitants per pharmacy. Legal basis for pharmacies is the Pharmacy Act 1875 (the "Principal Act") that established the Pharmaceutical Society of Ireland (PSI) as regulatory body to oversee pharmacies and pharmacists and to provide for a system of registration of pharmacists by the Society. The Pharmacy Act 1875 was amended in the Pharmacy Act 1962[614] and S.I. No.239/1987[615] European Communities (Recognition of Qualifications in Pharmacy) Regulations, 1987.

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612 IPHA 2005, http://www.ipha.ie/

613 Central statistic office (CSO); http://www.cso.ie/

614 The Pharmacy Act 1962; No. 14/1962, http://acts.oireachtas.ie/zza14y1962.1.html

615 S.I. No. 239/1987, http://www.irishstatutebook.ie/ZZSI239Y1987.html

In February 2006 there were 7,739 pharmaceuticals (including different pharmaceutical forms, dosages and package sizes) authorised, which is a rather low number compared to the EU average. In Ireland, there are less pharmaceuticals on the market (around 6,000) than are actually authorised (7,739). Unauthorised pharmaceuticals may be ordered and imported on a named patient basis.

Regulation 19(1) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, latest amended in 2005 imposes a statutory ban on supplying any medicinal product by mail order (including the internet sales).[616]

13.1.2.3 Patients

The role of the patients in the choice of a pharmaceutical is rather minor, although under 'The Freedom of the Information Act 1997'[617] and its Amendment 9/2003[618] every person has the right to access the records held by Government departments and certain public bodies (like HSE, local authorities and voluntary organisations). However, patients are usually not informed on products and their prices when they get their pharmaceutical prescribed.

One legal right of a patient is that of information on pharmaceutical treatment, e.g. the HSE and hospitals provide leaflets with explanations to patients. Hospitals have a Freedom of Information officer who assists patients to make requests in a way that complies with the Act. The Irish Patients Association is a non-political and independent Irish interface between patients and institutions which also assists patients in claiming specific medical treatment.

In 2001, the DoHC published The National Health Strategy "Quality and Fairness: A Health system for you". The strategy specifies that the empowerment and co-determination of patients should be improved. In the year 2003 the DoHC launched guidelines for a national standardised approach to the measurement of patient's satisfaction.[619].

13.2 Overview of Pharmaceutical System

Figure 13.1 gives an overview on the Irish pharmaceutical system.

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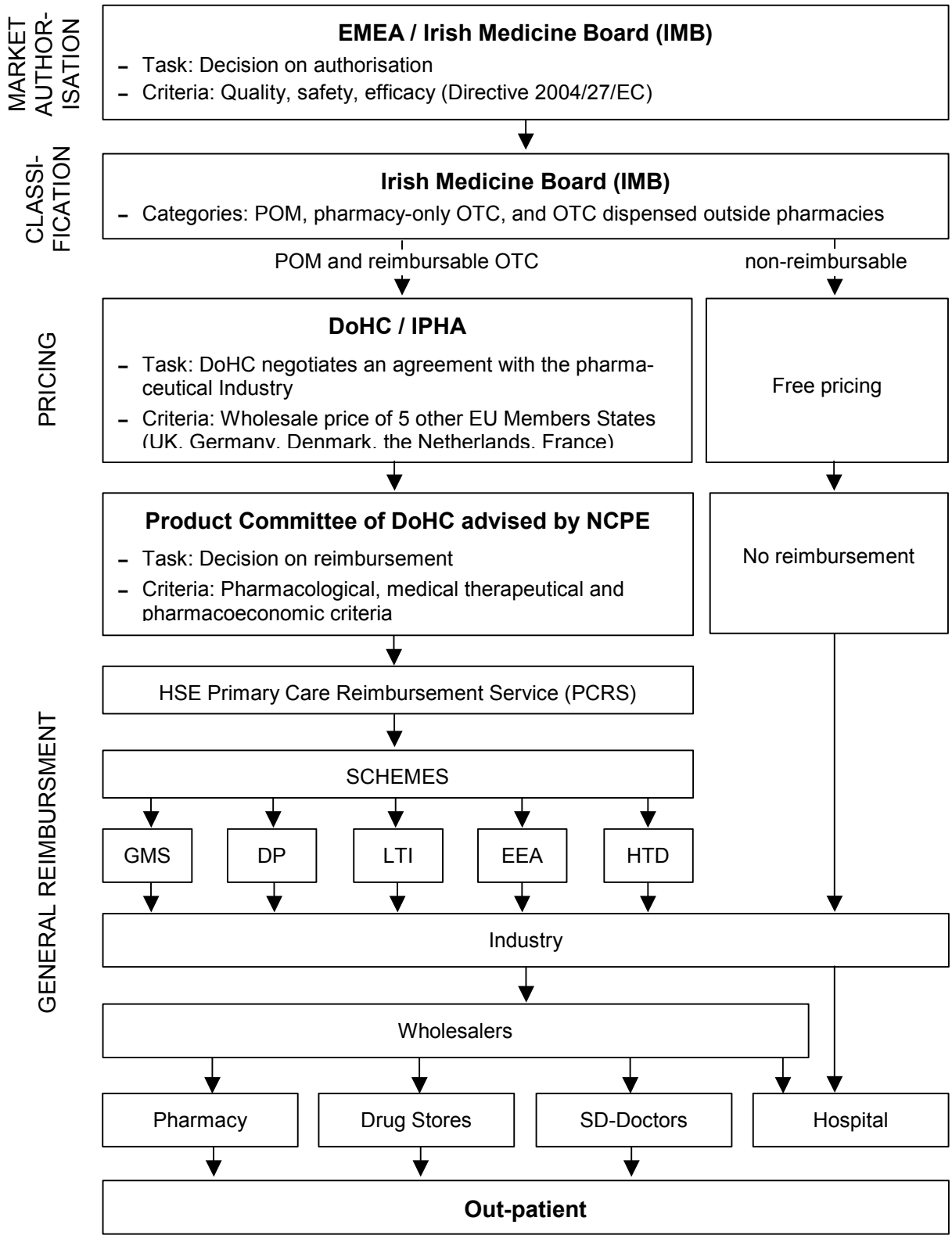
616 HSE 2005

617 The Freedom of Information Act 1997, No 13/1997, http://acts.oireachtas.ie/zza13y1997.1.html

618 The Freedom of Information (Amendment) 2003; No. 9/2003 http://www.oireachtas.ie/documents/bills28/acts/2003/a903.pdf

619 Department of Health and Children; Health Strategy Action 48 http://www.dohc.ie/issues/health_strategy/action48.pdf?direct=1

Figure 13.1: Ireland - Pharmaceutical System, 2006



Source: ÖBIG 2006

13.3 Pricing

13.3.1 Scope of Price Control

Pricing of pharmaceuticals to the health service is outlined in an voluntary agreement between the IPHA and the DoHC in which a price freeze was decided on. The first agreement between IPHA and the DoHC was in 1993, it was renewed in 1997 and extended in 2001 until 2005 (cf. 13.3.2.4). Thus, the pharmaceutical prices are still at the level of 1993. The agreement covers pharmaceuticals prescribed and reimbursable under the Community Drug schemes (e.g. the General Medical Services scheme) and all pharmaceuticals supplied to hospitals and the HSE (see below). Almost all reimbursable pharmaceuticals are listed in the GMS Code Book (cf. 13.4.1.2). The legal basis is the EC Directive 89/105/EC. The most important schemes are[620]:

- General Medical Services (GMS) Scheme

  Under the GMS scheme persons are eligible, who are unable, without undue hardship, to arrange general practitioner medical and surgical services for themselves and their dependants as well as all persons aged 70 years and over receive free general medical service. Pharmaceuticals and appliances supplied under this Scheme are provided through retail community pharmacies. In most cases the doctor gives a completed prescription to a person, who takes it to any pharmacy that has an agreement with the HSE to dispense GMS prescriptions. All GMS claims are processed and paid by the PCRS (cf. 13.1.1 and 13.4.1.1.1).

- Drugs Payment (DP) Scheme

  People who are eligible to the DP scheme are ordinarily resident in Ireland and are not eligible to the GMS scheme (people who have no current medical card). Under the DP scheme no individual or family is required to pay more than € 85 in a calendar month for approved pharmaceuticals for themselves or their families out-of-pocket. In order to benefit from this scheme, a person must be registered with the HSE. Items currently reimbursable under the DP Scheme are those listed in the GMS Code Book. DP claims are processed and paid by the PCRS (cf. 13.4.1.1.3).

- Long Term Illness (LTI) Scheme

  The LTI scheme entitles patients, who suffer from one or more of 15 defined illnesses, to obtain, without charge and irrespective of income, necessary pharmaceuticals and/or appliances for the management of these conditions. All LTI claims are processed and paid by the PCRS (cf. 13.4.1.1.2).

- Other schemes:

  There are further schemes like the European Economic Area (EEA) scheme for visitors from other EU Member States, EEA countries and Switzerland and the High Tech Drugs (HTD) scheme, introduced in 1996, which facilitates the supply of certain high cost phar-

620 HSE, http://www.hse.ie/en/Publications/HSEPublications/FiletoUpload,2579,en.pdf

maceuticals, e.g. those used in conjunction with chemotherapy, beta-interferon etc. by community pharmacies (previously these pharmaceuticals had been supplied primarily through hospitals (cf. 13.4.1.1.4).

One of the characteristics of the agreement between DoHC and IPHA is that Ireland links the wholesale price of pharmaceuticals to the lesser of either the currency-adjusted UK wholesale price or the average of the currency-adjusted wholesale prices of Denmark, France, Germany, the UK and the Netherlands. Since 1993 there has been a prize freeze on wholesale prices in Ireland.

If the average currency adjusted increase or decrease in the wholesale price in the 5 basket countries exceeds 10% - the price freeze may be reviewed. If a new pharmaceutical is not available in all nominated EU states on the date of initial price notification to the DoHC, the Irish wholesale price shall be agreed between representatives of the manufacturer or importer and the DoHC. Details are explained in section 13.3.1.2 and Table 13.2 provides a concise overview of the Irish pricing system.

Table 13.2: Ireland - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Non-reimbursable products, mostly OTC products	Non-reimbursable products, mostly OTC products	Non-reimbursable products, mostly OTC products
Price agreement	Reimbursable pharmaceuticals in schemes GMS, HTD, DPS, LTI and hospital products	Reimbursable pharmaceuticals in schemes GMS, HTD, DPS, LTI	Fixed fee for services
Price Negotiations	For pharmaceuticals not available in the nominated 5 EU Member States for external referencing	For pharmaceuticals not available in the nominated 5 EU Member States for external referencing	Not applied
Price/volume agreements, discounts/rebates	3% rebate for all pharmaceuticals dispensed under the GMS Scheme	5% rebate for pharmaceuticals reimbursed under the HTD Scheme	GMS: Wholesale price + dispensing fee € 2.98 DPS ; LTI: Wholesale price + dispensing fee € 2.59 + 50% mark-up HTD: Dispensing fee of € 49.64 / month
Institution in charge of pricing	DoHC and IPHA		
Basis	Legal background: EC Directive 89/105/EC DoHC / IPHA agreement Prize freeze agreement 1993		

GMS = General Medical Services Scheme, DP = Drugs Payment Scheme, LTI = Long Term Illness, Scheme, EEA = European Economic Area, HTD = High Tech Drugs Scheme, IPHA = Irish Pharmaceutical Healthcare Association, DoHC = Department of Health and Children, OTC = Over-the-counter

Source: ÖBIG 2006

13.3.1.1 Manufacturer Price

In general the DoHC is in charge of pricing in Ireland. Rather than statutory pricing, since 1993 the DoHC has been negotiating an agreement on the methodology how pharmaceutical prices are set with IPHA. The current price freeze agreement between IPHA and the DoHC was renewed in 1997 and extended in 2001 until 2005. Currently (since beginning of 2006) there are negotiations concerning another ongoing renewal. There is no specific legal basis in place, it is a written agreement but it is not publicly available.

Finally, the agreement makes provisions for appeals by manufacturers in exceptional circumstances for variation of any terms, including those on pricing. It is reviewed by the DoHC and the IPHA at regular intervals and any matters relating to interpretation or operation of the agreement are resolved in discussion between the two parties.

Regarding to pharmaceuticals for the GMS Scheme, it is agreed in the IPHA agreement that the manufacturers and main importers shall supply wholesalers at the appropriate manufacturer price. Manufacturers and importers shall themselves be free, if they so wish, to supply to pharmacists at the Irish trade price (pharmacy purchasing price). Pharmaceutical companies are allowed to supply pharmacies directly at the manufacturer price[621].

13.3.1.2 Wholesale Price

The IPHA and DoHC Agreement concerns the pricing of pharmaceuticals at wholesale level.

The wholesale price usually includes a 15% margin, equivalent to a mark up of 17.66% on the manufacturer price. For pharmaceuticals considered as innovative and expensive pharmaceuticals, i.e. those in the High Tech Drug Scheme cf. 13.3.1, the margin is 10% and discounts of 7-9% are common for POM.

The IPHA Agreement also regulates that the wholesale price of any new pharmaceutical introduced in Ireland, on or after August 1997, should not exceed the lesser of either the currency-adjusted UK wholesale price or the average of the currency-adjusted wholesale prices in Denmark, France, Netherlands, the UK and Germany (cf. 13.3.2.3).

If any new pharmaceutical is not available in all 5 nominated EU Member States on the date of initial price notification to the DoHC, the Irish wholesale price shall not exceed the average of the currency adjusted wholesale prices in the nominated EU States in which the new pharmaceutical is available. If a given pharmaceutical is not available in any of the nominated EU Member States, the Irish wholesale price will be agreed between representatives of the manufacturer concerned and the DoHC cf. 13.3.1.

621 IPHA/DoHC agreement, written information

Table 13.3: Ireland - Wholesale Margin Scheme, 2006

Type	Maximum Margin in % of wholesale price
"Standard" Pharmaceuticals	15%
Innovative Pharmaceuticals (High Tech Drug Scheme)	10%
Prescription only pharmaceutical	7 - 9%

Source: ÖBIG 2006

13.3.1.3 Pharmacy Retail Price

The pharmacy retail prices for pharmaceuticals vary depending on the applicable scheme and the formulation of the pharmaceutical prescribed (repeating i.e. this is the same as "applicable scheme"). In general the pharmacist is remunerated the trade (pharmacy purchase price / in Ireland called ex-wholesale price) price of the pharmaceutical and an additional service fee (cf. Table 13.4).

Community pharmacies are the primary dispensary network for POM in the country and most are signed up in the State Refund scheme, i.e. contracting with the HSE. The price of a pharmaceutical does not differ from its dispensing place. It is the same in community pharmacies, in drugstores or through self-dispensing doctors.

Table 13.4: Ireland - Pharmacy Mark Up Scheme, 2006

Pharmacy Retail Prices Depends on patient's reimbursement status	
Drug Scheme	Pharmacy Retail Price
GMS Scheme	Wholesale price + fixed dispensing fee of € 2.98
DPS/LTI Scheme	Wholesale price + 50% mark-up + fixed dispensing fee of € 2.59
High Tech Pharmaceuticals Scheme	Patient care fee: € 49.64/month

GMS = General Medical Services Scheme, DPS = Drugs Payment Scheme, LTI = Long Term Illness Scheme

Source: NCPE

Table 13.5: Ireland - Price of Pravastatin® 20 mg Daily Dose on the GMS, LTI and DP Schemes, 2006

GMS Scheme Price		DP/LTI Scheme Price	
Ingredient cost of 28 tablets	€ 43.44	Ingredient cost of 28 tablets: + 50% mark-up	€ 43.44 € 21.72
Dispensing fee	€ 2.98	Dispensing fee	€ 2.59
Oral formulation - no VAT	€ 0.00	Oral formulation - no VAT	€ 0.00
Total payment to pharmacy:	**€ 46.42**	**Total payment to pharmacy**	**€ 67.75**

GMS = General Medical Services Scheme, DP = Drugs Payment Scheme, LTI = Long Term Illness Scheme, VAT = Value Added Tax

Source: NCPE, 2005

13.3.1.4 Value Added Tax (VAT)

A VAT rate of 21% is charged on non-oral pharmaceuticals, e.g. topical products, in Ireland. The standard VAT rate is 21%. No VAT is charged on oral pharmaceuticals.[622]

13.3.2 Price Related Cost-containment Measures

13.3.2.1 Pharmaco-economic Evaluation

A demonstration of cost-effectiveness is not a pre-requisite for reimbursement but the DoHC has the right to seek cost benefit studies for any new chemical entity introduced to Ireland on or after August 1997. Consequently the DoHC may request a pharmaco-economic submission to be made by the pharmaceutical company to the National Centre for Pharmaco-Economics (NCPE). To aid this process NCPE has, together with the DoHC and the IPHA, developed explicit pharmaco-economic guidelines, the so called Irish Healthcare Technology Assessment Guidelines.[623]

These guidelines detail the data required in such a submission and the method for pharmacoeconomic analyses and provide a framework for the DoHC, the HSE, and prescribers, to obtain information on the cost effectiveness of health care technology. The framework is important because it potentially leads to a more cost effective use of healthcare resources.

622 European Commission - DG Taxation and Trade Union 2006

623 NCPE; http://www.ncpe.ie/u_docs/doc_62.doc

13.3.2.2 Internal Price Referencing

Internal price referencing plays no role in Ireland.

13.3.2.3 External Price Referencing / Cross country Referencing

Under the current agreement between DoHC and the IPHA, Ireland links the wholesale price by formula to those of five other EU Member States. The price to the wholesaler of any pharmaceutical shall not exceed the lesser of the currency adjusted wholesale price in United Kingdom or the average of wholesale prices in Denmark, France, Germany, Netherlands and the United Kingdom (cf. 13.3.1.1).

13.3.2.4 Price Freezes / Stops

Prices are fixed during the term of the pricing agreement. If international price movements lead to prices of products in the five reference Member States varying by 10%, both the DoHC and the IPHA can review the price freeze.

Price adaptations by manufacturers are permitted at the discretion of the DoHC, provided that such action is cost-neutral for HSE. The DoHC reserves the right to seek an appropriate compensation if the terms of the agreement are not adhered to.[624]

13.3.2.5 Margin Cuts

Wholesale margins on pharmaceuticals are regulated through a linear mark up-scheme, which is in place in an unchanged form since the introduction of the IPHA agreement in 1993 (cf. 13.3.1.2 and 13.3.1.3).

13.3.2.6 Discounts, Rebates and Company Profit Controls

Pharmaceutical manufacturers and importers must rebate to the PCRS 3% of the value within 3 days of the date of invoice, at wholesale price level, of all pharmaceuticals dispensed under the GMS scheme.

In the case of hospitals no discount will be given for orders under € 634.87 or orders placed with a wholesaler for pharmaceutical for which he/she is not the main agent or importer. The common business discounts are offered on the basis of normal monthly settlement of accounts.

HSE may be authorised to appoint one hospital within each region to combine single orders from satellite hospitals, so as to qualify them for any discounts.[625]

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624 PPR Concise Guide 2005

625 Health Service Executive (HSE), Gerald Byrne

13.3.2.7 Parallel Trade

An Irish-market pharmaceutical may be parallel-imported in Ireland provided that the importer obtains an authorisation to market the product from the IMB. This special marketing authorisation, known as a parallel product authorisation (PPA), is issued when someone other than the original product authorisation holder or his agent seeks to import into Ireland. The person responsible for the parallel importation of a product must hold a wholesalers licence under the Medical Preparation Regulations, 1993 - 1996.[626,627] If he/she intends to carry out the necessary labelling operations himself, he/she must hold a manufacturer's licence under the Medical Preparations (Licensing of Manufacture) Regulations, 1993 - 1996.[628] Parallel imports are always marked with "P.C.O. MFG." (Pharmaceutical Cosmetics and Over the Counter Product Manufacturer) to allow for easy identification for pharmacists and patients.

A guide to parallel product authorisation for human pharmaceutical use and a framework for parallel imports are disposable by IMB.[629] The same pricing and reimbursement rules are applied for parallel imported products as for their originals.

Nonetheless, parallel traders might be encouraged to import products from lower priced countries, as parallel import has a high relevance in the UK, which makes - due to the shared language - repackaging, labelling and adaptation of leaflets for the imported pharmaceuticals easier. But given Ireland's peripheral location in the EU and its proximity to a larger market with a shared official language, there has been more concern that parallel exportation from Ireland to the UK would cause shortages of medicinal products in Ireland. These anxieties should have lessened somewhat with the European Court of Justice (ECJ) decision in SI-FAIT v GlaxoSmithKline (Case C-53/03). Here the ECJ stated that the refusal by a dominant pharmaceutical company to fulfil all orders from wholesalers does not automatically constitute an abuse of a dominant position, despite such refusal clearly limiting parallel trade of the products in question.[630]

Judging from records of pharmacy sales in the Eastern regions of Ireland an analysis of the top 15 pharmaceuticals (in terms of expenditure on the GMS scheme, together accounting for 30% of total spending) indicates that parallel imports accounted for 1.3% of prescriptions issued and 1.24% of expenditure on those drugs in December 2004. Analysis of the top 20 pharmaceuticals by expenditure on the DP scheme in the Eastern region demonstrates that parallel imports accounted for approximately 1.9% of prescriptions and 2% of expenditure in this group in December 2004.[631]

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626 Directive 92/25/EEC transposed to (S.i. No. 39 of 1993 and Amendment S.i. No. 188 of 1999); http://www.irishstatutebook.ie/ZZSI188Y1999.html

627 Guidance note on the wholesaling of medicinal products for human use in Ireland, Irish Medicine Board (IMB); http://www.imb.ie/uploads/publications/1885878_IND-001-02x.pdf

628 S.i. No. 188 of 1999, http://www.irishstatutebook.ie/ZZSI188Y1999.html I

629 IMB, http://www.imb.ie/uploads/publications/5734018_PPAGuidelinemay04.pdf

630 HSE 2005

631 Unpublished information by NCPE, @ from 11 July 2006

13.3.3 Co-Payments

Pharmaceuticals prescribed for patients covered by the GMS scheme are fully reimbursed. There is also no patient co-payment for pharmaceuticals prescribed for the management of the chronic illnesses covered by the LTI scheme. When the DP scheme was introduced in July 1999 no individual or family was required to pay more than € 53.33. In December 2002 there was a increase to € 70.- per month. In 2005, the maximum patient co-payment was increased to € 85.- per month. This maximum co-payment limit is still valid.

In June 2005 a new initiative was implemented (the GP Visit Card), to assist those who do not qualify for a medical card on income grounds but for whom the cost of visiting a GP is often prohibitively high. The GP visit card enables patients to visit the GP for free, but does not cover the cost of pharmaceutical. It is intended to benefit approximately 200,000 people who do not have a medical card.

13.3.4 Information Transparency

In Ireland prices of pharmaceuticals are hard to access by patients and in former times also by doctors or other health experts, as there is no public information on prices like a general public price database. POM and OTC that are advertised to the public are not reimbursable (with the exception of nicotine replacement therapy which is advertised to the public and is reimbursed on the GMS scheme).[632]

The best widely available expert information source for pharmaceuticals is the MIMS service which is published as a paper version and up-dated monthly. MIMS is an independently written publication designed as a prescribing guide for general practitioners. MIMS is supplied free of charge to general practitioners in active practice and hospital consultants. The paper version contains the therapeutic index, new pharmaceuticals, pharmaceuticals no longer available, POM and a manufacturers' index. Another price register, the so-called GMS List of Reimbursable Items, published by the PCRS is not available to the public.

Pharmaceutical industry is the main source of pharmaceutical information for physicians in Ireland and physicians are ultimately the persons who decide on which medical treatment a patient will receive. Advertising and industry behaviour towards health professionals is regulated by law (gifts, benefits and bonuses are explicitly forbidden).[633] The amendment of Regulation 2001/83/EC in terms of the patient leaflet etc. are not yet fully implemented in Ireland, but there are transitional arrangements in place.[634] An example for an already implemented

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632 AESGP 2005

633 The Medical Preparations (Advertising) Regulations 1993, S.I. No. 76/1993, http://www.irishstatutebook.ie/ZZSI76Y1993.html amended 1996 (S.I. No. 24 of 1996).

634 http://www.imb.ie/uploads/publications/transitional%20arrangements_22nov.pdf

change is the modification for visual impaired persons ("Braille requirements"), which entered into force on 16 November 2005.[635].

General information on pharmaceuticals like the brand name, pharmaceutical form, the active ingredients, clinical particulars, special warnings and precautions for use, pharmacological properties and marketing authorisation holder are outlined in the IPHA Medicines Compendium.[636]

Furthermore, as part of the Health Service Reform Program, the Health Information and Quality Authority (HIQA) was established to ensure that high quality information is available to the health care system and thus, to facilitate delivery high quality services that are based on evidence-supported best practice. The HIQA will be responsible for developing health information, promoting and implementing quality assurance programmes nationally and overseeing Health Technology Assessment. The interim HIQA was established by statutory instrument in March 2005.

13.4 Reimbursement

There are several reimbursement schemes in place in Ireland. The predominant form is the GMS scheme, which covers approx. 30% of the population. The other schemes are the so-called DP, LTI, European Economic Area (EEA) and the HTD schemes (cf. 13.4.1.1 for their market relevance). Prior to reimbursement under the HSE a medicine has to be included in the GMS code book, i.e. the Irish positive list. Details may be found in section 13.3.1.

The majority of pharmaceutical expenditure in Ireland under the Community Drug Schemes (€ 1,092.7 million in 2004) relates to claims processed under the GMS, DP, LTI, EEA and the HTD Schemes. The number of prescription items, cost, eligibility criteria and patient co-payment for each of these schemes is shown in Table 13.6. The total expenditure on the schemes (including doctors, pharmacies, dentists, investment in General, High Tech Drugs scheme, optometrists, administration) was € 1.65 billion in 2004 and has grown to € 1.97 billion in the year 2005.

635 http://www.imb.ie/uploads/publications/Braille%20declaration%20Nov05.doc

636 http://www.medicines.ie

Table 13.6: Ireland - Number of Prescription and Expenditure, 2003 / 2004.

HSE	No. of prescriptions (millions)		Payment to pharmacies: pharmaceutical cost + dispensing fee + VAT (million €)		Eligibility	Patient co-payment
	2004	2003	2004	2003		
GMS	35.03	32.24	763.32	650.66	All below income threshold & all over 70 years	None
DP	9.93	9.31	226.83	204.42	All who are not eligible for GMS or LTII schemes	€ 85 per month maximum (2006)
LTI	1.67	1.46	85.55	73.35	Fifteen specific chronic conditions	None
HTD	0.17	0.14	6.80[637]	5.56	All patients for selected high cost pharmaceuticals	None, if GMS eligible, otherwise € 85 per month
EEA	0.08	0.07	1.80	1.60	EC national from other Members States	None
Other	0.29	0.23	8.4	7.62	-	-
Total	**47.17**	**43.45**	**1,092.69**	**943.21**		

HSE = Health Service Executive, GMS = General Medical Services Scheme; DP = Drugs Payment Scheme, LTI = Long Term Illness Scheme, EEA = European Economic Area, HTD = High Tech Drugs Scheme, Other = Methadone Treatment Scheme, Health (amendment) Act 1996 and Dental treatment Services Scheme

Source: HSE, GMS Report for the year ended 31 December 2004, HSE 2005

13.4.1 Pharmaceutical Lists and Reimbursement Categories

13.4.1.1 Community Drug Schemes

Ireland is characterised by a range of so-called Community Drug schemes (cf. section 13.2). The five major schemes are presented and in the end of the section Figure 13.2 shows the respective market shares of the schemes in terms of volume :

13.4.1.1.1 GMS Scheme

The number of eligible persons under the GMS scheme at the end of the year 2004 was 1,148,914 persons that is 28.42% of population. Over 96% of eligible GMS persons availed of pharmaceutical dental or ophthalmic services provided by more than 5,323 doctors, pharmacists, dentists and optometrists.

PCRS publishes the “GMS List of Reimbursable Items” (cf. 13.3.4) with monthly updates for general practitioners and pharmacists. There is no special regime for “essential products” in

[637] Payment to wholesalers under the HTD scheme 2004 amounted to € 141.41.

Ireland. All kind of pharmaceuticals that a general practitioner would routinely prescribe are GMS reimbursable.

To be reimbursed under the GMS Scheme, pharmaceuticals have to comply with the following prerequisites:

- The manufacturer/agent submits an application for reimbursement to DoHC
- Pharmaceuticals are approved by the DoHC and put on a monthly list, provided they must have a current EU Commission Marketing Authorisation (MA) or a Product Authorisation (PA) issued by the IMB
- Pharmaceuticals must belong to a category eligible for reimbursement under the GMS Scheme, pursuant to EU Council Directive 89/105/EC
- Pharmaceutical, if approved, is notified by DoHC to the PCRS on a monthly basis
- Monthly updates are prepared by the PCRS and sent out to all relevant contractors (doctors and pharmacists)
- Pharmaceuticals must comply with the pricing structure of the IPHA Agreement

13.4.1.1.2 Long Term Illness (LTI) SCHEME

At the beginning of the year 2005 there were 93,504 persons registered under the LTI scheme that is 2.31% of the population, and expenditure on pharmaceuticals under this scheme was € 85.55 million for the year 2004.

The LTI scheme entitles patients suffering from any one of fifteen specified chronic conditions (cf. Table 13.7 to full pharmaceutical reimbursement, for the management of these conditions, irrespective of income.

Table 13.7: Ireland - Chronic Conditions for Full Pharmaceutical Reimbursement in LTI Scheme, 2006

Patients with the following medical conditions are eligible for the LTI Scheme			
Mental Handicap	Cystic Fibrosis	Cerebral Palsy	Multiple Sclerosis
Haemophilia	Hydrocephalus	Epilepsy	Acute Leukaemia
Phenylketonuria	Muscular Dystrophies	Diabetes Mellitus	Parkinsonism
Spina Bifida	Diabetes Insipidus	Mental Illness for persons <16 years	

Source: NCPE 2004[638]

[638] NCPE 2004, http://monitor.isa/486550656/1257464T060323094655.txt.binXMysM0dapplication/mswordXsysM0dhttp://www.ncpe.ie/u_docs/doc_21.doc

13.4.1.1.3 Drugs Payment (DP) Scheme

The number of persons registered under the DP scheme at the end of the year 2004 was 1,469,251, that is 36.33% of the population.

The DP scheme was introduced in 1999 and applies to Irish residents who do not have a medical card. Under the DP scheme no individual or family will be required to pay more than € 85.- in any calendar month for approved prescribed pharmaceuticals. Family expenditure covers the nominated adult, his/her spouse and children less than 18 years - persons over 18 years and less than 23 years who are in full time education may be included as dependents.

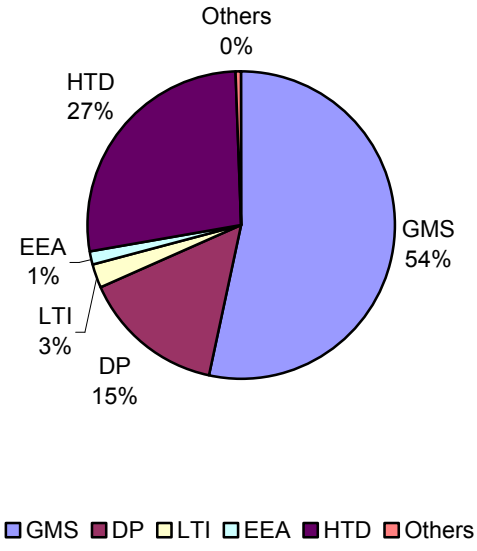
13.4.1.1.4 European Economic Area (EEA) Scheme and High Tech Drugs (HTD) Scheme

The EEA scheme provides for visitors from other EU/EEA countries and Switzerland, with established eligibility, emergency general practitioner services while on a temporary visit to Ireland. In 2004, prescription-only medicines dispensed under the EEA scheme amounted to € 1.8 million reimbursement.

Payments to wholesalers under the HTD Scheme totalled € 141.41 million and payment to pharmacies to cover dispensing fees was € 6,803,167.

Figure 13.2: Ireland - Breakdown of Prescriptions Claims, 2004

Volume of prescriptions claimed by pharmacies



GMS = General Medical Services Scheme, DP = Drugs Payment Scheme, EEA = European Economic Area, HTD = High Tech Drugs Scheme, LTI = Long Term Illness Scheme, Others = Methadone Treatment Scheme, Health (amendment) Act 1996 and Dental treatment Services Scheme

Source: Health Service Executive 2005

13.4.1.2 Pharmaceuticals on Positive List

In February 2006 7,740 pharmaceuticals were registered in Ireland. 4,628 of them are included in the GMS Reimbursement Code (GMS List of Reimbursable Items) (cf. 13.3). Besides, there is also a reimbursement list for the HTD Scheme which includes 270 pharmaceuticals (cf. 13.3.4).

13.4.1.3 Generics

Generics are subject to the IPHA pricing agreement (cf. 13.3.1). The manufacturer price offered by generic manufacturers is generally lower than the brand price. The prices of generics are usually set at 20% of the manufacturer price of the original pharmaceutical (= the now off-patent brand) although no minimum price difference is specified in the agreement.

Prescribing by generic name (International Non-proprietary Name, INN) - though allowed by law - is still relatively uncommon, as doctors prefer to retain control over the pharmaceutical that is dispensed - hence the branded nature of the generics market (cf. 13.4.4.2 for generic substitution).

In general reimbursement rules for generics and off-patent pharmaceuticals are the same as for on-patent products.

13.4.1.4 Non-reimbursable Pharmaceuticals

OTC products that are intended for self-medication are not reimbursable. There is no exemption, e.g. for old-age pensioners or children from this rule. POM and OTC that are advertised to the public are not reimbursable (with the exception of nicotine replacement therapy which is advertised to the public and is reimbursed on the GMS scheme).[639]

13.4.2 Reference Price System

In Ireland no reference price system is applied.

13.4.3 Pharmaceutical Budgets

On 1 January 1993 the Irish government introduced a financial incentive scheme directed towards doctors, the Indicative Drug Target Scheme (IDTS). The aim of the scheme was to encourage more rational and economic prescribing, by allowing GPs to invest savings made through more economic prescribing in practice development whilst recognising clinical independence. The scheme provides for the calculation of monetary prescribing targets for each GMS Scheme general practitioner, taking into consideration the makeup of his/her patient panel with regard to the age and sex of the patients

639 AESGP 2005

In each year certain specialist and high cost drugs are excluded from the target setting process and are treated on a budget neutral basis. The Scheme is voluntary and general practitioners retain the right and obligation to prescribe, as they consider necessary. Information on prescribing patterns and expenditure are provided to doctors on a regular basis, to enable them to keep within their budgets and improve their performance. Any savings achieved are divided between the GP concerned and the HSE to be used for the development of primary care services.

There are no sanctions in place for those who fail to meet their target. Savings are encouraged through the form of incentives. The IDTS is now under review and it is intended that this review will inform the way forward in relation to the value or otherwise of incentive schemes in relation to prescribing.[640]

13.4.4 Other Volume Control Oriented Measures

13.4.4.1 Prescription Monitoring and Other Doctors-related Measures

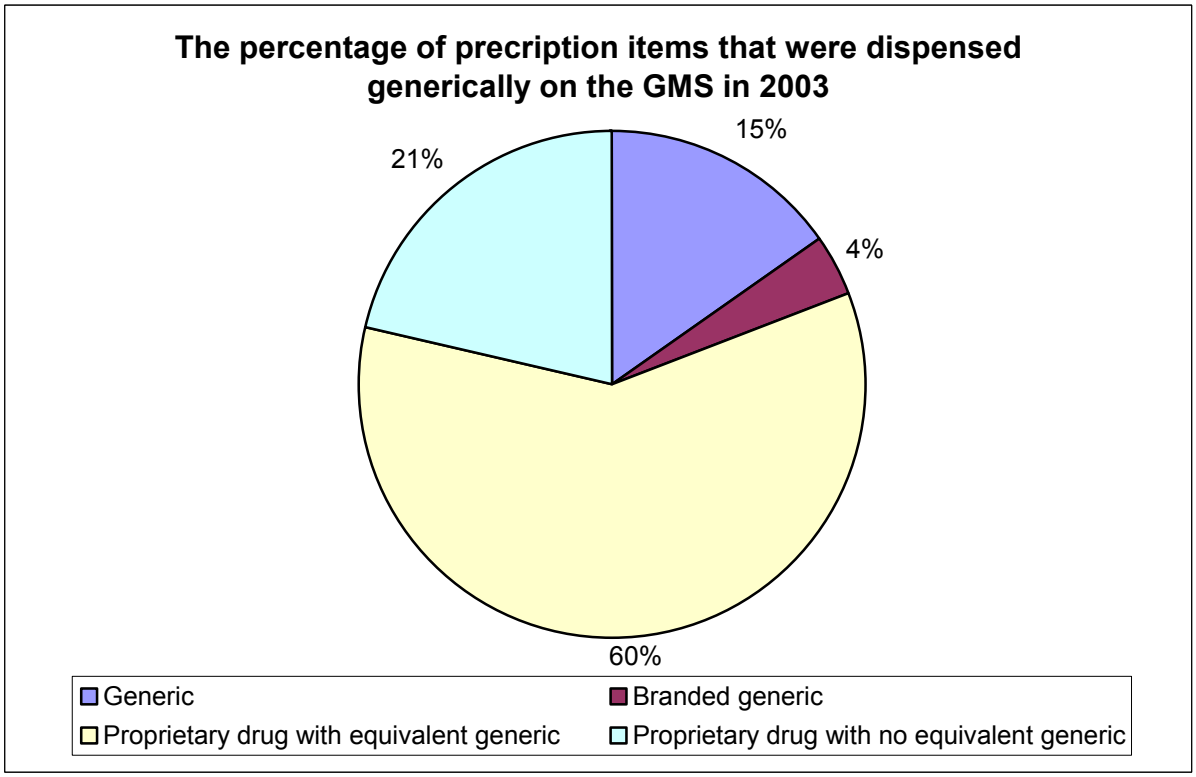
Under the GMS or DP scheme doctors are free to prescribe the pharmaceuticals of their choice from a list of pharmaceuticals. The DoHC has the right to influence the prescribing habits of doctors, e.g. via above mentioned IDTS. The National Medicines Information Centre (NMIC) provides independent information and advice to healthcare professionals in primary and secondary care, particularly general practitioners and community pharmacists, on all aspects of therapeutic and rational use of pharmaceuticals.

13.4.4.2 Generics and parallel trade

Although the DoHC has a policy of encouraging generic, i.e. INN prescribing, Ireland has had a rather low rate of generic drug utilisation for a long time. Approximately 19% of prescriptions on the GMS were dispensed generically in 2003 (cf. Figure 13.3).

640 HSE 2005

Figure 13.3: Ireland - Generics on the GMS, 2003



Source: NCPE 2005

Generic substitution by the pharmacist is prohibited, but pharmacists are encouraged via their contracts to dispense one of the less expensive pharmaceuticals available if the doctors has written an INN prescription.[641]

However, the Irish Consumer Strategy Group has recommended in their report in 2004 to allow generic substitution and to further evaluate the current Indicative Drug Target Scheme. Their recommendations were endorsed by a High Level Interdepartmental Committee in 2006.[642]

Though some reports[643] indicate huge savings through an enhanced use of generics it has to be observed, that many of the generics on the Irish market are branded (so-called “fancy generics”) rather than unbranded, meaning that they are still rather expensive as the generic manufacturers “brand” them to get a higher price.

As already stated in section 13.3.2.7 parallel trade plays - especially compared to the neighbour country United Kingdom - are relatively minor role.

641 Tilson et al. 2005

642 http://www.entemp.ie/publications/commerce/2006/consumerstrategy.pdf

643 http://www.irishhealth.com/?level=4&id=7849

13.5 Overview of the Reimbursement Market in Ireland

Tasks / Duties	Yes	No	Comment	Legal bases
Public Authorities				
Decide on prescription status	X			No. 69 of 1993, the Medical Preparation (Prescription and Supply) Regulation amended 2003 S.I. 540/2003
Decide on manufacturer price	X		A framework between DoHC and IPHA is negotiated for reimbursable POM and OTC, non-reimbursables are priced freely	IPHA agreement
Fix wholesale margin	X		Maximum margin of 15% and 10% for HTD Scheme / no margins for OTC	IPHA agreement
Fix pharmacy retail price	X		Depending on the applicable reimbursement scheme	Respective Community Drug Scheme
Decide on reimbursement status	X		Different reimbursement scheme	Respective Community Drug Scheme
Decide on reimbursement price	X		Reference price of the 5 basket countries	IPHA agreement
Use Pharmaco-economic guidelines	X		DoHC / NCPE	IPHA Agreement / Irish Health-care Technology Assessment Guidelines
Use Internal reference pricing		X		
Use External reference pricing	X		5 basket countries (UK, Germany, Denmark, the Netherlands, France)	IPHA agreement
Price freezes	X		Price freeze since 1993	IPHA agreement
Margin cuts	X			IPHA agreement
Discounts and Rebates	X		Under the HTD Scheme	IPHA agreement
Company profit control	X		Rebate of 3% under the GMS Scheme	IPHA agreement
Country specific:				
Pharmaceutical Industry				
Sets manufacturer price freely	X		Only non-reimbursable pharmaceuticals, mainly OTC	IPHA agreement
Notifies manufacturer price	X		Free to change the price of non-reimbursable pharmaceuticals, mainly OTC	IPHA agreement

Tasks / Duties	Yes	No	Comment	Legal bases
Negotiates manufacturer price	X		For pharmaceuticals that are not available in the 5 basket countries	IPHA agreement
Is free to set price below fixed manufacturer price	X			
Decides on application for reimbursement	X			IPHA agreement
Negotiates reimbursement price	X		Reimbursement price is identical with pharmacy retail price, manufacturers more or less set/negotiate their price within the framework of the IPHA agreement	IPHA agreement
Free to keep manufacturer price above reimbursement price			Not applicable	
Free to grant rebates / discounts to wholesalers	X		Mandatory discounts, cf. Table 13.2	Respective Community Drug Scheme
Free to grant rebates / discounts to pharmacies	X			
Can engage in marketing towards doctors	X		In line with code of conduct	
Can engage in public advertising		X		The Medical Preparations (Advertising) Regulations 1993 (exception: nicotine replacement therapy)
Can provide information toward patients	X		Yes, but only for non-reimbursable pharmaceuticals except NRT	IPHA Medicines Compendium
Applies for switches and de-listing	X			IMB
Country specific:				
Wholesaler				
Margins are fixed by statute	X		Traditionally 15%/ depends on the wholesale price of Denmark, UK, France, Germany and Netherlands	IPHA agreement
Margins are subject to statutory discounts/rebates	X		Innovative Pharmaceuticals (HTD Scheme) 5% rebates	IPHA agreement
Free to grant rebates/discounts to pharmacies	X			

Tasks / Duties	Yes	No	Comment	Legal bases
Pharmacists				
Margins are fixed by statute	X		Fixed fee for service	
Free to set retail price		X	But yes for non-reimbursable, mostly OTC products	
Obliged to inform patient on cheaper product		X	Only if doctor has prescribed by INN	
Obliged to substitute by a generic		X		
Allowed to substitute by a generic	X		Only if doctor has prescribed by INN	
Obliged to substitute by a parallel import		X		
Allowed to substitute by a parallel import	X		Only if doctor has prescribed by INN	
Therapeutic substitution is allowed		X		
Claw back system		X		
Are subject to statutory discounts and rebates	X		Mandatory discounts, cf. Table 13.2	Respective Community Drug Scheme
May grant rebates to customers	X		Mainly for non-reimbursable OTC	
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			Directive 89/105/EC as implemented of 21, OJ No l 40 of 11.2.1989
Are obliged to inform on co-payment	X			Directive 89/105/EC of 21, OJ No l 40 of 11.2.1989
Prescription habits are monitored	X			IDTS
Are subject to prescription guidelines	X			NMIC
Budgets are controlled	X			IDTS
Allowed to prescribe INN	X			

Tasks / Duties	Yes	No	Comment	Legal bases
Obliged to prescribe INN		X		
Can oppose generic substitution			Not applicable, as generic substitution by the pharmacists is prohibited unless the doctors has written the prescription by INN	
Can oppose therapeutic substitution				
Can oppose substitution by parallel import				
Country specific:			Certain pharmaceuticals on the HTD scheme must be prescribed by a specialist (e.g. Betaferon)	
Patients				
Can shop for cheapest price of the product	X		Only for non-reimburseable products	
Pay a flat rate per prescription/pack	X		Depends on the reimbursement scheme, maximum co-payment limit is € 85.- per family per month	Respective Community Drug Scheme
Co-payment at a certain percentage		X		
Can ask for substitution by a generic			Not applicable, as generic substitution by the pharmacists is prohibited unless the doctors has written the prescription by INN Not applicable, as generic substitution by the pharmacists is prohibited unless the doctors has written the prescription by INN	
Can oppose substitution by a Generic				
Can ask for substitution by a parallel import				
Can oppose substitution by a parallel import				
Can oppose substitution only on payment of price difference				
Has to pay the difference between reimbursement price and manufacturer price		X	No reference price system in place	
Has access to full public information on prices and products		X	Not free of charge, MIMS may be purchased	

Source: ÖBIG 2006

ITALY

14 Italy

14.1 Pharmaceutical System

14.1.1 Regulatory Framework and Authorities

Italy has a national health service (Servizio Sanitario Nazionale, SSN), financed by general taxation which is statutorily required to guarantee uniform provision of comprehensive health care throughout the country. Health care provision is organised by regional authorities (Aziende Sanitarie Locali, ASL); besides national taxes, their sources are local taxes and co-payments, which they may charge.

In recent years there has been a regionalisation: the shifting of powers from the federal level to the 20 regions (devolution) has also had an important impact in the pharmaceutical sector. The basis for the regionalisation was the 8 August 2001 Agreement between the government and the regions, establishing the shift of several public tasks, among them, healthcare to the regions and setting out funding for the period 2001-2004. The agreement was incorporated in the Law on Health Expenditure[644]. However, the regional fiscal autonomy (power to create or increase local taxes) was frozen in the years 2003 and 2004. In 2005, there were re-negotiations, and a new agreement was signed on 23 March 2005.

Another major organisational reform, which targeted the pharmaceutical sector, was the establishment of a Medicines Agency (Agenzia Italiana del Farmaco, AIFA), which started to take up its activities in July 2004.[645] The AIFA under the Ministry of Health incorporated commissions which had before been in charge of pricing and reimbursement. Today, the relevant players in the Italian pharmaceutical system are as follows:

- The Ministry of Health (Ministero della Salute), which is in charge of the overall strategic framework in pharmaceuticals.
- The AIFA, which is responsible for several aspects of the regulation of pharmaceuticals (market authorisation, vigilance, pricing and reimbursement). Key commissions are the AIFA are:
  - the Scientific-Technical Commission (Commissione Tecnico Scientifica, CTS), which assesses pharmaceuticals with regard to quality, safety and efficacy with the market authorisation and according to their reimbursement status.

644 Legge 16 novembre 2001, n. 405, “Conversione in legge, con modificazione, del Decreto-Legge 18 Settembre 2001, n. 347, Recante Interventi urgenti in materia di spesa sanitaria” http://www.parlamento.it/parlam/leggi/01405l.htm

645 Decreto-Legge 326/2003

- the Pricing and Reimbursement Committee (Comitato Prezzi e Rimborso, CPR), which is in charge of the negotiation with the manufacturers on the prices of reimbursable pharmaceuticals. The CPR took over the tasks previously performed the Drugs Committee (Commissione Unica del Farmaco, CUF) within the Ministry of Health.
- the Liason Centre between the AIFA and the regions (Centro di collegamento Agenzia-Regioni), which ensures the co-operation between the AIFA and the regions, in particular with regard to monitoring pharmaceutical expenditure, promoting the consumption of generics and co-ordinating advertising and promotional activities.

- The AIFA runs some observatories, among them the National Observatory on the Use of Pharmaceuticals (Osservatorio Nazionale sull'Impiego dei Medicinali, OsMED), which monitors all pharmaceuticals prescribed at the expense of the SSN.
- The regions, which are, at least partially, responsible for the containment of pharmaceutical expenditure and which may levy local taxes for funding and define the amount of co-payments (cf. 14.2.3).

Table 14.1 gives an overview on the relevant authorities and market players in the pharmaceutical system in Italy.

Table 14.1: Italy - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Ministero della Salute / Ministry of Health	Ministry of Health (overall strategic framework)	Ministry of Health Dipartimento Farmaci Viale dell'Industria 20 I-00144 Roma Italy Tel.: +39 6599 43666 www.ministerosalute.it/	Ms. Francesca D'Avello Dipartimento Farmaci Viale dell`Industria 20 I-00144 Roma Italy Tel.: +39 6599 43666
Agenzia Italiana del Farmaco (AIFA) / Italian Medicines Agency	Medicines Agency (Market Authorisation, vigilance, pricing and reimbursement)	AIFA Via Della Sierra Nevada 60 I-00144 Roma Italy Tel.: +39 6597 84737 Fax: +39 6597 84214 www.agenziafarmaco.it	Mr. Pietro Folino-Gallo Via Della Sierra Nevada 60 I-00144 Roma Italy Tel.: +39 6597 84737 Fax: +39 6597 84214 p.folinogallo@sanita.it
Istituto Superiore di Sanità (ISS) / High Institute of Health	Federal Authority under the Ministry of Health	ISS Viale Regina Elena 299 I-00161 Roma Italy Tel.: +39 6499 01 Fax: +39 6493 87118 www.iss.it/	Ms. Catia Buschittari Viale Regina Elena 299 I-00161 Roma Italy Tel.: +39 64990 3350 Fax: +39 64938 7118 buschitt@iss.it

Institution	Task	Contact details/URL	Responsible person
Agenzia per i Servizi Sanitari Regionali (ASSR) / Agency for Regional Health Services	Agency for Regional Health Services	ASSR Piazza G. Marconi 25 I-00144 Roma Italy Tel.: +39 0654 9511 Fax: +39 0654 9514 88 www.assr.it/	Mr. Francesco Taroni Regionali (ASSR) Piazza G. Marconi 25 I-00144 Roma Italy Tel.: +39 06549511 Fax: +39 0654 9514 88 assr@assr.it or farma@assr.it
Istituto Superiore per la Prevenzione e la Sicurezza del Lavoro (ISPEL) / High Institute of Prevention and Security of Work	Social Insurance	ISPEL Via Bargoni 8 I-00153 Roma Italy Tel.: +39 5839 271 Fax: +39 5833 0680 www.ispesl.it/	Mr. Paolo Giacobbo Scavo Via Bargoni 8 I-00153 Roma Italy Tel.: +39 5839 271 Fax: +39 5833 0680 Ispesl.diproma@tiscali.it
Associazione Nazionale dell' Industria Farmaceutica (Farmindustria) / National Association of Pharmaceutical Industry	Association of Industry	Farmindustria Piazza di Pietra 34 I-00186 Roma Italy Tel.: +39 6675 809 Fax: +39 6678 6494 www.farmaindustria.it/	Mr. Ivan Cavicchi Piazza di Pietra 34 I-00186 Roma Italy Tel.: +39 6675 809 Fax: +39 6678 6494 cavicchi@farmaindustria.it
Assogenerici / Italian Generic Medicines Association	Association of Generic Industry	Assogenerici Piazzale Ardigo 30 I-00142 Roma Italy Tel.: +39 6596 05324 Fax: +39 6542 30623 www.assogeneric.it/	Mr. Davide Businelli Piazzale Ardigo 30 I-00142 Roma Italy Tel.: +39 6596 05324 Fax: +39 6542 30623 assogeneric@tiscalinet.it
Associazione Nazionale dell' Industria Farmaceutica dell' Automedicazione (Anifa) / National Association of Selfmedication Industry	Association of Self-Medication Industry	Anifa Via Duilio 13 I-00192 Roma Italy Tel.: +39 2631 16245 Fax: +39 2631 16300 anifa@federchimica.it www.anifa.federchimica.it	Mr. Angelo Zanibelli Via Duilio 13 I-00192 Roma Italy Tel.: +39 2631 16245 Fax: +39 2631 16300

Institution	Task	Contact details/URL	Responsible person
Associazione Distributori Farmaceutici (ADF) / Association of Wholesalers	Association of Wholesalers	ADF Via Milano 58 I-00184 Roma Italy Tel.: +39 6487 0148 Fax: +39 6482 8606 www.adfsalute.it/	Mr. Giuseppe Scrofina Via Milano 58 I-00184 Roma Italy Tel.: +39 6487 0148 Fax: +39 6482 8606
Programmi Sanitari Integrati / Association of Parallel Traders	Association of Parallel Traders	Programmi Sanitari Integrati s.r.l Via G. Lanza 3 I-20121 Milano Italy Tel.: +39 8002 86122 Fax: +39 8002 86122 www.programmisanitariintegrati.it	Ms. Barbara Scognamiglio Via G. Lanza 3 I-20121 Milano Italy Tel.: +39 8002 86122 Fax: +39 8002 86122 info@ programmisanitariintegrati.it
Federazione Ordini Farmacisti Italiani (FOFI) / Federation of Italian Pharmacists	Association of Pharmacists	FOFI Via Palestro 75 I 00185 Roma Italy Tel.: +39 0644 50361 Fax: +39 0649 41093 fofi@fofi.it www.fofi.it	Mr. Giovanni Gerosa Via Palestro 75 I 00185 Roma Italy Tel.: +39 0644 50361 Fax: +39 0649 41093
Federfarma / Association of Pharmacies	Association of Pharmacies	Federfarma Via dei Tizii, 10 I-00185 Roma Italy Tel.: +39 0644 63140 Fax: +39 0649 59325 assiprof@tin.it www.federfarma.it	Mr. Giuseppe Impellizzeri Director General Via dei Tizii, 10 I-00185 Roma Italy assiprof@tin.it
Federazione aziende e dei servizi farmaceutici pubblici (A.S.SO.FARM) / Association of Public Pharmacies and Public Pharmaceutical Services	Association of Public Pharmacies and Public Pharmaceutical Services	A.S.SO.FARM Via Cavour, 179 A I-00184 Roma Italy Tel.: +39 0647 8657 0700 Fax: +39 0647 8657 10 assofarm@assofarm.it www.assofarm.it	Mr. Venanzio Gizzi President Via Cavour, 179 A I-00184 Roma Italy Tel.: +39 0647 8657 0700 Fax: +39 0647 8657 10 assofarm@assofarm.it

Institution	Task	Contact details/URL	Responsible person
Società Italiana di Farmacia Ospedaliera (SIFO) / Association of Hospital Pharmacies	Association of Hospital Pharmacies	SIFO Via Carlo Farini I-8120159 Milano Italy Tel.: +39 0260 71934 Fax: +39 0269 002476 sifosede@sifoweb.it www.sifoweb.it/euphorg/frssifo.htm	Ms. Giovanna Scroccaro President Via Carlo Farini I-81-20159 Milano Italy Tel.: +39 0260 71934 Fax: +39 0269 002476 segreteria@sifoweb.it
Federazione Nazionale degli Ordini de Medici Chirurghi e degli Odontoiatri (FnomCeO) / National Federation of Doctors, Surgeons and Dentists	Association of Doctors	FnomCeO Piazza Cola di Rienzo, 80/A I- 00192 Roma Italy Tel.: +39 0636 2031 Fax: +39 0632 22429 www.fnomceo.it	Mr. Giusepe del Baroni Piazza Cola di Rienzo, 80/A I-00192 Roma Italy Tel.: +39 0636 2031 Fax: +39 0632 22429 webmaster@fnomceo.it
Federazione Italiana Medici di Famiglia (FIMMG)/ Association of Family Doctors	Association of Family Doctors	FIMMG Pizza. G. Marconi 25 I-00144 Roma, Italy Tel.: +39 0659 17833 Fax: +39 0659 14327 www.fimmg.org/	Mr. Michele Arpaia Pizza. G. Marconi 25 I-00144 Roma Italy Tel.: +39 0659 17833 Fax: +39 0659 14327 michelearpaia@tin.it
Tribunale per i Diritti del Malato / Association for the Rights of Ill People	Association of Patients	Tribunale per i Diritti del Malato Via Mecenate 25 I-20138 Milano Italy Tel.: +39 2728 9441	Mr. Gianfrancesco Liuzzo Via Mecenate 25 I-20138 Milano Italy Tel.: +39 2728 9441 Cittadinanza.attiva@tiscalinet.it

Source: ÖBIG 2006

14.1.2 Market Players

14.1.2.1 Pharmaceutical Industry

Italy is an important pharmaceutical producer. With regard to the staff employed in the pharmaceutical industry, the Italian pharmaceutical industry ranks third in Europe (after Germany and France) and fifth worldwide (with the USA and Japan leading).

According to the Italian pharmaceutical industry's association Farmindustria, the key figures on the Italian pharmaceutical industry for 2004 are:

- There are 241 companies producing human pharmaceuticals, 89 producers of active substances and 40 producers of veterinary pharmaceuticals.
- The pharmaceutical industry is concentrated in Northern regions (in particular Lombardy) and Lazium.
- The Italian pharmaceutical industry employs 73,550 people, of which 6% work in research and development.
- Pharmaceutical production amounted to € 17.8 billion in 2004.
- The Italian pharmaceutical industry defines itself as research-oriented; € 839 million were invested in research and development.
- Pharmaceutical exports equalled € 9.5 billion, while imports amounted to € 11.3 billion.

Despite its strong pharmaceutical industry, Italy is today an importing country.[646] The reform measures for 2006 foresee an increase in exports (cf. “Programme Agreements” in 14.2.1.1). With regard to parallel trade, Italy is, however, more an exporter due to its low prices[647] (cf. 14.3.4.2).

Manufacturers have to apply to the AIFA for market authorisation (Autorizzazione all’immissione in commercio, AIC), which is in line with Community law. The Finance Law 2000[648] introduced the suspension of the marketing authorisation for pharmaceuticals not marketed for more than 12 months starting from the first launch date. The suspension could be cancelled by paying 30% of the marketing authorisation fee.

14.1.2.2 Distribution

Pharmaceutical wholesale is operated within a multi-channel system. There are around 300 wholesale outlets throughout the country. In the last decade, the Italian pharmaceutical wholesale has undergone a concentration process. Currently, 60-70% of the sales is handled by the leading wholesalers Comifar-Phoenix, Alleanza Salute, Farmintesa, Unico, Sofarmamorra, Farvima and Gehe. Besides, these full-line ranged wholesalers, being part of international groups, there are several small wholesale companies, operating only regionally.

Pharmaceuticals in Italy are mainly dispensed by pharmacies delivered by the pharmaceutical wholesale. However, in the course of the cost-containment reforms[649], direct distribution by the regions has started: Regions have directly purchased pharmaceuticals from the manufacturers and dispensed them to patients discharged from hospitals or out-patient clinics. The most common example is the dispensing of oncology pharmaceuticals for the first complete

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[646] Centro Studi della Farmindustria 2005

[647] Tilson, L.; Barry, M. 2005

[648] Legge 23 Dicembre 1999, n. 488: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2000)", http://www.parlamento.it/leggi/99488l.htm

[649] Legge 16 novembre 2001, n. 405, “Conversione in legge, con modificazione, del Decreto-Legge 18 Settembre 2001, n. 347, Recante Interventi urgenti in materia di spesa sanitaria”, http://www.parlamento.it/parlam/leggi/01405l.htm

cycle of treatment after discharge from hospitals. The expenses involved in the delivery are more than offset by the savings from the direct purchase from the manufacturers[650] which by law are obliged to give discounts to the SSN of 50% of the pharmacy retail prices (cf. 14.2.2.7) and which usually make higher reductions.

Besides direct distribution, pharmaceuticals in Italy are only dispensed in pharmacies. The Italian pharmaceutical retail sector is characterised as follows:

- There are 17,352 pharmacies in Italy (data as of April 2005), which corresponds to a pharmacy per 3,336 inhabitants.
- Pharmacy establishment is statutorily regulated[651]. The decree lays down that there should be at least 1 pharmacy per 4,000 inhabitants. There is a plan (Pianta organica delle farmacie) which ensures the provision of pharmacies throughout the country.
- Recently, the European Commission has issued a "reasoned opinion" against the Italian state over its regulation on the ownership and establishment of pharmacies. The Italian provisions are, according to the Commission, considered as a breach the EC Treaty concerning respectively the right of establishment and the free movement of capital in the EU.
- One legal[652] classification of pharmacies in Italy is the distinction between urban (in communities with more than 5,000 inhabitants) and rural pharmacies. This classification as urban or rural pharmacy has an impact on the discount which pharmacies have to grant the SSN (cf. 14.2.2.7). There are more than 6,000 rural pharmacies in Italy.
- The majority of pharmacies (15,987 pharmacies, data as of April 2005) are private retailers, but there are still 1,365 pharmacies owned and operated by the local authorities. The idea behind the public pharmacies is to guarantee access to pharmaceuticals also in rural, sparsely populated areas.
- Private pharmacies are represented by the association Federfarma, and public pharmacies by the Assofarm.
- The pharmacies' associations have concluded an agreement with the SSN ("convenzione farmaceutica"[653]) providing a framework on national as well as on regional level.
- A pharmacy must be owned by a pharmacist.
- Pharmacy chains are not allowed.
- Self-service for OTC in the pharmacy has been permitted by a decree-law in 2001[654].

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650 France, G.; Taroni, F.; Donatini, A. 2005

651 Decreto-Legge 221/1968 and Decreto-Legge 362/1991

652 Art. 1 del Decreto-Legge 221/1968

653 Convenzione Farmaceutica, D.P.R. 371/1998 as of 8 July 1998, published in the Gazzetta Ufficiale n. 251 as of 27 October 1998. It expired in 2001 and is now valid "in prorogatio"

654 Legge 16 novembre 2001, n. 405, "Conversione in legge, con modificazione, del Decreto-Legge 18 Settembre 2001, n. 347, Recante Interventi urgenti in materia di spesa sanitaria", http://www.parlamento.it/parlam/leggi/01405l.htm

- Distance selling and internet pharmacies are not allowed.
- Self-dispensing doctors are not permitted.

Pharmaceutical consumption has moderately increased in the recent years; in 2004, 1,600 million packs were sold in pharmacies.

14.1.2.3 Patients

The role of the patients in Italy has to be considered differently, depending on the prescription status of the pharmaceuticals.

In Italy, the EU's classification provisions were statutorily implemented in 1993[655]. Pharmaceuticals are thus classified into prescription-only medicines (POM) and OTC products (farmaci senza obbligo di prescrizione medica, SOP). Within the non-prescription segment, there is a special type of pharmaceuticals, namely the self-medication pharmaceuticals (farmaci di automedicazione). These pharmaceuticals, which are non-reimbursable, are allowed to be advertised to the general public in all media (cf. 14.2.4).

To qualify as an OTC product, special criteria are laid down in Guidelines by the Ministry of Health published in 1997[656] (e.g. safety and efficacy of the active ingredients largely demonstrated, widely used in therapy for at least 5 years in one EU Member State, treatment of minor and temporary ailments, small pack sizes which are suitable for short-time treatment) have to be met. In addition, the Finance Law for 2005[657] introduced a further sub-group of OTC products: so-called category "C-bis", for which advertising is also allowed (cf. 14.2.4).

With regard to prescription medicines, the patients have a minor role in the choice of having them prescribed.

Concerning pricing and reimbursement in general (for POM and OTC products alike) patients are not involved in this process.

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655 Decreto-Legge 539/1992, entering in force on 12 March 1993

656 Circolare Ministeriale 16.10.1997 (published in the Gazetta Ufficiale on 18 November 1997)

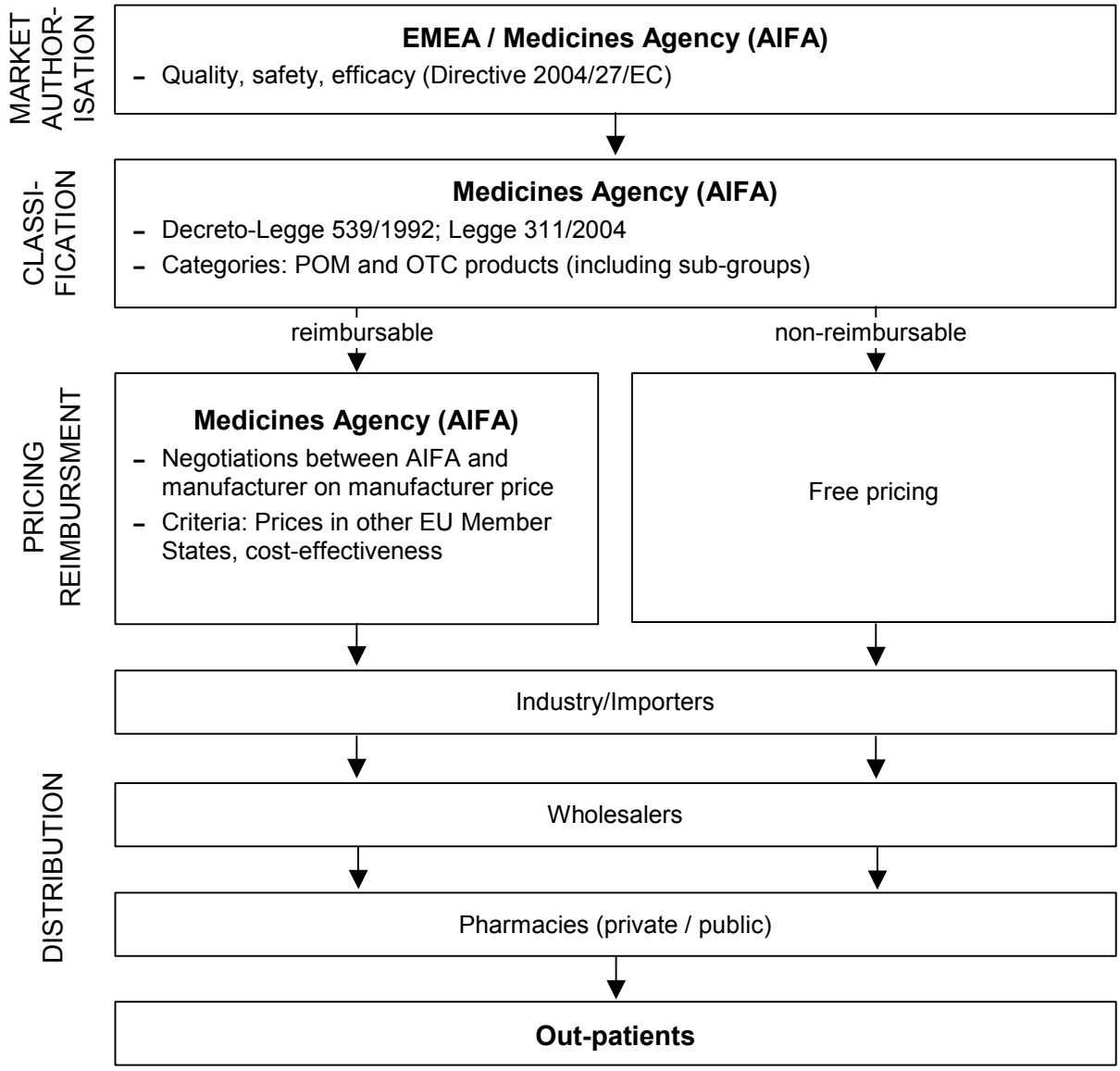
657 Legge 30 dicembre 2004, n. 311: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2005)", http://www.governo.it/GovernoInforma/Dossier/Finanziaria2005/finanziaria.pdf

14.1.3 Overview of the Pharmaceutical System

There are 8,557 pharmaceuticals (including different pharmaceutical forms, strengths and pack sizes) on the market (2004).

Figure 14.1 gives an overview on the current pharmaceutical system in Italy.

Figure 14.1: Italy - Pharmaceutical System, 2006



EU = European Union, POM = Prescription-only Medicines, OTC = Over-the-Counter

Source: ÖBIG 2006

14.2 Pricing

14.2.1 Scope of Price Control

In Italy, there is free pricing for non-reimbursable pharmaceuticals (so-called “class C pharmaceuticals” - cf. 14.3.1, usually OTC products) at all price levels.

For reimbursable pharmaceuticals (so-called “class A pharmaceuticals”, cf. 14.3.1), the manufacturer price is determined through negotiations of the manufacturer with the AIFA. There are statutorily fixed linear wholesale and pharmacy mark-ups for reimbursable pharmaceuticals. Table 14.2 provides an overview on the Italian pricing system in 2006.

Table 14.2: Italy - Pharmaceutical Pricing System, 2006

	Manufacturer level	Wholesale level	Pharmacy level
Free Pricing	Non-reimbursable pharmaceuticals	Non-reimbursable pharmaceuticals	Non-reimbursable pharmaceuticals
Statutory Pricing	Not applied	Reimbursable pharmaceuticals via a linear mark-up	Reimbursable pharmaceuticals via a linear mark-up
Price Negotiations	Reimbursable pharmaceuticals	Not applied	Not applied
Price/volume agreements, discounts/rebates	Yes	Yes	Yes
Institution in charge of pricing	- AIFA (CTS)		
Legal Basis	- Decree-Law: Decreto-Legge 326/2003 - Enactment: Deliberazione CIPE 1/2/01 - Law: Legge 662/1996 - Decree-Law: Decreto-Legge 87/2005		

AIFA = Agenzia Italiana del Farmaco, CTS = Commissione Tecnico Scientifica

Source: ÖBIG 2006

14.2.1.1 Manufacturer Price

There has always been and still is free pricing for new non-reimbursable pharmaceuticals (“class C” pharmaceuticals) in Italy. However, a 2005 law[658] provides that the prices of non-reimbursable pharmaceuticals may only be increased in the month of January in every odd year (before, price increases of non-reimbursable pharmaceuticals were possible once a

[658] Decreto-legge 27 maggio 2005, n. 87: "Disposizioni urgenti per il prezzo dei farmaci non rimborsabili dal Servizio sanitario nazionale", http://www.ministerosalute.it/imgs/C_17_normativa_670_allegato.pdf

year). Thus, the next pricing review will occur in January 2007. Price cuts are permitted at any time (cf. 14.2.2.5).

The pricing procedure for reimbursable pharmaceuticals has varied several times in the last decade:

- In 1996, Italy introduced a pricing calculation on the basis of an average European price (Prezzo Medio Europeo, PME), which took four countries (France, Spain, Germany, UK) in consideration.
- In 1998, under the pressure of the European Commission Italy altered its average price system (all EU Member States except Denmark and Luxembourg; actual exchange rates instead of purchasing power parities as previous).
- At the end of the 1990s, different procedures were introduced depending on the market authorisation of the pharmaceuticals. While the average European pricing procedure continued to be applied for nationally authorised pharmaceuticals (handled by the Interministerial Pricing Committee (Comitato Interministeriale per la Programmazione Economica, CIPE), price negotiations between the manufacturer and the then Drugs Committee CUF took place: in the beginning for pharmaceuticals with a central EU market authorisation, later also for pharmaceuticals authorised under the decentralised procedure.

Since January 2004, there have been pricing negotiations for all new reimbursable pharmaceuticals. In fact, the process of pricing and reimbursement is interlinked, as manufacturers submit one application to obtain a manufacturer price and access to reimbursement. The decision on the level of reimbursement is only after the price had been set (cf. 14.3.1).

With the establishment of the AIFA in July 2004, the task of negotiating with the manufacturers, which used to be undertaken by the former Drugs Committee CUF, was handed over the Medicines Agency[659], in particular to the Pricing and Reimbursement Committee CPR (cf. 14.1.1). The procedure remained the same. An Enactment from 2001[660] specifies the criteria applied in the negotiations:

- Cost-effectiveness for pharmaceuticals where no effective therapy exists
- Risk-benefit ratio compared to alternative pharmaceuticals for that indication
- Therapy costs per day in comparison to products of the same efficacy
- Evaluation of the economic impact on the national health system
- Estimated market share of the new pharmaceutical
- Prices and consumption data in European countries

659 Decreto-Legge 326/2003

660 Deliberazione CIPE 1/2/01: "Individuazione dei criteri per la contrattazione del prezzo dei farmaci"

In reality, the prices of the pharmaceutical in other European countries are the most important criterion (cf. 14.2.2.3). It seems unlikely that a new pharmaceutical gets a (significantly) higher price than in another EU Member State with statutory pricing (in particular France or Spain).

For innovative pharmaceuticals, the Finance Law 2003 established a “premium price”. There is a special financial pool, administered by AIFA, to fund these premium prices. In addition, the Finance Law 2006[661] foresees that, in order to promote research and development in the period 2006-2008, the Ministry of Economy and Finance and the Ministry of Health will publish a ministerial decree in 2006, allowing pharmaceutical companies to benefit from temporary premium prices, as long as the additional revenue is invested in R&D “Programme Agreements”, subject to specific criteria:

- opening or strengthening of national production centres
- value and increase of R&D staff in relation to marketing staff
- development of phase I and phase II clinical studies, with Italy being the co-ordinating committee
- increase in export value for raw materials and end products.

Generics, at least in theory, should be priced 20% below the original product to secure reimbursement (for further information cf. 14.3.1.4).

The two Committees within AIFA concerned with the pricing procedure (cf. 14.1.1) are:

- the Scientific-Technical Commission CTS, composed of experts nominated by the Minister of Health, by the Minister of Economy and Finance, by the Conference of the State and the Regions and by the General-Director of the AIFA, and
- the Pricing and Reimbursement Committee CPR with representatives nominated by the Minister of Health, by the Conference of the State and the Regions, by the Minister of Economy and Finance, Minister of Production, and by the General-Director of the AIFA.

The CPR assesses the applications, taking expenditure and consumption data provided by the National Observatory on the Use of Pharmaceuticals OsMED (cf. 14.1.1) as supporting information and undertakes the negotiations with the manufacturers. If an agreement, specifying price and access to reimbursement, is reached, it will be ratified by the CTS and then be forwarded to the Administration Board of AIFA for examination.

The decision, including marketing authorisation, price and reimbursement status, is officially published in a decree.

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661 Legge 23 dicembre 2005, n. 266: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2006)", http://www.governo.it/GovernoInforma/Dossier/finanziaria_2006/dl203_05.pdf

In spite of the decentralisation process, the prices of pharmaceuticals are the same all over the country. The greater role of the regions is reflected in its representation in AIFA's Committees (see above) as well as in its power in setting co-payments (cf. 14.2.3) which has an impact on the actual retail price which patients have to pay.

14.2.1.2 Wholesale Price

The wholesale price of pharmaceuticals reimbursed at the expense of the National Health Service SSN is fixed by law[662] which states that the margins of pharmaceutical industry, wholesale and pharmacies are 66.65%, 6.65% and 26.7% respectively.

Thus, the wholesale margin of reimbursable pharmaceuticals is 6.65% of the pharmacy retail price.

The wholesale margin for pharmaceuticals not reimbursed (pharmaceuticals in class C, cf. 14.3.1), which may be fixed freely, is around 8%.

14.2.1.3 Pharmacy Retail Price

The pharmacy margin is 26.7% of the pharmacy retail price for pharmaceuticals which are reimbursed [663].

The 26.7% margin is, however, the gross margin. In addition, there is a complex discount system in place, depending on the turnover of the pharmacy and if the pharmacy is situated in an urban or rural area (cf. 14.2.1.3). According to the Pharmacists' Association Federfarma, these official discounts lower, on average, the margins by around 5%.

Pharmacy margins for pharmaceuticals which are not reimbursed (pharmaceuticals of class C) are, in general, free. However, there is an - old - legal provision[664] still in place, stating that pharmacies are entitled to a margin not less than 25% of the public price. This is the only provision on pricing at retail level for non-reimbursable pharmaceuticals; there are no obligatory discounts.[665]

14.2.1.4 Value Added Tax (VAT)

The VAT on pharmaceuticals is 10%, thus lower than the standard rate of 20%.

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662 Decreto-Legge 662/1996 (there have been amendments later, but the original law is still the one of relevance)

663 Decreto-Legge 662/1996 (there have been amendments later, but the original law is still the one of relevance)

664 R.D., 3 Marzo 1927

665 https://www.federfarma.it/cms_published_2/margine_IT.html

14.2.2 Price Related Cost-containment Measures

14.2.2.1 Pharmaco-economic Evaluation

Pharmaco-economic considerations play a role in the decision on the admission to reimbursement and the pricing of reimbursable pharmaceuticals (cf. 14.2.1.1). Manufacturers are asked to provide available pharmaco-economic studies. This is not mandatory but highly recommended for orphan and innovative pharmaceuticals.

When, with a 1997 Enactment by the Interministerial Pricing Committee CIPE[666] and the Finance Law 1998[667], pharma-economics started to be an integral part of the pricing and reimbursement process in Italy, an expert group for pharmaco-economic evaluations (Gruppo Italiano per gli Studi di Farmacoeconomia, GISF) was created. The task[668] of GISF, which is composed of representatives of authorities, academia and the pharmaceutical industry, is to provide a methodological framework for pharmaco-economic evaluations.

14.2.2.2 Internal Price Referencing

Since September 2001, a reference price system has been in place (for further information cf. 14.3.2). Additionally, there is the provision that, in order to gain access to reimbursement, generics should be priced 20% lower than the original product (cf. 14.3.1.4).

14.2.2.3 External Price Referencing / Cross Country Referencing

Italy no longer applies the PME system (European average price) for pricing decisions. However, cross-country referencing is still a key element in the pricing procedure as prices in other European Member States are one of the criteria in the pricing negotiations. In fact, as stated in section 14.2.1.1, the prices of a pharmaceutical in other EU countries with statutory pricing (in particular France and Spain) seem to be the most important decision criterion.

14.2.2.4 Price Freezes / Stops

The prices of the non-reimbursable pharmaceuticals (“class C”, cf. 14.3.1) have been frozen from end May 2005 until January 2007.

14.2.2.5 Price Cuts

Price cuts have been used as a cost-containment strategy in Italy for many years, often in order to implement pay-backs by the pharmaceutical actors (cf. 14.2.2.7):

- a 15% price cut in 1999

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666 Delibera n. 109 del CIPE, published on 30 January 1997 in the Gazzetta Ufficiale

667 Legge 27 dicembre 1997, n. 450: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 1998)"

668 cf. http://www.gisf.it

- a 5% reduction on the prices of reimbursable branded pharmaceuticals, not covered by a patent in 2000
- price cuts of 5% on all reimbursable pharmaceuticals in 2002
- a 7% price cut in 2003
- application of price cuts on about 300 pharmaceuticals (high-selling products with a rise in sales in the first half of the year by more than the average for the whole market) in 2004.

The latest price cuts came into effect on 15 January 2006 and were based on an Enactment[669] by AIFA, in line with the Finance Law 2006[670]. Price cuts of 4.4% are applied

- to all pharmaceuticals reimbursed at 100% by the SSN ("class A" pharmaceuticals, cf. 14.3.1.1), with the exception of
  - pharmaceuticals priced at or below € 5.- not included in the transparence list (i.e. in the reference price system),
  - vaccines,
  - haemoderivatives.

Base prices of 31 December 2004, as listed in the 2003 "Prontuario" (i.e. reimbursement list, cf. 14.3.1.3) have been selected, as these exclude the price cuts introduced in the 2005 list. For pharmaceuticals authorised after the end of 2004, the price as of 15 January 2006 is taken as the base price.

In previous rounds of price cuts, these cost-containment measures only targeted manufacturers. As the current price reductions are, however, implemented at the pharmacy retail price, the pharmaceutical wholesale and pharmacists are also addressed. For the pharmaceutical industry, there is, in addition, a discount (cf. 14.2.2.7).

The 2006 price cuts are established as temporary ones. Using pharmaceutical expenditure data for the first three months of 2006, AIFA is expected to adjust the price cuts and other cost-containment measures (e.g. discounts) by 30 June 2006.

14.2.2.6 Margin Cuts

In the last years, the wholesale and pharmacy mark-ups for reimbursable pharmaceuticals have not changed. However, the introduction of obligatory pharmacy discounts in 2004 (cf. 14.2.2.7) is seen as sort of "hidden" margin cuts for pharmacists.

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669 Determinazione 30 dicembre 3005 concernente "Misure di ripiano della spesa farmaceutica convenzionata e non convenzionata per l'anno 2005". Published on 3 January 2006 in the Gazzetta Ufficial

670 Legge 23 dicembre 2005, n. 266: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2006)", http://www.governo.it/GovernoInforma/Dossier/finanziaria_2006/dl203_05.pdf

14.2.2.7 Discounts and Rebates

In Italy, there are different legal discount and clawback systems in place. In case that manufacturers directly sell to the SSN (or to regions, e.g. in case of direct distribution, cf. 14.1.2.2), they are obliged by law to give discounts to the SSN of 50% of the pharmacy retail prices.

Pharmacies are subject to a discount system, which has implicitly an impact on the margins (cf. 14.2.1.3). Pharmacies are statutorily obliged to grant discounts to the SSN. The level of discount depends on the location and the turnover of the pharmacy.

Table 14.3 provides detailed information.

Table 14.3: Italy - Legal pharmacy discounts to the SSN

Price range in €	Urban and non-subsidised rural pharmacies		Subsidised rural pharmacies	
	Turnover		Turnover	
	above € 258,228.45	below € 258,228.45	above € 387,342.67	below 387,342.67
from 0 to 25.82	3.75	1.5%	3.75%	1.5%
from 25.83 to 51.65	6%	2.4%	6%	
from 51.66 to 103.28	9%	3.6%	9%	
from 103.29 to 154.94	12.5%	5%	12.5	
above 154.94	19%	7.6%	19%	

Source: Federfarma[671]; information gathering and translation by ÖBIG

Italy has seen, for years, a problem of overspending in its pharmaceutical budgets (cf. 14.3.3). In 1998, payback arrangements were established in case of overspending. These provided for the SSN (including the regions) to re-pay 40%, and for the actors to re-pay60% (in proportion to their margins: 66.5%, 6.5% and 26.7% respectively). However, in spite of overspending in the pharmaceutical budgets of 1998 and 1999, no re-payments were made, and at the beginning of 2001 the payback system was abolished.

Due to the growth in pharmaceutical expenditure, a decree-law in mid-2004[672] re-activated the payback arrangements, already outlined in the Finance Law 2004[673]. Since then, besides price cuts, discounts have been used to cover the overspending of the budgets of the previous year.

With regard to the overspending of 2005, price reductions took place as of 15 January 2006 (cf. 14.2.2.5). As stated, these temporary price cuts for 2006 were implemented at pharmacy retail price level. Therefore the impact is shared between industry, wholesale and pharmacy

671 https://www.federfarma.it/cms_published_2/margine_IT.html

672 Decreto-Legge 24 Giugno 2004 , n. 156: “Interventi urgenti per il ripiano della spesa farmaceutica”

673 Legge 24 dicembre 2003, n. 350: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2004)", http://www.governo.it/governoinforma/dossier/finanziaria2004/index.html

sector, in proportion to their margins (66.5%, 6.5% and 26.7% respectively). The contribution amounts to € 331 million for industry, € 33 million for wholesalers and € 132 million for pharmacies to cover the whole repayment of € 496 million in the out-patient sector. On the reduced prices, a 0.6% discount of the pharmacy retail price (which corresponds to a 1% discount of the manufacturer price) is applied for all pharmaceuticals reimbursed at 100% by the SSN ("class A" pharmaceuticals, cf. 14.3.1.1), with the exception of

- pharmaceuticals in the reference price system,
- pharmaceuticals priced at or below € 5.- not included in the reference price system,
- vaccines,
- haemoderivatives.

As the price cuts, these discounts are also implemented as temporary ones, and AIFA will decide on the timeframe for these measures by end of June 2006 after evaluation of the impact.

Concerning discounts offered by pharmacies to customers, a new decree-law[674] provides that pharmacists now have the option of offering a discount of up to 20% on the maximum price. The discount must be applied to all customers of the pharmacy without any discrimination.

14.2.2.8 Company Profit and Promotion Controls

The profits of the pharmaceutical industry are indirectly influenced by the above mentioned payback arrangements.

The Finance Law 2006[675] provides that the revenue received from "premium prices" granted for innovative pharmaceuticals (cf. 14.2.1.1), may not exceed 10% of the total cost of the company's R&D program.

In addition, controls over promotional costs are another focus of the reform measures:

- The Finance Law 2004[676] provided for the creation of an independent scientific information fund, towards which pharmaceutical manufacturers allocate 5% of their marketing expenses. The fund is designed to focus on orphan drugs, research, comparative studies and pharmacovigilance. Resources for 2003 and 2004 amounted to € 94.5 million. The Finance Law 2004 also allowed the regions to impose their own limits on promotional activities by industry. In fact, several regions have introduced measures for regulating access of sales representatives to doctors.

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674 Decreto-legge 27 maggio 2005, n. 87: "Disposizioni urgenti per il prezzo dei farmaci non rimborsabili dal Servizio sanitario nazionale", http://www.ministerosalute.it/imgs/C_17_normativa_670_allegato.pdf

675 Legge 23 dicembre 2005, n. 266: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2006)", http://www.governo.it/GovernoInforma/Dossier/finanziaria_2006/dl203_05.pdf

676 Legge 24 dicembre 2003, n. 350: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2004)", http://www.governo.it/governoinforma/dossier/finanziaria2004/index.html

- As “mini-meetings” (often lunches or dinners) of sales representatives with healthcare professionals had been identified as drivers of the increase in pharmaceutical expenditure, the Minister of Health decided that from September 2004 on these meetings may no longer be limited to discussing just one product and must be sponsored by at least two companies.

14.2.2.9 Parallel Trade

As for parallel imported pharmaceuticals, there have been complaints by the European Commission that the regulatory procedure takes too long (cf. 14.3.4.2). This is, however, a deliberate strategy by Italy to discourage parallel imports.[677]

As stated in 14.1.2.1, Italy is, due to its low price level, a major parallel exporter of pharmaceuticals.

14.2.3 Co-Payments

At the beginning of 2001[678], prescription fees, which had been € 1.55 for one pack on a prescription form and € 3.10 for two or more packs on a prescription form country-wide, were abolished. In the same year, the law on regionalisation[679] (cf. 14.1.1) allowed regions to re-implement co-payments to contain pharmaceutical expenditure. In the beginning, several regions (in particular the poorer ones) introduced prescription fees which most of them have abolished meanwhile. As of today, only 7 out of the 20 Italian regions apply prescription fees[680]. By now, there are no plans to re-implement a national prescription fee in Italy.

Besides (regional) prescription fees, patients have to co-pay for pharmaceuticals in the reference price system priced above the reference price (cf. 14.3.2).

In addition, patients pay the full price of OTC products, which, in general, do not fall under the reimbursement system, and of so-called “class C” pharmaceuticals (with a reimbursement rate of 0%; cf. 14.3.1.1).

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677 PPR 2004

678 Legge 23 dicembre 2000, n. 388

679 Legge 16 novembre 2001, n. 405, “Conversione in legge, con modificazione, del Decreto-Legge 18 Settembre 2001, n. 347, Recante Interventi urgenti in materia di spesa sanitaria”, http://www.parlamento.it/parlam/leggi/01405l.htm

680 An up-date on the regional implementation of prescription fees is provided on the website of Pharmacists’ Association: http://www.federfarma.it

14.2.4 Information Transparency and Marketing

As described in section 14.1.2.3, pharmaceuticals in Italy are classified into prescription-only medicines (POM) and OTC products. A special group of OTC products, the self-medication pharmaceuticals, are allowed for being advertised to the general public in all media. Additionally, the Finance Law for 2005[681] introduced a further sub-group of OTC products: so-called "class C-bis" pharmaceuticals for which advertising is also allowed. All other OTC products are not allowed for advertising to the general public, as laid down in a decree-law[682] from the early 1990s, implementing the EU's provisions on pharmaceutical advertising.

However, the Finance Law 2001[683] introduced the notion of silent assent for the approval of OTC advertising: In case that there is no reaction within 45 days from submission, the advertising is considered as approved by the Ministry of Health.

No authorisation needs to be requested if:

- The print advertising is limited to the name of the product (reminder advertising).
- The print advertising contains an integral reproduction of the patient leaflet and a clear invitation to carefully read the patient information leaflet. In this case, it is possible to use a photograph or a graphic representation of the external packaging.

The Ministry of Health officially recognised the Self-Disciplinary Advertising Institute (Istituto dell'Autodisciplina Pubblicitaria, IAP) as the body authorised to carry out the pre-control of OTC advertising in radio, newspapers and magazines with effect from July 1993.

Further provisions regarding pharmaceutical advertising are as follows:

- Free samples may be given only to doctors and should always be accompanied by the Summary of Product Characteristics. Special rules provide for further documentation to be given to the doctors receiving free samples.
- There are no limits on OTC sampling to doctors.
- No free samples of pharmaceuticals may be given to the public or to pharmacists.
- Advertising on the internet is allowed following authorisation.
- Comparative advertising is not allowed for pharmaceuticals in Italy.
- In case of breach of the advertising laws, fines may be imposed on the companies.
- Medical claims for non-authorised "miracle products" are not allowed.

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681 Legge 30 dicembre 2004, n. 311: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2005)", http://www.governo.it/GovernoInforma/Dossier/Finanziaria2005/finanziaria.pdf

682 Decreto-Legge 541/1992, entering in force on 12 March 1993

683 Legge 23 dicembre 2000, n. 388: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2001)", http://www.parlamento.it/parlam/leggi/01405l.htm

With regard to patient information, a decree-law[684], published simultaneously as the one on advertising, implemented the EU's regulatory provisions. All packs must carry a patient leaflet unless the information can be printed on the package label. In addition, a Circular[685] by the Minister of Health stressed the importance of developing package leaflets in a language clearly understandable for patients, avoiding the use of scientific terms. Only pharmaceuticals dispensed in hospitals or directly by a specialist are exempted from this provision.

In the 1997 Circular[686] by the Minister of Health on guidelines for OTC products, detailed instructions were given for the presentation of the leaflet in a consumer friendly way.

Finally, the Law on Health Expenditure[687] in 2001 introduced a new measure stipulating that a special mark should be printed on the outer packaging of all OTC products starting March 2002 in order to make it easier for the patients to recognise them.

Prices of pharmaceuticals can be accessed via a database on the website of the AIFA and the Ministry of Health[688]. The AIFA drafted so-called transparency lists ("liste di trasparenza") with equivalent pharmaceuticals[689], available on their website[690], including the reference prices (cf. 14.3.2). There is also a transparency list for non-reimbursable ("class C") prescription pharmaceuticals (cf. 14.3.4.2), which the pharmacist has to display in the pharmacy[691].

14.3 Reimbursement

14.3.1 Pharmaceutical Lists and Reimbursement Categories

In Italy, there is a national formulary for pharmaceuticals reimbursed at the expense of the SSN: the so-called "Prontuario". This **positive list** now contains only pharmaceuticals fully reimbursed as the category of 50% reimbursement was abolished.

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684 Decreto-Legge 540/1992, entering in force on 12 March 1993

685 Circolare Ministeriale, 8 Aprile 1993

686 Circolare Ministeriale 16.10.1997 (published in the Gazetta Ufficiale on 18 November 1997)

687 Legge 16 novembre 2001, n. 405, "Conversione in legge, con modificazione, del Decreto-Legge 18 Settembre 2001, n. 347, Recante Interventi urgenti in materia di spesa sanitaria", http://www.parlamento.it/parlam/leggi/01405l.htm

688 Website: http://www.ministerosalute.it/medicinali/bancadati/SceltaFarmaco.jsp

689 Decreto-Legge 178/2002

690 http://www.agenziafarmaco.it

691 Decreto-Legge 27 maggio 2005, n. 87: "Disposizioni urgenti per il prezzo dei farmaci non rimborsabili dal Servizio sanitario nazionale", http://www.ministerosalute.it/imgs/C_17_normativa_670_allegato.pdf

Currently, there are the following reimbursement categories:

- Class A: reimbursement of 100%
  Within this class, there is a sub-group of class H for hospital-only medicines which are also 100% reimbursed.
- Class C: 0% reimbursement

There had also been a Class B with 50% reimbursement (mainly oral contraceptives and antibiotics) which was abolished at the beginning of 2001. In February 2002, Class B was re-introduced in a modified form, namely split between Class B1 (80% reimbursement) and B2 (50% reimbursement). It was up to the regions to decide to implement the two B classes or to leave the affected pharmaceuticals fully reimbursed or delist them (cf. 14.3.1.6). However, in October 2002, classes B1 and B2 were formally abolished and ceased to exist in January 2003 when the revised "Prontuario" was published, thus creating a single reimbursement list.

14.3.1.1 Reimbursement Price

In Italy, the procedure of pricing and reimbursement is interlinked. The relevant committee is now the Pricing and Reimbursement Commission CPR of the AIFA who took over the task previously (before the establishment of the AIFA) performed by the Drugs Committee CUF (cf. 14.1.1).

The manufacturer applies for a price of reimbursable pharmaceuticals (cf. 14.2.1.1), and once a price has been set by AIFA, the decision on the reimbursement status is taken according to certain criteria (see below). Thus, this price decided on by AIFA after negotiations with the manufacturer is the base price for reimbursement. The actual reimbursement price is then lowered due to obligatory discount which distribution actors have to grant to the SSN (cf. 14.2.2.7).

14.3.1.2 Selection Criteria

Under the old system of the 3 classes, the reimbursement criteria focused on the therapeutic benefit and the severity of the diseases (class A for life supporting pharmaceuticals, class B for pharmaceuticals in the treatment of less severe disorders, and class C for pharmaceuticals without proven efficacy or efficacy for minor diseases).

Under the new system with either 100% or 0% reimbursement, the preconditions for being reimbursed are as follows:

- New pharmaceuticals with a particular therapeutic benefit following a cost-efficacy evaluation and taking into consideration prices in the homogeneous therapeutic category.
- New pharmaceuticals with a particular therapeutic benefit if the price is equal to lower than those in its homogeneous therapeutic category.

With the change in the reimbursement system, the Drugs Committee CUF re-assessed the positive list "Prontuario" on the basis of the above mentioned cost-benefit criteria during 2002. Pharmaceuticals had to prove their "relevance". The assessment was carried out

based on the defined daily doses (DDD) of the pharmaceuticals. Following the calculation of the weighted expenditure of the DDD for each active ingredient, a cut-off point was determined, corresponding to the maximum permitted reimbursement level in terms of DDD expenditure for all pharmaceuticals in that homogenous therapeutic group (ATC 4 level). In case of prices above the allowed reimbursement price, manufacturers were “asked” to reduce their price which most of them did (in order to avoid delisting, cf. 14.3.1.6). The regrouping of the former “class B” pharmaceuticals led to 90 active ingredients added to class A and 78 active ingredients to class C.

14.3.1.3 Pharmaceuticals on Positive List

The pharmaceuticals reimbursed at the expense of the SSN (100%) are put in the positive list (“Prontuario”, cf. 14.3.1.3). As described in the previous section, the “Prontuario” was reorganised after the abolition of class B in 2002, and the new “Prontuario 2003” was introduced in January 2003.

The Finance Law 2004 provided for an annual review of the Prontuario by the AIFA, designed to keep spending within the budget (cf. 14.3.3). In fact, the Prontuario 2003 was revised and updated, and replaced by the Prontuario 2005 which entered into force at 1 January 2005. In comparison to the Prontuario 2003, the 2005 version includes 43 new patent protected active ingredients and generic versions of 15 additional active ingredients for which patent protection has expired. Despite the provision of an annual update, the Prontuario 2005 is the one currently in place.

14.3.1.4 Generics

In order to gain admission to reimbursement, generics should be priced at least 20% below the original product.

However, with the advent of the reference price system introduced in 2001 (cf. 14.3.2), manufacturers of original products have substantially reduced their prices in order to maintain market share. In these cases, the difference between the original product (even if priced above the reference price of the group) and the generics decreased to less than 20%. As a result, where generic versions of a specific product are already on the market, new generics are no longer required to meeting the 20% rule at launch.

14.3.1.5 Non-reimbursable Pharmaceuticals

Non-reimbursable pharmaceuticals are not included in the positive list “Prontuario”. In Italy, the pharmaceuticals not reimbursed at the expense of the SSN are today either “Class C” pharmaceuticals and “Class C bis” pharmaceuticals. The group of “class C bis” was newly introduced at the beginning of 2005 on the basis of the Finance Law for 2005[692] and covers

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692 Legge 30 dicembre 2004, n. 311: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2005)", http://www.governo.it/GovernoInforma/Dossier/Finanziaria2005/finanziaria.pdf

only OTC products (cf. 14.1.2.3). Advertising to the general public is allowed for “class C bis” pharmaceuticals (cf. 14.2.4).

14.3.1.6 Delisting and switches

Delisting (removing pharmaceuticals from the positive list “Prontuario”) is ow only allowed at the national level, done by the AIFA. In setting up the Prontuario 2005, currently in place, no delistings took place. In general, delistings were a rather rarely used cost-containment instrument in Italy; in general, manufacturers agreed to price reductions to avoid exclusion from reimbursement.

After the regionalisation in 2001, a central list of pharmaceuticals considered as non-essential was drawn up and regions were allowed to delist pharmaceuticals from that list. In 2003, regional delisting was abolished (while regional co-payment continues to be allowed, cf. 14.3.2).

In connection with delistings, the changes from prescription to OTC status (switches) are also of relevance, as, in practice, OTC products are non-reimbursable in Italy (cf. 14.3.1.5). In the last decade, there have been few significant switches in Italy. In order to facilitate such switching, the OTC association Anifa has requested the AIFA to set up an ad-hoc committee to look into simplifying the criteria for switching which are laid down in guidelines by the MoH[693].

14.3.2 Reference Price System

In September 2001, a reference price system was introduced in Italy[694]. The SSN reimburses up to the reference price, and the patient has to pay the difference.

Initially, the reference price was calculated on the basis of the weighted average of generics in a group of products with the same active ingredient, pharmaceutical form and pack size. This Could be a generic, a me-too-drug or, in theory, also an original product. Now, it is the lowest price for a pharmaceutical in a group that is taken as the reference price. Reference prices should be updated every 6 months.

Besides the national reference price list, there are also regional reference price systems. All regions should prepare their own lists, integrating the national reference list (containing all pharmaceuticals on the market and their reference price) with pharmaceuticals actually available in the region’s pharmacies. In reality, the regional lists only vary insignificantly, and the national reference price list, which is published on the AIFA’s website, is the one which is valid.

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693 Circolare Ministeriale, 16 Ottobre 1997 (Gazetta Ufficiale, 18 Novembre 1997)

694 Legge 16 novembre 2001, n. 405, “Conversione in legge, con modificazione, del Decreto-Legge 18 Settembre 2001, n. 347, Recante Interventi urgenti in materia di spesa sanitaria”, http://www.parlamento.it/parlam/leggi/01405l.htm

14.3.3 Pharmaceutical Budgets

The 2006 healthcare budget[695] totals almost € 93,000 million, consisting of € 90,960 million already budgeted, plus an additional € 2,000 million to cover deficits in the period 2002-2004 arising form national level decisions made after budgets had been set. This additional € 2,000 million allocation will be distributed based on the number of inhabitants per region. But regions will only have access to this funding pool if they have submitted their healthcare plans for 2006-2008 to the government by 31 March 2006.

For 2006, pharmaceutical expenditure at the expense of the SSN is limited to 16% of total public budgeted healthcare expenditure. AIFA has the power to apply price reductions throughout the distribution chain (industry, wholesale, and pharmacies) and integrate these with an additional discount applicable to the pharmaceutical industry only. As described in section 14.2.2.7, this system is being applied to collect the re-payments of the previous year 2005, due in 2006.

In addition, since 2005 regions whose pharmaceutical expenditure rises above the target ceiling have been asked to adopt cost-containment measures in the following year equivalent to 50% of their own overspend[696]. Regional fiscal autonomy, which had been frozen for 2003 and 2004, was given back to the regions (cf. 14.1.1).

There are no prescribing budgets for doctors; however, their prescription pattern is monitored (cf. 14.3.4.1).

14.3.4 Other Volume Control Oriented Measures

14.3.4.1 Prescription Monitoring and Other Doctors-related Measures

There are prescribing guidelines (“note”) in place which detail the circumstances under which pharmaceuticals may be prescribed at the expense of the SSN. The guidelines are worked out by the AIFA (previously by the Drugs Committee CUF), in co-operation with the general practitioners’ association FIMMG (Federazione Italiana Medici di Famiglia). In 2001, there was a major revision of the guidelines, with 20 “note” being retreated and the remaining 39 guidelines becoming less restrictive.

695 Legge 23 dicembre 2005, n. 266: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2006)", http://www.governo.it/GovernoInforma/Dossier/Finanziaria2005/finanziaria.pdf

696 Legge 30 dicembre 2004, n. 311: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2005)", http://www.governo.it/GovernoInforma/Dossier/Finanziaria2005/finanziaria.pdf

Additionally, the Finance Law 2004[697] provided for controls at the doctor's and patient's level through bar-coded prescription forms and a new healthcare card. However, the implementation of the healthcare cards took longer than expected (they should have been in place in 2005). The Finance Law 2006[698] now foresees the distribution of the healthcare cards at the national level by 31 March 2006. According to the same law[699] general practitioners and paediatricians are now required to transfer at least 70% of prescriptions to an online electronic system if they are to qualify for financial and technical support payments.

14.3.4.2 Generics and Parallel Trade

The generic market has grown slowly, though continuously: It accounted for nearly 10% by value in 2004 - compared to 2% in 2001.

This is seen as an effect of the implementation of the reference price system in 2001 (cf. 14.3.2). Generic substitution also had an impact: In 1999, a sort of limited "voluntary" generic substitution was introduced, allowing pharmacists to dispense generics if the prescribed pharmaceutical was not available or could not be delivered via "the normal distribution channels". In 2002, generic substitution got mandatory, i.e. the pharmacist has to dispense the cheaper generic unless the doctor explicitly prohibits substitution or the patient is willing to pay the price difference up to the most expensive pharmaceutical. Till mid-2005, this measure applied only to reimbursable ("class A") pharmaceuticals. A 2005 decree-law[700] established generic substitution by pharmacists also for prescription non-reimbursable ("class C") pharmaceuticals. The pharmaceuticals are included in the so-called transparency list ("lista di trasparenza", cf. 14.2.4) developed by the AIFA which the pharmacist has to display in the pharmacy. Pharmacists who do not supply a generic in place of an original product (when asked to and when available) could receive penalties (financial or a 15-day closure of the pharmacy).

For continuing generic promotion, the Finance Law 2005[701] provides that AIFA will allocate a budget of up to one million € per year 2005, 2006 and 2007 to fund information programs, directed towards the public and doctors, to promote the usage of generics. POM in the off-patent sector are now called "equivalents", rather than generics, in order to increase patients' acceptance.

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697 Legge 24 dicembre 2003, n. 350: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2004)", http://www.governo.it/governoinforma/dossier/finanziaria2004/index.html

698 Legge 23 dicembre 2005, n. 266: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2006)", http://www.governo.it/GovernoInforma/Dossier/finanziaria_2006/dl203_05.pdf

699 Legge 23 dicembre 2005, n. 266: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2006)", http://www.governo.it/GovernoInforma/Dossier/finanziaria_2006/dl203_05.pdf

700 Decreto-legge 27 maggio 2005, n. 87: "Disposizioni urgenti per il prezzo dei farmaci non rimborsabili dal Servizio sanitario nazionale", http://www.ministerosalute.it/imgs/C_17_normativa_670_allegato.pdf

701 Legge 30 dicembre 2004, n. 311: "Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2005)", http://www.governo.it/GovernoInforma/Dossier/Finanziaria2005/finanziaria.pdf

With regard to parallel trade, Italy is, due to its comparatively low prices, a major parallel exporter[702] (cf. 14.1.2).

Concerning the use of parallel imports, in 2002 the European Commission issued a formal request for Italy to remove obstacles discouraging the parallel import of pharmaceuticals. An excessively long time taken to issue parallel import licences and gain access to reimbursement are highlighted as major obstacles by the European Commission. The then Minister of Health expressed himself in favour of discouraging parallel trade.[703]

14.4 Overview of the Reimbursement Market in Italy

Tasks / Duties	Yes	No	Comment	Legal bases
Public authorities				
Decide on prescription status	X		AIFA	
Decide on manufacturer price		X		
Agree on manufacturer price		X	Price negotiations between Medicines Agency AIFA and manufacturers for reimbursable pharmaceuticals	Decree-Law 326/2003 Enactment by CIPE 1/2/01
Fix wholesale margin	X		Statutory wholesale mark-up for reimbursable pharmaceuticals	Law 662/1996
Fix pharmacy retail price	X		Statutory pharmacy mark-up for reimbursable pharmaceuticals	Law 662/1996
Decide on reimbursement status	X		AIFA	Decree-Law 326/2003
Decide on reimbursement price	X		AIFA	Decree-Law 326/2003
Use Pharmaco-economic guidelines		X	No pharmaco-economic guidelines, but pharmaco-economics should play a role in the pricing and reimbursement decision	Enactment No. 109/1997 by CIPE Law 450/1997 (Finance Law 1998)
Use Internal reference pricing	X		Reference price system since 2001	Law 405/2001

[702] Tilson, L.; Barry, M. 2005

[703] PPR 2004

Tasks / Duties	Yes	No	Comment	Legal bases
Use External reference pricing	X		Official European average price system is no longer applied, but the prices of pharmaceuticals are considered as an important criterion in the price negotiations	
Price freezes/stops	X		Prices for non-reimbursable pharmaceuticals frozen till January 2007	
Margin cuts		X	But introduction of obligatory discounts for pharmacies to the SSN	
Discounts and Rebates	X		Discount scheme for pharmacies to the SSN	
Company profit control	(X)		Allocation of 5% of manufacturers' marketing expenses to an independent scientific information fund	Law 350/2003 (Finance Law 2004)
Country specific				
Pharmaceutical Industry				
Sets manufacturer price freely	X		Free price setting and price decreases for non-reimbursable pharmaceuticals. Free to price increases of non-reimbursable pharmaceuticals, but only in January of the odd year	Decree-Law 87/2005
Notifies manufacturer price	X		See above	
Negotiates manufacturer price	X		Price negotiations for reimbursable pharmaceuticals with Medicines Agency AIFA	Decree-Law 326/2003 Enactment by CIPE 1/2/01
Is free to set price below fixed manufacturer price	X			
Decides on application for reimbursement	X			
Negotiates reimbursement price	X		Price negotiations for reimbursable pharmaceuticals with Medicines Agency AIFA	Decree-Law 326/2003 Enactment by CIPE 1/2/01
Free to set price below reimbursement level	X			

Tasks / Duties	Yes	No	Comment	Legal bases
Free to grant rebates / discounts to wholesalers	X			
Free to grant rebates / discounts to pharmacies	X			
Can engage in marketing towards doctors	X		In line with code of conduct	
Can engage in public advertising	X		For self-medication OTC pharmaceuticals	
Can provide information toward patients	X		For self-medication OTC pharmaceuticals	
Applies for switches and de-listing	X			
Country specific:				
Distribution Chain				
Wholesaler				
Margins are fixed by statute	X		For reimbursable pharmaceuticals	Law 662/1996
Margins are subject to statutory discounts / rebates		X		
Free to grant discounts / rebates to pharmacies	X			
Pharmacists				
Margins are fixed by statute	X		For reimbursable pharmaceuticals	Law 662/1996
Free to set retail price	X		For non-reimbursable pharmaceuticals	R.D. as of 3 March 1927
Obliged to inform patient on cheaper product	X			
Obliged to substitute by a generic	X			
Allowed to substitute by a generic	X			
Obliged to substitute by a parallel import		X	N.app.	
Allowed to substitute by a parallel import		X	N.app.	

Tasks / Duties	Yes	No	Comment	Legal bases
Therapeutic / analogous substitution is allowed		X		
Are subject to statutory discounts / rebates	X		Complex discount system, depending on turnover and location of pharmacies	
Claw back system exists	X		In the form of price cuts in the next year. In 2006: temporary price cuts of 4.4% on reimbursable pharmaceuticals at pharmacy retail price level	Enactment as of 30 December 2005 by AIFA
May grant rebates to customers	X		Up to 20% discount on non-prescription non-reimbursable pharmaceuticals.	Decree-Law 87/2005
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			
Are obliged to inform on co-payment / deductibles		X		
Prescription habits are monitored	X		Only contract doctors	
Are subject to prescription guidelines	X		So-called product-specific “Note”	
Budgets are controlled	X		Public pharmaceutical expenditure is limited to an allowed ceiling (16% in 2006) of the healthcare budget	Annual Finance Laws
Allowed to prescribe INN	X			
Obliged to prescribe INN		X		
Can oppose generic substitution	X			
Can oppose therapeutic substitution		X	N.app.	
Can oppose substitution by parallel import		X	N.app.	

Tasks / Duties	Yes	No	Comment	Legal bases
Country specific:				
Patients				
Can shop for cheapest price of the product		X	However, discounts are possible for non-reimbursable OTC pharmaceuticals	Decree-Law 87/2005
Pay a flat rate per prescription/pack	X		Depending on regions (only a few regions still have prescription fees)	Law 405/2001
Pay a certain percentage per prescription / pack or a deductible		X	N.app.	
Annual minimum co-payment		X		
Annual maximum co-payment		X		
May ask for substitution by a generic	X			Law 405/2001
May oppose substitution by a generic	X		Patient has to pay the difference between the reference price (reimbursement price) and the actual pharmacy retail price	Law 405/2001
May ask for substitution by a parallel import		X	N.app.	Law 405/2001
Can oppose substitution by a parallel import		X	N.app.	Law 405/2001
Can oppose substitution only on payment of price difference	X			Law 405/2001
Has to pay the difference between reimbursement price and retail price	X			Law 405/2001
Has access to full public information on prices and products	X		Websites of AIFA and Pharmacist's Association	
Country specifics:				

N. app. = Not applicable, N. a. = Not available

Source: ÖBIG 2006

LATVIA

15 Latvia

15.1 Pharmaceutical System

15.1.1 Regulatory Framework and Authorities

Health care in Latvia is organised on the basis of a social health insurance system. However it is not funded through social insurance contributions but via central government's budget allocation. The State Compulsory Health Insurance Agency (Veselibas obligetas apdrošinašanas valsts agentura, VOAVA), which was established in 1998 under the control of the Ministry of Health (Latvijas Republikas veselibas ministrija, VM), receives this central government's budget and distributes it to its 5 regional sickness funds. The amount of the health insurance coverage is statutorily set[704].

The principal activities in the pharmaceutical field are regulated in the Pharmaceutical Law[705]. It ensures that pharmaceuticals, which are produced and distributed, are safe, qualitative and effective. The Pharmaceutical Law determines the responsibilities of the main players in the pharmaceutical sector in Latvia, who are the following:

- the Ministry of Health[706] (Latvijas Republikas veselibas ministrija, VM), advised by the Department of Pharmacy, which is responsible for the strategic planning in terms of pharmaceuticals,
- the State Medicines Pricing and Reimbursement Agency[707] (Zalu Cenu Valsts Agentura, ZCA), which is responsible for the therapeutic and economic evaluation of pharmaceuticals as a basis for setting a reasonable price covered by the national health care system and to elaborate the positive list of reimbursable pharmaceuticals,
- the State Agency of Medicines[708] (Valsts zalu agentura, VZA), which is responsible for issuing market authorisation and classification according to the prescription status,
- the State Compulsory Health Insurance Agency[709] (Veselibas obligetas apdrošinašanas valsts agentura, VOAVA).

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704 Regulation No. 13, January 1999

705 Pharmaceutical Law (E0050), http://www.ttc.lv/index.php?skip=15&itid=likumi&id=10&tid=50&l=EN

706 http://phoebe.vm.gov.lv/faili_eg/Regulation.pdf

707 Regulation of Cabinet of Ministers of the Republic of Latvia No. 1007 of 7 December 2004

708 Regulation No. 381 (E0292), http://www.ttc.lv/index.php?skip=120&itid=mk_noteikumi&id=10&tid=71&l=EN, http://www.vza.gov.lv/english/pdf/doc1-006.pdf, Regulation of Cabinet of Ministers of the Republic of Latvia No. 138 (E0242), http://www.ttc.lv/index.php?skip=75&itid=mk_noteikumi&id=10&tid=71&l=EN

709 State Insurance Law (E0574), http://www.ttc.lv/index.php?skip=135&itid=likumi&id=10&tid=50&l=EN

In accordance with the EU Directive 2004/27/EC, VZA authorises pharmaceuticals as well as classifies them according to their prescription status into POM, subcategories of POM (such as prescription only by a specialist) and OTC[710]. VZA publishes a database with all authorised pharmaceuticals[711]. Table 15.1 contains an overview of relevant stakeholders in Latvia.

Table 15.1: Latvia - Relevant Authorities and Market Players in the Pharmaceutical Sector,2006

Institution	Task	Contact details/URL	Responsible person
Latvijas Republikas veselibas ministrija (VM) / Ministry of Health	Ministry of Health (Regulatory body for pharmaceuticals)	Ministry of Health Brîvîbas 72 LV-1011 Riga Latvia Tel.: +371 7876 000 Fax: +371 7876 002 vm@vm.gov.lv www.vm.gov.lv/	Mr. Uldis Likops Brîvîbas 72 LV-1011 Riga Latvia Tel.: +371 7043 754 Fax: +371 7876 002 uldis_likops@vm.gov.lv
Zalu Cenu Valsts Agentura (ZCA) / State Medicines Pricing and Reimbursement Agency	Pricing and Reimbursement	ZCA 72, Brivibas Street LV-1011 Riga Latvia Tel.: +371 7876 128 Fax: +371 7876 129 info@zca.gov.lv www.zca.gov.lv/	Ms. Daiga Behmane Director 72, Brivibas Street LV-1011 Riga Latvia Tel.: +371 7876 128 Fax: +371 7876 129 Daiga_behmane@zca.gov.lv
Valsts zalu agentura (VZA) / State Agency of Medicines	Authorisation of pharmaceuticals	VZA 15 Jersikas street LV-1003 Riga Latvia Tel.: +371 7078 400 Fax: +371 7078 428 info@vza.gov.lv www.vza.gov.lv	Mr. Gatis Ozolins 15 Jersikas street 1003 Riga LV-Latvia Tel.: +371 7078 427 Fax: +371 7078 428 Gatis_Ozolins@vza.gov.lv
Veselibas obligetas apdrošinašanas valsts agentura (VOAVA) / State Compulsory Health Insurance Agency	Third Party Payer; State Compulsory Health Insurance Agency	VOAVA Baznicas iela 25 LV-1010 Riga Latvia Tel.: +371 7043 700 or + 371 7043 767 Fax: +371 7043 701 voava@voava.lv www.voava.lv	Ms. Viktorija Zefirova Director Baznicas iela 25 LV-1010 Riga Latvia Tel.: +371 7043 700 Viktorija.zefirova@voava.lv

710 Enactment No. 381, http://www.vza.gov.lv/english/pdf/doc1-006.pdf

711 http://www.vza.gov.lv/atlase/zales.exe

Institution	Task	Contact details/URL	Responsible person
Association of Pharmaceutical Wholesalers of Latvia	Wholesaler association	Association of Pharmaceutical Wholesalers of Latvia Hospitalu Str. 55 LV-1013 Riga Latvia Tel.: +371 7377 024 Fax: +371 7377 024	Mr. Vladislav Strods Hospitalu Str. 55 LV-1013 Riga Latvia Tel.: +371 7377 024 Fax: +371 7377 024 Lzla@latnet.lv
Latvijas Farmaceitu Biedriba (LFB) / Latvian Pharmaceutical Society	Association of pharmacists	LFB R. Vagnera icla 13 LV-1050 Riga Latvia Tel.: +371 7224 221 Fax: +371 7216 821	Mr. Aigars Enins President R. Vagnera icla 13 LV-1050 Riga Latvia Tel.: +371 7224 221 Fax: +371 7216 903 Lfb@parks.la
Latvijas Arstu Biedriba (LAB) / Latvian Physicians Association	Medical doctors' association	LAB Skolas Str. 3 LV-1010 Riga Latvia Tel.: +371 7220 661 Fax: +371 7220 657	Mr. Viesturs Boka Skolas Str. 3 LV-1010 Riga Latvia Tel.: +371 7220 661 Fax: +371 7220 657 lab@parks.lv
Association of International Research-based Pharmaceutical Manufacturers (SIFFA)	Association of pharmaceutical manufacturers	SIFFA Skolas Str. 3 LV-1010 Riga Latvia Tel.: +371 9253 093 Fax: +371 7332 148 siffa@siffa.lv www.siffa.lv	Mr. Valdis Freidenfelds Executive Director Skolas Str. 3 LV-1010 Riga Latvia Tel.: +371 9253 093 Fax: +371 7332 148 valdis_freidenfelds@neonet.lv

Source: ÖBIG 2006

15.1.2 Market Players

15.1.2.1 Pharmaceutical Industry

The local pharmaceutical production is relatively small. Only around 5% of the pharmaceuticals dispensed in Latvia are locally produced. Therefore, Latvia is in general an import country rather than an export country (cf. 15.2.2.7). In 2005, there were 12 active pharmaceutical manufacturers in Latvia, of which Grindeks and Olainfarm are the most important pharmaceutical manufacturers.

The Cabinet of Ministers of the Republic of Latvia has published regulations regarding the manufacture and the control of medicinal product[712].

15.1.2.2 Distribution

Pharmaceutical wholesale is organised as a multi-channel system. In 2005, there were 40 wholesalers registered, the 5 leading wholesalers have a market share of 80%. The most important wholesaler is Tamro, who has a market share of 30%. Further relevant wholesalers are Recipe Plus, Magnum Medical, Oriola Riga and Briz. The interests of the wholesalers are represented in the Association of Pharmaceutical Wholesalers.

Pharmaceuticals in Latvia are sold through pharmacies operated by pharmacists. The Cabinet of Ministers of the Republic of Latvia has released regulations on the criteria for the location of pharmacies and branches of pharmacies[713]. One regulation specifies geographic and demographic criteria for the establishment of pharmacies. In the course of the liberalisation of pharmacies 5 pharmacy chains with each 20 pharmacies have been established. In 2004, there were 882 pharmacies, which corresponds to 2,629 inhabitants per pharmacy.

Additionally health care centres are also authorised to dispense pharmaceuticals in case that a pharmacist is working there.

Certain OTC products, which are included in a special list approved by the VM, may theoretically be sold outside of pharmacies. In practice this distribution channel is not in use.

There are no self dispensing doctors in Latvia[714].

15.1.2.3 Patients

Patients are not involved in the pricing and reimbursement process of pharmaceuticals. Their rights are ensured and protected in the Patients Rights Law[715]. This law states that, among others, patients have the right to choose and change their doctor. Furthermore, patients have the right to receive the medical treatment they opt for and to have the expenditure for medicinal treatment and reimbursable pharmaceuticals / pharmaceuticals under the reference price system covered.

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712 Regulation No. 432 (E0217), http://www.ttc.lv/index.php?skip=60&itid=mk_noteikumi&id=10&tid=71&l=EN

713 Regulation No. 421 (E041), and regulation No. 422 (E041), http://www.ttc.lv/index.php?skip=195&itid=mk_noteikumi&id=10&tid=71&l=EN

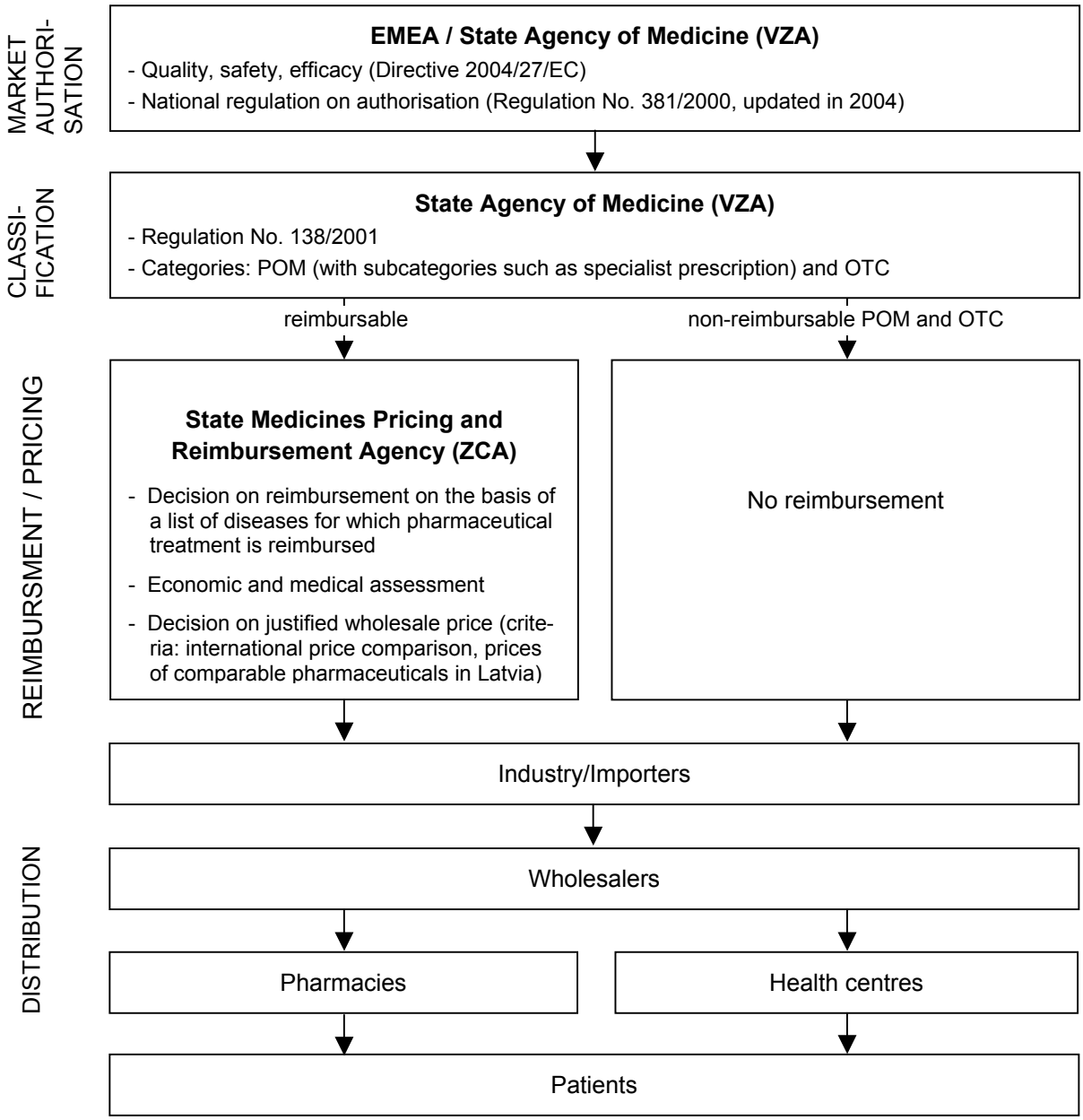
714 ZCA, personal communication, 27. April 2006

715 Patients Rights Law, http://phoebe.vm.gov.lv/faili_eg/Patients_Rights_Law.pdf

15.1.3 Overview of the Pharmaceutical System

Figure 15.1 gives an overview of the pharmaceutical system in Latvia.

Figure 15.1: Latvia - Pharmaceutical System, 2006



POM = Prescription-only Medicine, OTC = Over-the-Counter

Source: ÖBIG 2006

15.2 Pricing

15.2.1 Scope of Price Control

In Latvia only reimbursable pharmaceuticals fall under a statutory price regulation[716] (on manufacturer, wholesale and pharmacy price level), whereas at manufacturer price level there is free pricing for non-reimbursable pharmaceuticals of all categories such as POM, OTC, generics and hospital pharmaceuticals.

Pharmaceutical companies apply at the same time for reimbursement and for the approval of the wholesale price at ZCA (cf. 15.3). The application is reviewed by the ZCA and the VZA. It has to include, amongst others, information on the manufacturer, the proposed wholesale price, the price of similar pharmaceuticals in Latvia as well as an international price comparison (cf. 15.2.2.2). Budget impact analysis on the basis of estimated sales volume and pharmaco-economic evaluation (cf. 15.2.2.1) for new active substances must also be submitted with the application.

The decision on justified wholesale prices is taken by the VZA, who also publishes the prices of reimbursable pharmaceuticals[717] (cf. 15.3.1).

In 2004, the Baltic States published a common resolution on the system of financing health care in the Baltic States[718]. This includes public tendering for expensive pharmaceuticals, such as for the treatment of hepatitis C, HIV/AIDS and osteoporosis.

Table 15.2 provides an overview of the pricing system in Latvia.

716 Regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239

717 http://www.zca.gov.lv/search/e/

718 Resolution on the system of financing health care in the Baltic States, http://www.baltasam.org/?DocID=258

Table 15.2: Latvia - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Non-reimbursable pharmaceuticals	Not applied	Not applied
Statutory Pricing	Reimbursable pharmaceuticals	All pharmaceuticals - *non-reimbursable* pharmaceuticals with a maximum wholesale mark-up of 15% - *reimbursable* pharmaceuticals regulated via a regressive mark-up scheme	All pharmaceuticals regulated via a regressive mark-up scheme
Price Negotiations	Not applied	Not applied	Not applied
Price/volume agreements, discounts/rebates	Not applied	Not applied	Not applied
Institution in charge of pricing	State Medicines Pricing and Reimbursement Agency (ZCA)		
Legal Basis	Regulation of Cabinet of Ministers of the Republic of Latvia No. 1007 of 7 December 2004 Regulation No. 418 http://www.farmacija-mic.lv/main/likums_w/20030202123239		

Source: ÖBIG 2006

15.2.1.1 Manufacturer Price

Prices for reimbursable pharmaceuticals are set by ZCA, however at wholesale level (cf. 15.2.1 and 15.3). Manufacturers apply at the same time for the approval of the wholesale price at ZCA and for reimbursement. The manufacturer price for reimbursable pharmaceuticals is indirectly regulated through the regressive mark-up scheme (cf. Table 15.3) Pharmaceutical companies may freely set the manufacturer prices for non-reimbursable pharmaceuticals.

15.2.1.2 Wholesale Price

In Latvia, the wholesale mark-ups for all pharmaceuticals are regulated by the State, differentiating between reimbursable and non-reimbursable pharmaceuticals. For non-reimbursable pharmaceuticals the maximum wholesale mark-up is set at 15% of the manufacturer price. For reimbursable pharmaceuticals, there is a regressive mark-up (cf. Table 15.3), which was updated on 12 June 2005 and is displayed in the Appendix No. 3 of Regulation No. 418[719].

[719] Regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239

Table 15.3: Latvia - Wholesale Mark-ups for Reimbursable Pharmaceuticals, 2006

Ex-factory price/CIP from…to…in LVL / €	Wholesale mark-up in % of the manu-facturer price / CIP
LVL 0.01 / € 0.01 - LVL 1.99 / € 2.99	10
LVL 2.00 / € 3.01 - LVL 3.99 / € 6.00	9
LVL 4.00 / € 6.01 - LVL 7.99 / € 12.02	7
LVL 8.00 / € 12.03 - LVL 14.99 / € 22.54	6
LVL 15.00 / € 22.55 - LVL 19.99 / € 30.05	5
from LVL 20.00 / € 30.06 on	4

CIP = Cost, Insurance and Packaging

Source: Regulation No. 428/1998 (amended in 2002)

15.2.1.3 Pharmacy Retail Price

Pharmacy mark-ups are also statutorily fixed for all pharmaceuticals[720], as shown in Table 15.4 for reimbursable pharmaceuticals and in Table 15.5 for non-reimbursable pharmaceuticals. The regressive pharmacy mark-up scheme for reimbursable pharmaceuticals was updated on the 1 January 2006 and is displayed in the Appendix No. 4 of Regulation No. 418[721]. The pharmacy retail price is calculated on the basis of the wholesale price, the mark-up coefficient and the correction sum.

Table 15.4: Latvia - Pharmacy Mark-ups for Reimbursable Pharmaceuticals, 2006

PPP from...to...in LVL / €	Maximum pharmacy mark-up	
	Coefficient	Correction sum in LVL / €
from LVL 0.01 / € 0.02 to LVL 0.99 / € 1.49	1.30	LVL 0.00 / € 0.00
from LVL 1.00 / € 1.50 to LVL 1.99 / € 2.99	1.25	LVL 0.05 / € 0.08
from LVL 2.00 / € 3.00 to LVL 2.99 / € 4.49	1.20	LVL 0.15 / € 0.23
from LVL 3.00 / € 4.50 to LVL 4.99 / € 7.50	1.17	LVL 0.30 / € 0.45
from LVL 5.00 / € 7.51 to LVL 9.99 / € 15.02	1.15	LVL 0.40 / € 0.60
from LVL 10.00 / € 15.03 to LVL 14.99 / € 22.53	1.10	LVL 0.90 / € 1.35
from LVL 15.00 / € 22.54 to LVL 19.99 / € 30.05	1.07	LVL 1.35 / € 2.03
from LVL 20.00 / € 30.06 to LVL 49.99 / € 75.15	1.05	LVL 1.75 / € 2.63
from LVL 50.00 / € 75.16 on	1.00	LVL 4.25 / € 6.39

PPP = Pharmacy Purchase Price

Source: Regulation No. 428/1998 (amended in January 2006)

720 Regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239

721 Regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239

The mark-ups for reimbursable pharmaceuticals are generally applied up to the maximum by the distribution actors, whereas for non-reimbursable pharmaceuticals, wholesalers and pharmacies usually do not make use of the maximum mark-ups allowed. Thus, the retail prices of non-reimbursable pharmaceuticals vary between pharmacies.

Table 15.5: Latvia - Pharmacy Mark-ups for Non-reimbursable Pharmaceuticals, 2006

PPP from...to...in LVL / €	Maximum pharmacy mark-up	
	Coefficient	Correction sum in LVL / €
from LVL 0.01 / € 0.02 to LVL 0.99 / € 1.49	1.40	LVL 0.01 / € 0.02
from LVL 1.00 / € 1.50 to LVL 1.99 / € 2.99	1.35	LVL 0.06 / € 0.09
from LVL 2.00 / € 3.01 to LVL 2.99 / € 4.49	1.30	LVL 0.16 / € 0.24
from LVL 3.00 / € 4.50 to LVL 4.99 / € 7.50	1.25	LVL 0.31 / € 0.47
from LVL 5.00 / € 7.51 to LVL 9.99 / € 15.02	1.20	LVL 0.56 / € 0.84
from LVL 10.00 / € 15.03 to LVL 19.99 / € 30.05	1.15	LVL 1.06 / € 1.59
from LVL 20.00 / € 30.06 on	1.10	LVL 2.06 / € 3.10

PPP = Pharmacy Purchase Price

Source: ZCA 2005

15.2.1.4 Value Added Tax (VAT)

The standard VAT is 18%, and for pharmaceuticals a reduced VAT of 5% is applied[722].

15.2.2 Price Related Cost-containment Measures

15.2.2.1 Pharmaco-economic Evaluation

Since 1 October 2003 manufacturers have been required to submit a pharmaco-economic analysis when applying for reimbursement in case of new active ingredients, in accordance with the regulations of ZCA, based on the Baltic Guideline for Economic Evaluation of Pharmaceuticals[723].

In 2002, common Guidelines for Economic Evaluation were developed in a cooperation of the Latvian Pricing and Reimbursement Agency (ZCA), the Estonian Health Insurance Fund and the Lithuanian Department of Pharmacy (FD) to simplify the application for pricing and reimbursement for pharmaceutical manufacturers. The Guidelines are oriented towards pharmaceutical manufacturers and give information, among others, on the preferred perspective (health care system); on costs to be included in the analysis, on how they shall be

722 Regulation No. 550 (E0699), http://www.ttc.lv/index.php?skip=405&itid=mk_noteikumi&id=10&tid=71&l=EN

723 Baltic Guideline of Economic Evaluation of Pharmaceuticals (Pharmaco-economic Analysis), http://www.zca.gov.lv/docs/new2002/doc24-1.pdf

established and on discount rates to be used. The Guidelines aim at harmonising pharmaceutical prices in the Baltic States.

15.2.2.2 Internal Price Referencing

In the course of an application for reimbursement, the applied price is compared with prices of other pharmaceuticals with the same active ingredient or with pharmaceuticals from the same therapeutic group. There is a reference price system in place, introduced on 1 July 2005 (cf. 15.3.2).

15.2.2.3 External Price Referencing / Cross Country Referencing

If pharmaceutical companies apply for reimbursement, they need to include internal price comparisons (cf. 15.2.2.2) as well as data on the name and the price of the pharmaceutical in other European countries. The price in Latvia should not exceed the prices of the other Baltic States.

15.2.2.4 Price Freezes / Stops

There were no price freezes in Latvia[724].

15.2.2.5 Margin Cuts

There were no margin cuts in Latvia during the 10 last years[725].

15.2.2.6 Discounts and Rebates

There are no discounts and rebates on a voluntary basis in Latvia[726].

15.2.2.7 Parallel Trade

As mentioned in section 15.1.2.1, Latvia generally imports most of its pharmaceuticals, since local production accounts for around 5% of the market. VZA has issued a regulation on the import, export and distribution of pharmaceuticals[727]. This regulation also specifies the requirements for the establishment and operation of pharmaceutical wholesalers. Import licences are issued for 5 years.

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724 ZCA, personal communication, 27. April 2006

725 ZCA, personal communication, 27. April 2006

726 ZCA, personal communication, 27. April 2006

727 Regulation No. 88, http://www.vza.gov.lv/english/PDF/LE03LC9S.pdf

Parallel importers have to undertake the same procedure when applying for reimbursement and for a price.

For reimbursement parallel traded products have to be at least 15% cheaper (at wholesale level) than the price on the positive list.[728]

15.2.3 Co-Payments

Patients have to pay the full pharmacy retail price for all pharmaceuticals that are excluded from the positive list. For pharmaceuticals that are sold at the expense of the social insurance, patients have to pay the difference between the pharmacy retail price and the reimbursement price. The amount of co-payment can differ for the same pharmaceutical depending on the underlying diagnosis (cf. 15.3.1.1).

The reimbursement categories (cf. 15.3) are relevant for the whole population; there are no exemptions for socially disadvantaged or elderly people. However, there are additional diagnose groups with a reimbursement rate of 50% for children under the age of 3.

On 1 January 2005 the dispensing fee of LVL 0.1 / € 0.14 that had to be paid for each pharmaceutical in the pharmacy was abolished.

15.2.4 Information Transparency and Marketing

In Latvia, prices of reimbursable pharmaceuticals are relatively easy to access, since ZCA publishes the positive list on its website[729].

Generally speaking, doctors, pharmacists and pharmaceutical companies are allowed to inform patients about the characteristics and the prices of pharmaceuticals as long as the provisions on pharmaceutical advertising are fulfilled.

Latvia has harmonised its legislation to the requirements of the European Directive 2001/83/EC. VZA has published regulations on the advertising procedure for pharmaceuticals[730]. Furthermore, there are special regulations on the labelling and on packaging of pharmaceuticals[731].

728 ZCA, personal communication, 27. April 2006

729 http://www.zca.gov.lv/search/e/

730 http://www.vza.gov.lv/english/pdf/doc3-001.pdf

731 Regulation No. 136 (E0538), http://www.ttc.lv/index.php?skip=285&itid=mk_noteikumi&id=10&tid=71&l=EN

15.3 Reimbursement

In the year 2003, VOAVA spent around 13% of its budget on the reimbursement of out-patient pharmaceuticals as well as for the central purchase of in-patient pharmaceuticals.

ZCA is the relevant authority for the therapeutic and economic evaluation of pharmaceuticals as a basis for setting a reasonable reimbursement price and for the drafting of the positive list of reimbursable pharmaceuticals[732] (cf. 15.3.1.3).

Reimbursement of pharmaceuticals shall be provided according to the character and severity of the disease. Reimbursable diagnoses (diseases) are listed in the Appendix No. 1 of the Regulation No. 418.

Reimbursable pharmaceuticals are prescribed by family doctors as well as certain specialists who have agreements with the VOAVA.

15.3.1 Pharmaceutical Lists and Reimbursement Categories

ZCA is responsible for developing the **positive list** of reimbursable pharmaceuticals. The positive list also includes the maximum reimbursement price. It is publicly available, as ZCA publishes it on its website[733]. ZCA reviews the positive list every three months; and once a year an up-date version is published. However, pharmaceuticals may remain for two years in the positive list, thereafter the pharmaceutical company has to apply once again for an inclusion of the pharmaceutical in the positive list. In July 2005 the positive list was split into list A with interchangeable pharmaceuticals (cf. 15.3.2) and list B with products without comparable pharmaceuticals.

The application for reimbursement needs to include, among others, information on the pharmaceutical company, on the pharmaceutical, a justification on the proposed price as well as an indication of expected sales.

The positive list includes pharmaceuticals that are prescribed for the treatment of the diagnoses that are defined in the Appendix No. 1 of the Regulation No. 418.

As it was mentioned before, reimbursement is provided according to the diagnoses and the severity of the disease. Pharmaceuticals used in the treatment of listed diseases are reimbursed at the following categories[734]:

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732 Regulation No. 428 (E0437), http://www.ttc.lv/index.php?skip=210&itid=mk_noteikumi&id=10&tid=71&l=EN, as amended by regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239

733 http://www.zca.gov.lv/search/e/

734 Regulation No. 428 (E0437), http://www.ttc.lv/index.php?skip=210&itid=mk_noteikumi&id=10&tid=71&l=EN, as amended by regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239

- Category 1: 100% reimbursement for the treatment of severe chronic diseases with life threatening character such as cancer and HIV/AIDS
- Category 2: 90% reimbursement for the treatment of severe chronic diseases, which affect vital life functions such as endocrine diseases
- Category 3: 75% reimbursement for the treatment of chronic diseases such as asthma and hypertension
- Category 4: 50% reimbursement for the treatment of acute or chronic diseases such as rheumatic diseases

There are some diseases where additional regulations with regard to reimbursement apply, such as age (children under three years) or time limits for a therapy. A pharmaceutical used for different indications can be reimbursed at different rates - according to the reimbursement rate assigned to the underlying condition (cf. 15.2.3).

15.3.1.1 Reimbursement Price

The reimbursement price is fixed on the basis of the price in the positive list and the corresponding diagnosis.

15.3.1.2 Selection Criteria

The main criteria for a pharmaceutical to be reimbursed are:

- the burden of the disease
- the therapeutic value of the pharmaceutical
- cost-effectiveness data
- the impact on the health care budget

15.3.1.3 Pharmaceuticals on Positive List

The positive list includes around 750 pharmaceuticals (including different pharmaceutical forms, strengths and pack sizes) and 240 active ingredients. This amounts to around 20% of the pharmaceutical market.

Table 15.6: Latvia - Pharmaceuticals, 2005

Pharmaceuticals	2005
Pharmaceutical - quantity	2005
Authorised	~ 4,500
POM	~ 3,195
OTC	~ 1,305
Reimbursable	~ 750

POM = Prescription-only medicines, OTC = Over-the-Counter pharmaceuticals

Source: ÖBIG 2005

15.3.1.4 Generics

As mentioned in section 15.2.1, there is free pricing for non-reimbursable pharmaceuticals. In case that a generic is used for the treatment of a diagnosis considered as not reimbursable, no statutory pricing procedure is applied.

15.3.1.5 Non-reimbursable Pharmaceuticals

There is no negative list. However, homeopathic pharmaceuticals and OTC products are excluded from reimbursement.

15.3.1.6 Delisting

ZCA can decide to take a pharmaceutical from the positive list, if the pharmaceutical company charges a higher price. Furthermore ZCA can decrease the reimbursement price, if for instance the actual sales expand the expected sales by 30%.

15.3.2 Reference Price System

In July 2005 a reference price system came into effect. Before the introduction of the reference price system with price comparisons with the same active ingredients (ATC 5 level) or within the same therapeutic group (ATC 4 level) had already been applied.

As it was mentioned in section 15.3.1, in July 2005 the positive list was split into list A and list B according to the following criteria:

- List A pharmaceuticals are grouped into clusters of interchangeable pharmaceuticals, meaning that they have the same indication, the same method of administration, no clinically relevant differences in effectiveness and side effects, and are intended for the same patient group. A cluster contains identical pharmaceuticals with the same pharmaceutical form and dosage. For each cluster of pharmaceuticals a reference price is assigned, which is the price of the cheapest pharmaceutical in that cluster.
- List B contains pharmaceuticals which are considered not to be interchangeable.

15.3.3 Pharmaceutical Budgets

In order to bare the growing expenditure of pharmaceuticals, the reimbursement system contains a range of cost-containment measures, such as fixed budgets for doctors, special reimbursement categories for very expensive pharmaceuticals (cf. 15.3.1), patient co-payments (cf. 15.2.3), rational pharmaco-economic guidelines (cf. 15.2.2.1).

There are prescription budgets for doctors, with penalties for overspending, consequently the doctors have an interest in prescribing economically.

15.3.4 Other Volume Control Oriented Measures

15.3.4.1 Prescription Monitoring and Other Doctors-related Measures

ZCA is responsible for collecting and analysing information and data about the expenditure of pharmaceuticals. This information is shared with professional associations and institutions in order to develop prescribing guidelines and promote rational use of pharmaceuticals. Doctors are required to prescribe the most suitable, effective and cheapest treatment for patients[735].

Additional pressure is put by the VOAVA, who seeks to lower the expenditure of POM by negotiating the terms of their contracts with doctors.

15.3.4.2 Generics and Parallel Trade

Generic prescribing is strongly encouraged by the VM as part of its commitment to cost-effectiveness. Doctors are penalised if their budgets are overspent, so generics are seen as an effective way of controlling prescribing expenditure.

If the doctors use the general name of a pharmaceutical when writing a prescription, the pharmacist is obliged to dispense the cheapest pharmaceutical included in the positive list[736].

Latvia imports most of its pharmaceuticals, as it is mentioned in section 15.2.2.7.

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735 Regulation No. 428 (E0437), http://www.ttc.lv/index.php?skip=210&itid=mk_noteikumi&id=10&tid=71&l=EN, as amended by regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239

736 Regulation No. 428 (E0437), http://www.ttc.lv/index.php?skip=210&itid=mk_noteikumi&id=10&tid=71&l=EN, as amended by regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239

15.4 Overview of the Reimbursement Market in Latvia

Tasks / Duties	Yes	No	Comment	Legal bases
Public Authorities				
Decide on prescription status	X		VZA	Regulation No. 381 (E0292), http://www.ttc.lv/index.php?skip=120&itid=mk_noteikumi&id=10&tid=71&l=EN, http://www.vza.gov.lv/english/pdf/doc1-006.pdf, Regulation of Cabinet of Ministers of the Republic of Latvia No. 138 (E0242), http://www.ttc.lv/index.php?skip=75&itid=mk_noteikumi&id=10&tid=71&l=EN
Decide on manufacturer price	X		ZCA sets the prices of reimbursable pharmaceuticals at wholesaler level – the manufacturer prices are indirectly set, through a regressive mark-up scheme at wholesale level free pricing for non-reimbursable pharmaceuticals	Regulation of Cabinet of Ministers of the Republic of Latvia No.1007 of 7 December 2004 Regulation No 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239
Agree on manufacturer price		X	N.app.	
Fix wholesale margin	X		ZCA; for non-reimbursable pharmaceuticals the maximum wholesale mark-up is set at 15% of the manufacturer price; there is a regressive mark-up scheme for reimbursable pharmaceuticals	Regulation of Cabinet of Ministers of the Republic of Latvia No.1007 of 7 December 2004 Regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239
Fix pharmacy retail price	X		ZCA; different regressive mark-up schemes for reimbursable and non-reimbursable pharmaceuticals	Regulation of Cabinet of Ministers of the Republic of Latvia No.1007 of 7 December 2004 Regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239
Decide on reimbursement status	X		ZCA	Regulation No 428 (E0437), http://www.ttc.lv/index.php?skip=210&itid=mk_noteikumi&id=10&tid=71&l=EN, as amended by Regulation No 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239
Agrees on reimbursement price		X	N.app.	

Tasks / Duties	Yes	No	Comment	Legal bases
Decide on reimbursement price	X		ZCA	Regulation No. 428 (E0437), http://www.ttc.lv/index.php?skip=210&itid=mk_noteikumi&id=10&tid=71&l=EN, as amended by regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239
Use Pharmaco-economic guidelines	X		ZCA	Baltic Guideline of Economic Evaluation of Pharmaceuticals (Pharmaco-economic Analysis), http://www.zca.gov.lv/docs/new2002/doc24-1.pdf
Use Internal reference pricing	X		ZCA	Regulation No. 428 (E0437), http://www.ttc.lv/index.php?skip=210&itid=mk_noteikumi&id=10&tid=71&l=EN, as amended by regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239
Use External reference pricing	X		ZCA	Regulation No. 428 (E0437), http://www.ttc.lv/index.php?skip=210&itid=mk_noteikumi&id=10&tid=71&l=EN, as amended by regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239
Price freezes		X	N.app	
Margin cuts		X	N.app	
Discounts and Re-bates		X	N.app	
Company profit con-trol		X	N.app	
Country specific:				
Pharmaceutical Industry				
Sets manufacturer price freely	X		For non-reimbursable phar-maceuticals	Regulation of Cabinet of Ministers of the Republic of Latvia No.1007 of 7 December 2004 Regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239
Notifies manufacturer price		X	N.app.	
Negotiates manufacturer price		X	N.app.	
Is free to set price below fixed manufacturer price	X			
Decides on application for reim-	X			

Tasks / Duties	Yes	No	Comment	Legal bases
bursement				
Negotiates reimbursement price		X	N.app.	
Free to keep manufacturer price above reimbursement price			N.a.	
Free to grant rebates/discounts to wholesalers	X		On a voluntary basis	
Free to grant rebates/discounts to pharmacies	X		On a voluntary basis	
Can engage in marketing towards doctors	X			
Can engage in public advertising	X			http://www.vza.gov.lv/english/pdf/doc3-001.pdf
Can provide information toward patients	X			http://www.vza.gov.lv/english/pdf/doc3-001.pdf
Applies for switches and de-listing	X		ZCA	
Promotional control		X	N.app.	
Country specific:				
Distribution Chain				
Wholesaler				
Margins are fixed by statute	X		ZCA; for non-reimbursable pharmaceuticals the maximum wholesale mark-up is set at 15% of the manufacturer price; there is a regressive mark-up scheme for reimbursable pharmaceuticals	Regulation of Cabinet of Ministers of the Republic of Latvia No.1007 of 7 December 2004 Regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239
Margins are subject to statutory discounts/rebates		X	N.app.	
Free to grant discounts/rebates to pharmacies	X		On a voluntary basis	
Pharmacists				

Tasks / Duties	Yes	No	Comment	Legal bases
Margins are fixed by statute	X		ZCA; different regressive mark-up schemes for reimbursable and non-reimbursable pharmaceuticals	Regulation of Cabinet of Ministers of the Republic of Latvia No.1007 of 7 December 2004 Regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239
Free to set retail price		X	N.app.	
Obliged to inform patient on cheaper product	X			Regulation No. 428 (E0437), http://www.ttc.lv/index.php?skip=210&itid=mk_noteikumi&id=10&tid=71&l=EN, as amended by regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239
Obliged to substitute by a generic	X			Regulation No. 428 (E0437), http://www.ttc.lv/index.php?skip=210&itid=mk_noteikumi&id=10&tid=71&l=EN, as amended by regulation No. 418, http://www.farmacija-mic.lv/main/likums_w/20030202123239
Allowed to substitute by a generic	X			
Obliged to substitute by a parallel import		X	N.app.	
Allowed to substitute by a parallel import	X			
Therapeutic/ analogous substitution is allowed	X			
Are subject to statutory discounts/ rebates		X	N.app.	
Claw back system exists		X	N.app.	
May grant rebates to customers	X		On a voluntary basis	
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			
Are obliged to inform on co-payment/ deductibles	X			
Prescription habits are monitored	X			

Tasks / Duties	Yes	No	Comment	Legal bases
Are subject to prescription guidelines	X			
Budgets are controlled	X			
Allowed to prescribe INN	X			
Obliged to prescribe INN		X		
Can oppose generic substitution		X	N.app.	
Can oppose therapeutic substitution		X	N.app.	
Can oppose substitution by parallel import		X	N.app.	
Country specific:				
Patients				
Can shop for cheapest price of the product	X			
Pay a flat rate per prescription/pack		X	N.app.	
Pay a certain percentage per prescription/pack or a deductible		X	N.app.	
Annual minimum co-payment		X	N.app.	
Annual maximum co-payment		X	N.app.	
May ask for substitution by a generic	X			
May oppose substitution by a generic		X	N.a.	
May ask for substitution by a parallel import		X	N.a.	
Can oppose substitution by a parallel import		X	N.a.	
Can oppose substitution only on payment of price difference		X	N.a.	
Has to pay the difference between reimbursement price	X			

Tasks / Duties	Yes	No	Comment	Legal bases
and retail price				
Has access to full public information on prices and products	X			http://www.zca.gov.lv/search/e/
Country specifics:				

N. app. = Not applicable, N. a. = Not available

Source: ÖBIG 2006

LITHUANIA

16 Lithuania

16.1 Pharmaceutical System

16.1.1 Regulatory Framework and Authorities

The health care system in Lithuania was gradually transformed from a centralised Semashko model to a social insurance system after the political changes in the year 1990. In 1996 the State Sickness Fund (Valstybinė ligonių kasa, VLK) was founded, since 2003 the VLK has been organised in five territorial branches under the supervision of the Ministry of Health (Sveikatos apsaugos ministerija, SAM). The VLK is funded through social insurance contributions of the insured and employers, contributions from the income taxes and state budget allocations.

Primary care is provided mainly in municipality health centres and polyclinics. Primary care physicians are remunerated on a capitation basis and act as gatekeepers to the specialist services. The SAM sets the fees for medical services, all primary care facilities have to offer services at these fees. Almost all hospitals and polyclinics are in public hands.

The principles of the Lithuanian health care system, its relevant institutions and their responsibilities are held in the Law of the Health System.[737]

The most relevant players in the Lithuanian pharmaceutical system are

- the Lithuanian Ministry of Health (SAM), being responsible for the strategic planning in terms of the pharmaceutical system
- the Department of Pharmacy (Farmacijos Departamentas, FD) under the Ministry of Health, responsible for the implementation of the pharmaceutical policy and for ensuring the provision of efficient and safe pharmaceuticals at socially acceptable prices
- the State Medicines Control Agency (Valstybinė vaistų kontrolės tarnyba, VVKT) under the Ministry of Health, carrying out regulatory and control functions
- the State Patient Fund (VLK) under the Ministry of Health, being in charge of reimbursement and the procurement of high priced pharmaceuticals via tenders and
- the Medicines Reimbursement Committee (cf. 16.3), consisting of representatives of the SAM, the FD, the VVKT and the VLK; giving advise to the Minister of Health with regard to reimbursement decisions.

[737] Law on the Health System; No. I-552, 1 December 1998

The VVKT - an authority under the SAM - bears the responsibilities of granting marketing authorisation, classifying (with regard to prescription status), pharmacovigilance, inspections of pharmaceutical industry and pharmaceutical distribution companies including pharmacies, controlling the quality of pharmaceuticals and controlling the advertisement of pharmaceuticals.[738]

The marketing authorisation process has been fully harmonised to EU legislation; however pharmaceuticals with non EU-conform marketing authorisation may still be marketed within Lithuania until the end of 2006.[739] A time schedule was published by the VVKT in accordance with the marketing authorisation holders, stating the date until which they shall apply for upgrading the marketing authorisation to the VVKT, so that the transitional term is kept.[740] Registration certificates are valid for a period of five years.

The VVKT classifies pharmaceuticals into the categories of prescription-only medicines (POM) with subcategories and non-prescription medicines (Over-the-Counter, OTC). Beside, the categories of homeopathic preparations and food products of special medicinal purpose and medicated cosmetics are applied. With regard to switching prescription status the VVKT refers to the EC Guidelines, a switch may be initiated by the marketing authorisation holder or by national authorities.[741, 742]

The registration of homeopathic preparations underlies the general rules of marketing authorisation for pharmaceuticals; simplified procedures are in place for market authorisation of orally or externally applied preparations without certified therapeutic indications.[743]

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738 Law on Medicines, No. I-1633, 19 November 1996;
http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=41376

Law on Pharmaceutical Activities, No. I-1025, 4 June 2002;
http://www3.lrs.lt/pls/inter2/dokpaieska.showdoc_l?p_id=168746

739 Order No. 669 of the Minister of Health of the Republic of Lithuania concerning conformation of general regulations for Granting marketing authorisation, 22 December 2001

740 VVKT 2005 - Schedule for submitting upgrading information;
http://www.vvkt.lt/engl/upgraded_docs/upgrading_products_schedule.pdf

741 European Commission - DG Industry, 1998

742 www.vvkt.lt/t_aktai_en/isvedimas.php?temos_id=9&title=Marketing+authorisation+of+medicinal+products

743 AESGP 2005

Table 16.1: Lithuania - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Lietuvos Respublikos Sveikatos Absaugos Ministerija / Ministry of Health of the Republic of Lithuania	Ministry of Health (regulatory body for pharmaceuticals)	Ministry of Health of the Republic of Lithuania Vilniaus 33, LT-01119 Vilnius, Lithuania Tel.: +370 5268 5110 Fax: +370 5266 14 02 info@sam.lt www.sam.lt	Mr. Zilvinas Padaiga Minister Vilniaus 33 LT-01119 Vilnius Lithuania Tel.: +370 5266 1400 Fax: +370 5266 1402 ministerija@sam.lt
Farmacijos departamentas prie Sveikatos absaugos ministerrios / Department of Pharmacy under the Ministry of Health	Pharmaceutical Department under the MoH (reimbursement lists, pricing)	Department of Pharmacy Traku St. 14, LT-2001 Vilnius Lithuania Tel.: +370 5212 4795 Fax: +370 5261 7881 www.fd.lt	Mr. Linas Mažeika Director Traku St. 14 LT-2001 Vilnius Lithuania Tel.: +370 5 212 4795 Fax: +370 5 261 7881 linas.mazeika@fd.lt
Valstybine vaiste kontroles tarnyba (VVKT) / State Medicines Control Agency	Medicines Agency (market authorisation, classification, vigilance, etc.)	VVKT Traku St. 14 LT-2001 Vilnius Lithuania Tel.: +370 5263 9264 Fax: +370 5263 9265 vvkt@vvkt.lt www.vvkt.lt	Mr. Mindaugas Plieskis Director Traku St. 14 LT-2001 Vilnius Lithuania Tel.: +370 5261 4040 Fax: +370 5263 9265 mindaugasplieskis@vvkt.lt
Valstybinė ligonių kasa prie Sveikatos apsaugos ministerijos (VLK) / State Patient Fund under Ministry of Health	Third Party Payer (reimbursement, pharmaceutical tenders)	VLK Gerosios Vilties str. 1A LT-03505 Vilnius 9 Lithuania Tel.: +370 5213 9727 Fax: +370 5213 9730 vlk@vlk.lt www.vlk.lt	Mr. Algis Sasnauskas Director Gerosios Vilties str. 1A LT-03505 Vilnius 9 Lithuania Tel.: +370 52 36 4100 Fax: +370 5213 9730 algis.sasnauskas@vlk.lt
Etiniu Farmacijos Kompaniju Atstovybiu Asociacija (EFA) / Association of Representative Offices of Ethical Pharmaceutical Manufacturers	Association of Pharmaceutical Industry	EFA Gedimino ave, 28/2 - 409 LT-2600 Vilnius Lithuania Tel.: +370 5212 1013 Fax: +370 5212 1037 info@efa.lt www.efa.lt	Mr. Barcys Gintautas Director Gedimino ave, 28/2 - 409 LT-2600 Vilnius Lithuania Tel.: +370 5212 1013 gintautas@efa.lt

Institution	Task	Contact details/URL	Responsible person
Vaistu gemintoju asociacija (VGA) / Association of Generic Manufacturers	Association of Generic Pharmaceutical Manufacturers	VGA Jasinskio g. 16A LT-2009 Vilnius Lithuania Tel.: +370 5269 1947 Fax: +370 5269 1952 info@vgalietuva.lt www.vgalietuva.lt	Mr. Evaldas Navickas Jasinskio g. 16A LT-2009 Vilnius Lithuania Tel.: +370 5269 1947 Fax: +370 5269 1952 info@vgalietuva.lt www.vgalietuva.lt
Lietuvos farmacijos pramonės įmonių asociacija / Lithuanian Association of Pharmaceutical Enterprises	Association of local Pharma ceutical Indusry	Farmacijos pramonės įmonių asociacija Vytauto g. 3 LT-44354 Kaunas Tel.: +370 37 30 27 55 Fax: +370 37 20 52 25 lfpia@takas.lt	Mr. Albertas Bertulis President Putvinskio str. 44 LT-44354 Kaunas Tel.: +370 37 30 27 55 Fax: +370 37 20 52 25 lfpia@takas.lt
ALP / Association of Lithuanian Pharmaceutical Wholesalers	Wholesaler Association	ALP Gedimino av. 26 LT-2001 Vilnius Lithuania Tel.: +370 5261 7357 Fax: +370 5262 6886 asociacija@mail.vaistai.lt	Mr. Rimas Žemaitis Chairman of the Association Board Gedimino av. 26 LT-2001 Vilnius Lithuania Tel.: +370 5261 7357 Fax: +370 5262 6886
Lietuvos Farmacijos Sajunga / Lithuanian Pharmaceutical Association	Association of Pharmacists	Lithuanian Pharmaceutical Association P.O. Box 1230 LT-2001 Vilnius Lithuania Tel.: +370 5262 8758 Fax: +370 5262 8758 LFSpharm@takas.lt	Mr. E. Tarasevicius Traku 14 LT-2025 Vilnius Lithuania Tel.: +370 6871 4474 LFSpharm@takas.lt
Lietuvos Gydytoju Sjunga (LGS) / Lithuanian Medical Association	Medical Doctors' Association	LGS Liubarto g. 2/15 LT-2001 Vilnius Lithuania Tel.: +370 5273 14 00 Fax: +370 5273 14 00 info@lgs.lt www.lgs.lt	Mr. Liutauras Labanauskas President Liubarto g. 2/15 LT-2001 Vilnius Lithuania Tel.: +370 5273 14 00 kristina.tob@mail.lt

Source: ÖBIG 2006

16.1.2 Market Players

16.1.2.1 Pharmaceutical Industry

In Lithuania 14 local pharmaceutical manufacturers were registered in 2006, the biggest local producers being Sanitas AB. The main markets of the local pharmaceutical industry are, besides Lithuania, Russia and the CIS countries.

16.1.2.2 Distribution

In 2006, there were 74 wholesale licenses registered with VVKT in Lithuania. The wholesale market is in private hands. Besides a number of smaller companies, there are approximately ten big wholesalers offering more than 1,600 pharmaceuticals in their product range. The five leading wholesalers had a common market share of about 70% in 2004. Tamro and Limedika each cover approximately 20% of the market, followed by Medikona and Armila.

In general, the dispensing of all pharmaceuticals and homeopathic products is only allowed in pharmacies.[744] Besides, health care centres may dispense pharmaceuticals in rural areas to ensure the supply of pharmaceuticals to the patients, although this is of minor importance. These health care centres must have a contract with a pharmacy.

Since the ruling of the Constitutional Court in the year 2002 there are no longer geographic or demographic criteria for the establishment of a new pharmacy.[745] Municipalities grant pharmacy concessions according to criteria set by SAM. Pharmacy chains are permitted in Lithuania, of which one of the biggest is “Eurovaistiné”, an international pharmacy chain with approximately 200 outlets in Lithuania. Furthermore, there is vertical integration with wholesalers owning pharmacies. For instance Tamro, a major wholesaler, engaged in the retail market in 2003 by establishing its own pharmacy chain “Seimos vaistine”. In 2004, Tamro purchased the pharmacy chain “Farmacijos projektai” with 46 pharmacies and took over further 13 pharmacy outlets of the Vogne chain in 2005. Only approximately 20% of the pharmacies are still independent pharmacies, most of them being in rather non-profitable rural areas.[746]

In spring 2006, there are a total of 1,427 pharmacy outlets in Lithuania, of which 481 were registered pharmacies and 946 subsidiaries.[747] Thus, there is one pharmacy outlet per 2,384 inhabitants in 2006.

There are no legal provisions allowing distance selling or tele-shopping of pharmaceuticals.[748]

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744 Law on Pharmaceutical Activities, No. I-1025, 4 June 2002; http://www3.lrs.lt/pls/inter2/dokpaieska.showdoc_l?p_id=168746

745 Ruling of the Constitutional Court of the Republic of Lithuania on the compliance of Art. 2.11 of the Law on Pharmaceutical Activities; http://www.lrkt.lt/Documents1_e.html

746 AESGP 2005

747 VVKT 2005

748 AESGP 2005

16.1.2.3 Patients

In general the decisions of the patients are limited by a framework consisting of a restrictive reimbursement list, a reference price system and non-uniform pharmacy retail prices (PRP) throughout the country.

The importance of self-medication and non-prescription medicines is strengthened by a restrictive reimbursement policy. Therefore patients might be encouraged to choose a pharmacy as their source of information, rather then to contact a doctor.[749]

Patient information on packages and leaflets has to be in conformity with EU requirements and has to be clear to the patients.[750] Advertising to patients is only allowed for OTC products, it has been decided by the Constitutional Court in 2005 that the prohibition to advertise POM to patients via mass media (radio and television) does not distort competition.[751] Advertising for pharmaceuticals is regulated by law and under the control of the VVKT.[752]

The list of authorised pharmaceuticals, Patient Information Leaflets (PIL) and Summary of Product Characteristics (SmPC) are available on the Internet.[753] Furthermore the reimbursement lists are available publicly, stating the maximum pharmacy retail price and the base price (cf. 16.3.1.1) as the basis for reimbursement.[754]

Since 2004 within the reimbursable segment doctors are obliged to prescribe by INN - from 2002 to 2004 doctors were allowed to prescribe by trade name as well.[755] Pharmacists are obliged to offer the cheapest generic product available to the patient. Thus the patient has some choice of selection at his own expense (co-payment).

16.1.3 Overview - Pharmaceutical System

Lithuania takes place 9 in the ranking of pharmaceutical retail markets in the CEE, with a market share of 2.8% of the leading 12 CEE pharmaceutical retail markets.[756] In 2005, the Lithuanian pharmaceutical market grew approximately 17% in terms of value compared to

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749 AESGP 2005

750 Decree No. 308 of the Minister of Health of the Republic of Lithuania, 29 May 2001

751 Ruling of the Constitutional Court of the Republic of Lithuania on the compliance of Art 17.4 of the Law of Pharmaceutical Activities with the Constitution of the Republic of Lithuania; http://www.lrkt.lt/Documents1_e_2005.html

752 Law on Advertising; No. VIII-1871, 18 July 2000 and Decree No 298 of the Minister of Health of the Republic of Lithuania, 30 May 2000, http://www.vvkt.lt/t_aktai/isvedimas.php?temos_id=7&title=Vaist%F8+reklama

753 http://www.vvkt.lt

754 http://www.fd.lt

755 FD, personal communication, April 2006

756 IMS 2005

year 2004 and is dominated by importers. The generic market share is very high with 72.7% of the market in terms of volume and 41.6% in terms of value in the year 2004.[757]

Table 16.2: Lithuania - Pharmaceutical Market, 2006

Pharmaceutical Market	2006
No. of authorised pharmaceuticals total	4,072
POM	3,054
OTC	1,018
Pharmaceutical - turnover (in millions)[1]	**2005**
total	LTL 1,340 / € 390.-

OTC = Over-the-Counter, POM = prescription-only medicines

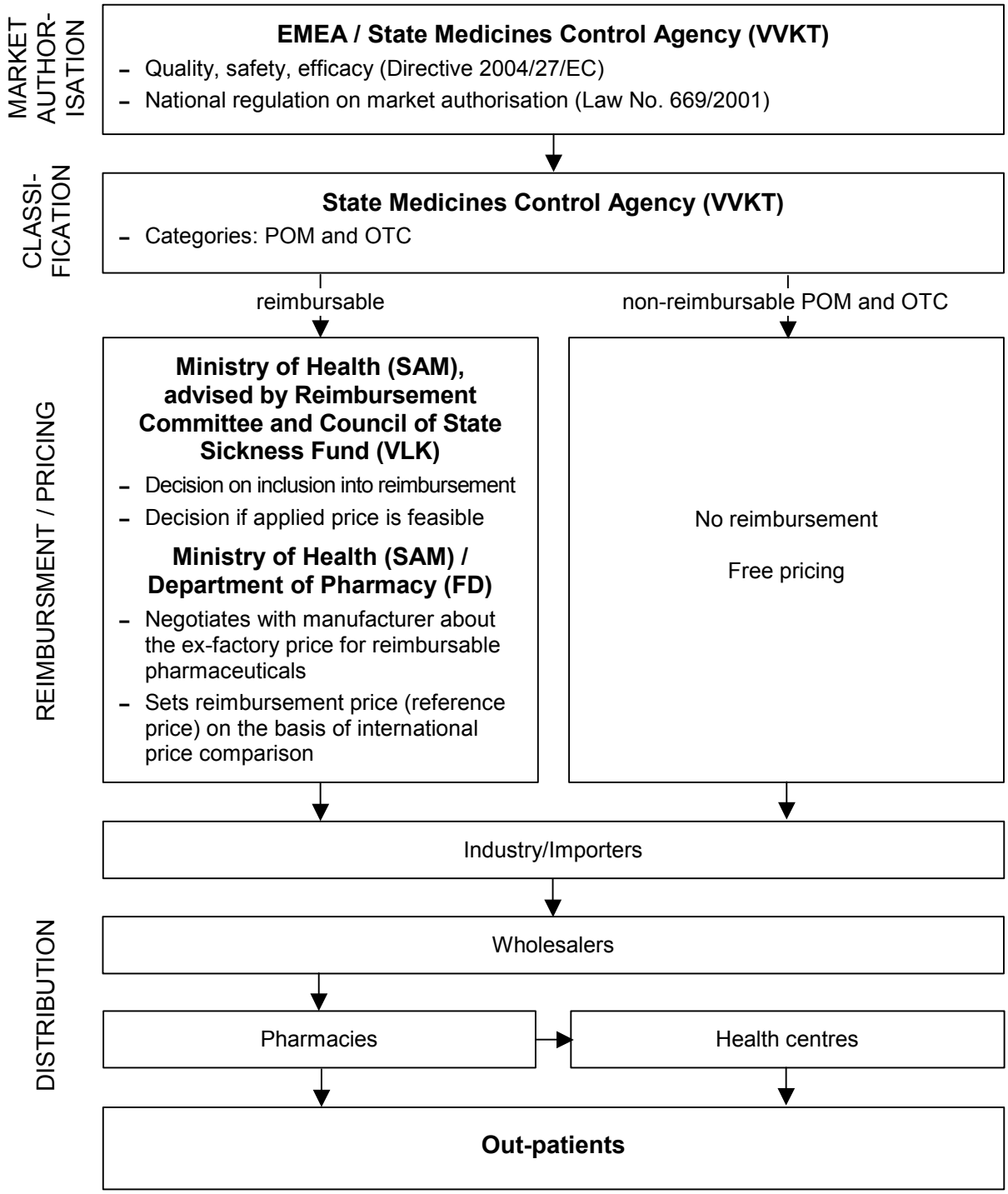
[1] at pharmacy retail prices

Source: ALP 2006; FD 2006; data gathering by ÖBIG

Figure 16.1 provides a quick overview of the pharmaceutical system in Lithuania.

[757] EGA 2005

Figure 16.1: Lithuania - Pharmaceutical system, 2006



EC = European Community, EMEA = European Medicines Agency, FD = Farmacijos Departementas, OTC = Over-the-Counter, POM = Prescription-only medicines, SAM = Sveikatos apsaugos ministerija, VLK = Valstybinė ligonių kasa, VVKT = Valstybinė vaistų kontrolės tarnyba

Source: ÖBIG

16.2 Pricing

16.2.1 Scope of Price Control

Prices for non-reimbursable pharmaceuticals are free. Since 2003 manufacturer or CIP prices (covering cost and insurance for import to Lithuania) for reimbursable pharmaceuticals are negotiated between the FD (on behalf of the SAM) and the pharmaceutical companies.

Maximum wholesale and pharmacy mark-ups for reimbursable pharmaceuticals are regulated as regressive schemes. Thus pharmaceuticals may be sold by pharmacies at prices not higher than the maximum pharmacy retail price (PRP) established by the SAM.[758] In the non-reimbursable segment, there are no regulations on wholesale and pharmacy mark-ups.

In the hospital sector there is free pricing. Some very expensive pharmaceuticals for hospital use or dispensing via hospitals are centrally purchased by the VLK.

Table 16.3: Lithuania - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Non-reimbursable pharmaceuticals	Non-reimbursable pharmaceuticals	Non-reimbursable pharmaceuticals
Statutory Pricing	Not applied	Maximum price of reimbursable pharmaceuticals regulated via a regressive mark-up scheme	Maximum price of reimbursable pharmaceuticals regulated via a regressive mark-up scheme
Price Negotiations	Prices for reimbursable products	Not applied	Not applied
Price/volume agreements, discounts/rebates	VLK has some price volume agreements with manufacturers	Discounts to pharmacies are allowed	Discounts to patients are allowed
Institution in charge of pricing	SAM / FD (advised by Reimbursement Committee and Council of VLK)		
Legal Basis	- Decree No. 459 of the Ministry of Health of the Republic of Lithuania, 12 August 2000 - Decree No. V-170 of the Ministry of Health of the Republic of Lithuania, 30 March 2004 - Decree No. V-171 of the Ministry of Health of the Republic of Lithuania, 11 April 2002		

FD = Farmacijos departamentą, No. = Number, SAM = Sveikatos apsaugos ministerija, VLK = Valstybinė ligonių kasa

Source: ÖBIG 2006

[758] Decree No. 459 of the Ministry of Health of the Republic of Lithuania, 12 August 2000 (last amended by Decree V-992 on 19 December 2005); http://www3.lrs.lt/pls/inter2/dokpaieska.showdoc_e?p_id=107054&p_query=&p_tr2=

16.2.1.1 Manufacturer Price

As mentioned above, prices for non-reimbursable pharmaceuticals are free at all price levels.

Pharmaceutical companies applying for inclusion of a product to reimbursement have to submit an application to the SAM. Amongst others the following information needs to be included in the application: requested manufacturer or for imported pharmaceuticals CIP price (manufacturer price plus import costs), the manufacturer price of the pharmaceutical in six reference countries, estimated sales volumes for the first three years, costs compared to and estimated effects on sales of competing pharmaceuticals and pharmaco-economic analyses.

Manufacturer / CIP prices are negotiated between the Ministry of Health and the marketing authorisation holders on a yearly basis.

Applications for price increases or decreases of reimbursable pharmaceuticals have to be submitted to the SAM / FD. In case of a price decrease the FD then changes the price in the price list, in case of an application for a price increase Reimbursement Committee is consulted.

In general, the same rules apply to pricing of generics - although a simplified procedure is applied for the reimbursement decision if the INN is already on the positive list. Still the manufacturer price of the generic product in the reference countries has to be submitted together with the pricing and reimbursement application.

16.2.1.2 Wholesale Price

In Lithuania there are statutory wholesale margins for reimbursable pharmaceuticals[759], margins for non-reimbursable pharmaceuticals are not regulated by the state and are therefore a matter of negotiation between the actors involved (pharmaceutical industry, wholesalers, pharmacies).

The wholesale mark-up scheme for reimbursable pharmaceuticals is regulated as a regressive scheme with maximum values as displayed in Table 16.4. Margins were reduced in 2004, before they had been lowered by an average of 2% in 2002.

[759] Decree No. V-170 of the Ministry of Health of the Republic of Lithuania, 30 March 2004

Table 16.4: Lithuania - Wholesale Mark-ups for Reimbursable Pharmaceuticals, 2006

Ex-factory price/CIP from...to...in LTL / €	Maximum wholesale mark-up in % of the ex-factory price/CIP in LTL / €
up to LTL 6.43 / € 1.86	14%
from LTL 6.44 / € 1.87 to LTL 10.00 / € 2.89	LTL 0.90 / € 0.26
from LTL 10.01 / € 2.90 to LTL 19.44 / € 5.63	9%
from LTL 19.45 / € 5.64 to LTL 25.00 / € 7.24	LTL 1.75 / € 0.51
from LTL 25.01 / € 7.25 to LTL 53.57 / € 15.51	7%
from LTL 53.58 / € 5.52 to LTL 68.18 / € 9.74	LTL 3.75 / € 1.09
from LTL 68.19 / € 19.75 to LTL 909.09 / € 263.28	5.5%
from LTL 909.10 / € 263.29 on	LTL 50.00 / € 14.48

CIP = Cost, Insurance and Packaging

Source: Decree No. 459 of the Ministry of Health of the Republic of Lithuania, 12 August 2000 (amended by Decree No. V-170 of the Ministry of Health of the Republic of Lithuania, 30 March 2004)

Wholesale mark-ups for non-reimbursable pharmaceuticals are not statutorily regulated. The average gross wholesale-margin was 16.5% in 2004, after discounts to the pharmacies the net margin amounted to 9.5%. In the year 2005 the average margin after discounts amounted to 8-9%.[760]

Wholesalers are not obliged to grant any discounts to the VLK or other state institutions. Discounts granted to pharmacies are without any legal regulation and are subject to negotiations between wholesalers and pharmacies.

16.2.1.3 Pharmaceutical Retail Price

Pharmacy margins are also statutorily fixed for reimbursable pharmaceuticals by a decree of the Ministry of Health.[761] The mark-up scheme takes a regressive form and mark-ups are of maximum nature (cf. Table 16.5). Thus pharmacies may set their prices below the maximum allowed pharmacy retail price as held in the reimbursement pricelist. Mark-ups for non-reimbursable pharmaceuticals and OTC again are not regulated.[762] Therefore prices of non-reimbursable pharmaceuticals, but also of reimbursable pharmaceuticals might vary between pharmacies.

760 ALP, written communication, March 2005 and March 2006

761 Decree No. V-171 of the Ministry of Health of the Republic of Lithuania, 11 April 2002

762 Decree No. 459 of the Ministry of Health of the Republic of Lithuania, 12 August 2000

Table 16.5: Lithuania - Pharmacy Mark-ups for Reimbursable Pharmaceuticals, 2006

PPP from...to...in LTL / €	Maximum pharmacy mark-up in % of the PPP in LTL / €
up to LTL 8.19 / € 2.37	22%
from LTL 8.20 / € 2.38 to LTL 10.00 / € 2.89	LTL 1.80 / € 0.52
from LTL 10.01 / € 2.90 to LTL 15.28 / € 4.42	18%
from LTL 15.29 / € 4.43 to LTL 25.00 / € 7.24	LTL 2.75 / € 0.80
from LTL 25.01 / € 7.25 to LTL 27.28 / € 7.90	11%
from LTL 27.29 / € 7.91 to LTL 75.00 / € 21.72	LTL 3.00 / € 0.87
from LTL 75.01 / € 21.73 to LTL 500.00 / € 144.81	4%
from LTL 500.00 / € 144.81 on	LTL 20.00 / € 5.79

PPP = Pharmacy Purchase Price

Source: Decree No. V-171 of the Ministry of Health of the Republic of Lithuania, 11 April 2002

16.2.1.4 Value Added Tax (VAT)

The standard VAT rate in Lithuania is 18%. A reduced VAT of 5% applies to all pharmaceuticals.[763]

16.2.2 Price Related Cost-containment Measures

All cost-containment measures apply only to pharmaceuticals seeking admission to the reimbursement list or already being reimbursable - as for non-reimbursable pharmaceuticals pricing is free at all distribution levels.

16.2.2.1 Pharmaco-economic Evaluation

Since 1 October 2003 pharmaceutical companies have been required to submit pharmaco-economic analyses, in accordance with the regulations of the SAM and based on the Baltic Guideline for Economic Evaluation of Pharmaceuticals.[764]

As the Baltic States share similar social and economic conditions, common guidelines for economic evaluation were developed in cooperation with the Latvian Pricing and Reimbursement Agency (ZCA); the Estonian Health Insurance Fund and the Lithuanian Department of Pharmacy (FD) to simplify the application process for pharmaceutical companies. The guidelines are oriented towards the pharmaceutical industry and give information on the preferred perspective (health care system; i.e. including only direct health care costs and benefits to the health care system vs. a societal perspective which includes economic cost

763 Law on Value Added Tax, No. IX-751, 5 March 2002 (amended by No. IX-1960, 15 January 2004), http://www3.lrs.lt/c-bin/eng/preps2?Condition1=232178&Condition2

764 Baltic Guideline for Economic Evaluation of Pharmaceuticals (Pharmaco-economic Analysis); http://www.zca.gov.lv/docs/new2002/doc24-1.pdf

e.g. workdays lost outside the healthcare system); on the costs (direct healthcare costs vs. indirect costs and intangible costs) to be included in the analysis and how they should be established, as well as on the discount rates to be used, etc..

16.2.2.2 Internal Price Referencing

Internal price referencing applies to innovative pharmaceuticals in so far, as pharmaceutical companies have to file information on the cost of their product compared to existing treatment alternatives. Thus the price of the new pharmaceutical is pitted against that of the cheapest alternative already included in the reimbursement. The product's potential sales, its effect on the sales of competing pharmaceuticals and the price in other European countries (cf. 16.2.2.3) is also taken into consideration.

Internal price referencing is mainly used as a criterion for the pricing and admission to reimbursement pricelist of generics. Besides providing information on international prices (external price referencing), as a general rule manufacturers of generics have to price their products at least 30% beneath the original product to get their product on the reimbursement list.

Furthermore Lithuania operates a reference price system on the basis of INN (ATC 5 level; cf. 16.3.2).

16.2.2.3 External Price Referencing / Cross Country Referencing

In setting the base price (cf. 16.3.1.1) for reimbursement, pharmaceutical prices of neighbouring countries had been taken into account for some years. But as the price level in Lithuania was higher than in Latvia and Estonia as well as in some EU Member States, a new calculation formula for determine the base price for reimbursement was introduced by the SAM in 2003. It was planned that the base price for reimbursement may not exceed +5% of the lowest price in any EU Member State. Up to 2005, transitional rules were in place to gradually decrease the base price for reimbursement to this level, in order to avoid a sudden increase of the patient co-payment at the beginning of 2006.

In 2005 a change in the calculation of the base price for reimbursement was undertaken, the reference countries were reduced to six with similar GDP per-capita.[765] Base prices for reimbursement are now calculated by a complex formula taking into account the average of the manufacturer prices in the Czech Republic, Estonia, Latvia, Poland, Slovakia and Hungary, minus 5%.

Thus pharmaceutical companies are allowed to set their prices above the calculated average of the manufacturer prices in the Czech Republic, Estonia, Latvia, Poland, Slovakia and Hungary, minus 5%, but as to retain their market share it is in their interest to reduce prices towards this price level.

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765 Decree No. VIII-994 of the Ministry of Health of the Republic of Lithuania, 13 September 2005, http://www3.lrs.lt

16.2.2.4 Price Freezes / Cuts

There have been no direct statutorily introduced price freezes since the change of the Health Insurance Law in 2002.

Since 2002 price negotiations between the SAM and the pharmaceutical industry have been taken place, which led to price reductions. For example, in June 2002 the prices of 46 pharmaceuticals were cut by an average of 18.5% on average.

16.2.2.5 Margin Cuts

Wholesale and pharmacy margins on reimbursable pharmaceuticals are regulated through regressive mark-up schemes (cf. 16.2.1.2 and cf. 16.2.1.3). Statutory distribution margins have been lowered in the past years; pharmacy margins were cut by law in 2002 by 5% on average. Wholesale margins were reduced by law in 2004; already in 2002 they had been cut by 2% on average.

16.2.2.6 Discounts and Rebates

Neither the pharmaceutical industry nor wholesalers or pharmacies are obliged to grant any discounts, rebates or claw-backs to VLK or any other public body.

But there are some price-volume agreements in place between the pharmaceutical companies and the VLK.

Pharmaceutical companies are allowed to grant discounts to wholesalers, as wholesalers are allowed to grant discounts to pharmacies - these discounts are not regulated and subject to negotiations between the distribution actors.

Pharmacies grant discounts to their customers on non-reimbursable but also on reimbursable pharmaceuticals, thus reducing patient co-payment.

16.2.2.7 Company Profit Controls

There are no direct company profit controls in place. Prices of reimbursable pharmaceuticals are negotiated at manufacturer price level, while pharmaceutical companies are free to set prices for non-reimbursable pharmaceuticals. (cf. 16.2.1.1)

In setting the base price for reimbursement (cf. 16.3.1.1) according to international price comparisons (external price referencing, cf. 16.2.2.3) and considering co-payments and the purchasing power, it is in the interest of the pharmaceutical companies to keep their prices close to the base price for reimbursement to retain a market share.

16.2.2.8 Parallel Trade

As Lithuania is a small market with relatively low per-capita income, there are no parallel imports into Lithuania.

Product patents have been in place in Lithuania since 1994, before that date process patents had been granted to pharmaceutical companies. Because of concerns of the pharmaceutical industry the Accession Treaty includes a derogation to limit exports from the new EU Member States, when intellectual property rights differed at the time of the market launch of a pharmaceutical. Also the G10 High Level Group recommended governing parallel imports between EU Member States. The derogation holds, that holders of Supplementary Protection Certificates (SPC), which had been granted in the EU-15 before product patents were available in the new EU Member States may prevent exports from the new Member States. Furthermore, parallel importers have to notify patent holders of their intention to import a pharmaceutical 30 days prior to their application for a parallel import product licence, thus pharmaceutical companies have the chance to take legal action if they feel that the derogation of the EU-Accession Treaty is violated.

16.2.3 Co-Payments

Proportional co-payments are in place in Lithuania, thus patients are obliged to pay the difference between the reimbursement sum, calculated from the base price (cf.16.3.1.1) for reimbursement and the reimbursement category (percentage), and the pharmacy retail price (PRP). The base price for reimbursement is always lower than the maximum PRP (with the exception of some insulines).

Reimbursement categories vary according to the positive list (List A - disease based list and List B - reimbursement out of social reasons; cf. 16.3.1). List A comprises four reimbursement categories (100%, 90%, 80% and 50%) varying with the severity of the disease. List B has two reimbursement categories; 100% for children up to 18 years and disabled persons and 50% for pensioners, etc.. In addition, children up to 18 years and persons with disability (category I) fall into the 100% reimbursement category, when receiving pharmaceuticals of List A.

The reimbursement sum is calculated from the reimbursement category and the base price of reimbursement. This base price is also called “reference price”, which is somehow misleading - as it is a reference price based on the price of the cheapest pharmaceutical of a reference price group (same INN) for off-patent pharmaceuticals (cf. 16.3.1); while for on-patent pharmaceuticals the base price is calculated by a formula according to external price referencing (cf. 16.2.2.3).

So even in the case of 100% reimbursement the patient has to pay the difference between the base price for reimbursement and the actual PRP, with the only exemption of insulin, where the base price equals the maximum PRP.

Furthermore, there is a category of special reimbursement on an individual basis for very expensive pharmaceuticals (cf. 16.3.1). As with in-patient treatment there is no extra co-payment for these pharmaceuticals.

Reimbursable pharmaceuticals represent approximately 30% of the pharmaceutical market - a significant share of pharmaceuticals is not covered by social health insurance and therefore privately paid. Private health insurance to cover this expenditure is of minor importance in Lithuania.

16.2.4 Information Transparency and Marketing

Information on pharmaceuticals is easy to obtain in an electronic form. The list of registered pharmaceuticals, Patient Information Leaflets (PIL) and Summary of Product Characteristics (SmPC) are available on the internet.[766] Furthermore, the reimbursement lists are available publicly, stating the maximum retail price and the base price (cf. 16.3.1.1) as the basis for reimbursement.[767]

Patients might shop around for favourable prices of pharmaceuticals, as prices do not have to be uniform throughout the county. This applies in particular to non-reimbursable pharmaceuticals where free margins apply, but also distribution margins for reimbursable pharmaceuticals are of maximum nature and prices of these pharmaceuticals may vary between pharmacies.

In general, advertising and industry behaviour towards health professionals is regulated by the Lithuanian Law on Pharmaceutical Activity[768]. Advertising to the general public is regulated by a Decree of the Ministry of Health (SAM)[769], the VVKT is the competent institution for controlling the advertising of pharmaceuticals (cf. 16.1.2.3).

The Association of Representative Offices of Ethical Pharmaceutical Manufacturers (Etiniu Farmacijos Kompaniju Atstovybiu Asociacija, EFA) in cooperation with the Association of Generic Manufacturers (Vaistu gamintoju asociacija, VGA) and the Association of Lithuanian Pharmaceutical Enterprises (Lietuvos farmacijos pramonės įmonių asociacija) have released a Code of Pharmaceutical Marketing Practices on the basis of the guidelines of the International Federation of Pharmaceutical Manufacturers Association (IFPMA).[770] The code is binding on members of all three associations, complaints about member companies who are al-

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766 http://www.vvkt.lt; up to 2004 Information was available from http://vic.vvkt.lt (Drug Information Centre of the VVKT)

767 http://www.fd.lt

768 Law on Pharmaceutical Activities; No. I-1025, 31 January 1991; last amended on 29 September 2005; and Law on Advertising; No. VIII-1871, 18 July 2000; http://www3.lrs.lt

769 Decree No 298 of the Minister of Health of the Republic of Lithuania, 30 May 2000, http://www.vvkt.lt/t_aktai/isvedimas.php?temos_id=7&title=Vaist%F8+reklama

770 http://www.efa.lt/ekodeksas.html

leged to be in breach of the code may be filed to the EFA, which deals with the matter. Reports on complaints are published - there are no financial penalties.

Furthermore, the Lithuanian Medical Doctors Association (LGS) has issued a code of conduct. There is tight cooperation between LGS and EFA in preparation of one common code, regulating the relationship between doctors and the pharmaceutical industry. The main reason for cooperation is the coordination of the conduct of doctors and EFA representatives in complicated situations trying to avoid the breach of medical ethics.

However, pharmaceutical industry is still the main source of pharmaceutical information for doctors - providing information via representatives or seminars - and doctors are the ones who decide on which medical treatment a patient will receive.

The role of patients is rather small in this process. The VLK has influence on the prescribing habits of doctors in terms of prescription monitoring and treatment algorithms for some diseases (cf. 16.3.4.1).

Pharmacists take an active role with regard to the selection of non-prescription medicines and self-medication. Pharmacists are trained on non-prescription medicines by university study programmes and seminars organised by other institutions.[771]

16.3 Reimbursement

The Law on Health Insurance[772] regulates the reimbursement of pharmaceuticals.

Lithuania operates a positive list, which contains pharmaceuticals eligible for reimbursement under stated conditions in the out-patient sector. The remuneration for pharmaceuticals used in hospital treatment is included in the diagnosis related payments by the VLK to the hospitals, there is no patient fee for pharmaceuticals in hospital. Expensive pharmaceuticals are centrally purchased by the VLK.

The Ministry of Health (SAM) is the institution deciding on the inclusion of pharmaceuticals to the positive list. SAM is advised by the Medicines Reimbursement Committee, which is an interdisciplinary committee consisting of representatives of the SAM (2), the FD (1), VVKT (1) and the VLK (1). The decision of the Medicines Reimbursement Committee is then presented to the Obligatory Health insurance Council, which may comment on the decision. The non-binding recommendations of the Medicines Reimbursement Committee and the Obligatory Health insurance Council are then submitted to the SAM, who takes the decision.

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771 AESGP 2005

772 Law on Health Insurance, No. I-1343 , 21 May 1996, http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_e?p_id=41370&p_query=&p_tr2=

Criteria for inclusion to reimbursement are the budget impact (VLK), therapeutic value, cost-effectiveness and safety of the pharmaceutical compared to therapeutic alternatives as well as the severity of disease (cf. 16.3.1.2).

A pharmaceutical is included onto the reimbursement list for a maximum period of 3 years, after this period a re-application for reimbursement has to be filed.

The positive list covers about 320 INN and accounts for 30% of the pharmaceutical market. OTC products are excluded from the positive list.

16.3.1 Pharmaceutical Lists and Reimbursement Categories

In Lithuania - like in the other Baltic States - pharmaceuticals are reimbursed in the out-patient sector according to a list of defined diseases, with the reimbursement category hinging on the severity of the disease.[773] Besides reimbursement according to defined diseases, pharmaceuticals may be reimbursed out of social reasons. Thus, the positive list has two categories:

- List A covers pharmaceuticals, which are reimbursed with regard to the severity of the disease at:
  - 100% (e.g. cancer, asthma, schizophrenia);
  - 90% (a category introduced in 2002);
  - 80% (e.g. hepatitis B and C) or
  - 50% (e.g. osteoporoses).

  List A includes approximately 250 INN. Reimbursement from the disease based list accounts for to approximately 85% of the total drug reimbursement. Under the Health Insurance Law 2002 the criteria for inclusion into the 100% reimbursement category were revised, and a new reimbursement category 90% was introduced.
- List B covers all pharmaceuticals, which are reimbursed because of social reasons at:
  - 100% (treatment of children under the age of 18 and disabled people) or
  - 50% (retired people and other social groups).

  There is a tendency to include pharmaceuticals reimbursed for social reasons on List A as well; therefore the list B is progressively reduced. Approximately 80 INN are covered by List B.

All reimbursement categories correspond to the base price of the pharmaceutical (basis for calculation of reimbursement sum), which is always lower than the pharmacy retail price (PRP).

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[773] Decree No. 49 of the Ministry of Health of the Republic of Lithuania, 28 January 2000 (last amended by Decree No. V-1016 of 30 December 2005); http://www3.lrs.lt/pls/inter2/dokpaieska.susije_e?p_id=94805&p_rys_id=1

Besides above mentioned categories of reimbursement, patients may apply for reimbursement of a pharmaceutical on a individual basis. This mainly regards to very expensive pharmaceuticals which are centrally purchased through the VLK, and is granted to persons in the out-patient sector only after prior approval of three specialists and the head of a hospital.

16.3.1.1 Reimbursement Price

Besides the prices relevant in the distribution channel (manufacturer price, wholesale price and pharmacy retail price) there is the base price, which is relevant for the reimbursement of pharmaceuticals (used for calculation of the reimbursement sum: base price x reimbursement category). The Ministry of Health sets - on proposal of the Department of Pharmacy (FD) - the so-called base price for reimbursable pharmaceuticals as the basis for reimbursement calculation. The base price may either be the reference price in case of a reference price group or in the case of on patent products a price set below the maximum pharmacy retail price on the basis of external price referencing (see below). The base price is always lower then the pharmacy retail price, so even in the case of 100% reimbursement the patient has to bear a co-payment (with the exception of some insulines). In September 2005, a new law was passed regulating that the base price would be set based on a price comparison with six EU Member States having a similar per capita income to Lithuania[774] (cf. 16.2.2.3). The manufacturer prices in the reference countries have to be submitted by the marketing authorisation holder on a yearly basis (cf. 16.2.2.3)

Furthermore, a reference price system, clustering pharmaceuticals with the same active ingredients in reference price groups, is applied. The reference price for such clusters is set at the price of the cheapest pharmaceutical of each group, which then is the base price for all pharmaceuticals included in the reference price group..

16.3.1.2 Selection Criteria

Like in the other Baltic countries out-patient reimbursement of pharmaceuticals hinges not on the pharmaceutical itself - as in most EU Member States countries - but rather on the underlying disease. With regard to List A a basic selection criterion for admission to reimbursement is that the pharmaceutical is registered for the indication, which is included in the list of diseases for which pharmaceutical treatment shall be reimbursed by the VLK.[775]

Reimbursement levels are based on the severity of the underlying disease, therefore a pharmaceutical which may be used in treatment of different diagnosis, may be reimbursed at different reimbursement levels.

List B comprises pharmaceuticals which are reimbursed on the basis of social criteria.

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774 Decree No. VIII-994 of the Government of the Republic of Lithuania, 13 September 2005, http://www3.lrs.lt

775 Decree No. 49 of the Ministry of Health of the Republic of Lithuania, 28 January 2000 (last amended by Decree No. V-1016 of 30 December 2005); http://www3.lrs.lt/pls/inter2/dokpaieska.susije_e?p_id=94805&p_rys_id=1

Criteria considered for inclusion to positive list are the impact on the VLK budget, therapeutic advantages of the product over alternative therapies in terms of effectiveness and side effects, the products place in therapy (first, second or third line product in treatment algorithm) and the severity of the disease as stated above.

16.3.1.3 Pharmaceuticals on Positive List

In 2005 there were about 250 INN on List A and 80 INN on List B available for out-patient reimbursement. This corresponds to nearly 1,500 brand names including dose and pack size variations on the reimbursement list.

16.3.1.4 Generics

The overall generic market share is very high with 72.7% of the market in terms of volume and 41.6% in terms of value (year 2004, cf. 16.1.2.1).

Generics fall under the reference price system. Since 2004 doctors are obliged to prescribe using INN for reimbursable pharmaceuticals, from 2002 till 2004 they were allowed to prescribe by trade name also within the reimbursable segment. Brand names nowadays may only be used with prescription of non-reimbursable pharmaceuticals. Pharmacists are obliged to offer the cheapest available generic to the patients. The patients take the choice at their expense, as the VLK reimburses the base price (reference price) for the INN at a given reimbursement rate.

Generics are considered to be economically priced, if their price is 30% lower then the original. At this price every generic applying for admission to reimbursement is included to the positive list.

16.3.1.5 Non-reimbursable Pharmaceuticals

The positive list for pharmaceuticals in the out-patient sector is rather small - compared to the reimbursement standards in the old Member States. Thus, non-reimbursable pharmaceuticals account for between 60 and 70% of the pharmaceutical market, which poses a burden to patients.

OTC products, pharmaceuticals used in hospital setting and pharmaceuticals with lower medical benefit compared with already reimbursed pharmaceuticals are excluded from reimbursement. Furthermore, pharmaceuticals with minimal effectiveness and therapeutic value, pharmaceuticals for which inadequate advertisement had been made or pharmaceuticals for which false information was included in the reimbursement application are excluded from reimbursement as well.

16.3.1.6 Appeal Procedure

A pharmaceutical company receiving a negative decision from the SAM on the inclusion to the positive list may re-apply for reimbursement. In this case the Medicines Reimbursement Committee is dealing with the re-application; there is no separate appeal committee at this level. If the Medicines Reimbursement Committee comes again to a negative decision, the pharmaceutical company may turn directly to the Minister of Health, and in case of receiving a negative decision by the Minister of Health may turn to court.

16.3.1.7 Delisting

A pharmaceutical is included onto the reimbursement list for a maximum period of 3 years, after this period a re-application for reimbursement has to be filed.

Delisitings were made according to therapeutic value, new data on medicinal product safety or effectiveness on behalf of public bodies SAM, VLK, VVKT or FD.

16.3.2 Reference Price System

A reference price system is applied in Lithuania. Since 2003 the reference price of INN groups (off-patent pharmaceuticals) is set according to the cheapest pharmaceutical, before that is was set 20% above the price of the cheapest generic.

Every generic product of a INN which is approved for the positive list, is included on application to the list of reimbursable pharmaceuticals.

INN prescribing is obligatory to doctors, in turn “generic substitution” is allowed to pharmacists, who are obliged to inform patients on the cheapest generic product available.

16.3.3 Pharmaceutical Budgets

Prescribing budgets have been in place in 2002 and 2003 mainly for health centres. According to the LGS, the VLK has included budgets in their contracts with the doctors. If the budget is exceeded, the medical institution simply does not receive the exceeded assets from VLK. The LGS considers this as a big problem as in some cases doctors were for a certain period of time unable to prescribe pharmaceuticals needed by the patients due to the exceeded budget. If they still prescribed, then their salaries were reduced by the difference.[776]

Pharmaceutical budgets are no longer applied.

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[776] LGS; written communication, April 2005

16.3.4 Other Volume Control Oriented Measures

16.3.4.1 Prescription Monitoring and Other Doctors-related Measures

A prescribing passport promotes rational prescribing for all patients, including 25 prescriptions. A copy of the prescription remains in the booklet, to increase transparency and decrease double prescriptions.

Disease treatment algorithms (guidelines) were introduced in 2002 aiming at rational pharmacotherapy for major diseases like diabetes, hypertensive disease some forms of cancer, etc.

16.3.4.2 Generics and Parallel Trade

Prescribing by INN is obligatory for doctors since 2004, pharmacists are obliged to offer the cheapest generic alternative to the patient. There is no active information policy on generics provided to the patients by the SAM or VLK (cf. 16.3.1.4), the co-payment system though provides an incentive to the patient to opt for cheaper generics.

There is no parallel import of pharmaceuticals into Lithuania, so this topic is of no importance to the Lithuanian pharmaceutical market or reimbursement system (cf. 16.2.2.8).

16.4 Overview of the Reimbursement Market in Lithuania

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Public Authorities				
Decide on prescription status	X		VVKT	
Decide on manufacturer price		X	Free for non-reimbursable pharmaceuticals; negotiations for reimbursable pharmaceuticals taking into account manufacturer prices in reference countries, estimated sales volumes, costs compared to and effects on sales of competing pharmaceuticals and pharmaco-economic analyses	
Agree on manufacturer price	X		SAM/FD	
Fix wholesale margin	X		Maximum mark-up scheme for reimbursable pharmaceuticals	Decree No. 459 of the Ministry of Health of the Republic of Lithuania, 12 August 2000 Decree No. V-170 of the Ministry of Health of the Republic of Lithuania, 30 March 2004
Fix pharmacy retail price	X		Via maximum mark-up scheme for reimbursable pharmaceuticals; thus maximum PRP	Decree No. 459 of the Ministry of Health of the Republic of Lithuania, 12 August 2000 Decree No. V-171 of the Ministry of Health of the Republic of Lithuania, 11 April 2002
Decide on reimbursement status	X		SAM on advise of Medicines Reimbursement Committee and Council of Obligatory Health Insurance	Law on Health Insurance, No. I-1343 , 21 May 1996
Decide on reimbursement price	X		SAM /FD	Decree No. 459 of the Ministry of Health of the Republic of Lithuania, 12 August 2000
Use pharmaco-economic guidelines	X		With reimbursement applications, according to Baltic Guidelines	Baltic Guideline for Economic Evaluation of Pharmaceuticals (Pharmaco-economic Analysis); http://www.zca.gov.lv/docs/new2002/doc24-1.pdf
Use Internal reference pricing	X		For Reimbursement decision of some INN and some pharmaceutical forms	Decree No. VIII-994 of the Government of the Republic of Lithuania, 13 September 2005,
Use External reference pricing	X		For setting the base price for reimbursement (LV, EST, PL, HU, CZ and SK)	Decree No. VIII-994 of the Government of the Republic of Lithuania, 13 September 2005

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Price Freezes / Cuts		X		
Margin cuts			Margins in the reimbursable segment are set by the SAM; SAM has cut wholesale and pharmacy margins on reimbursable pharmaceuticals in 2002 and additionally reduced wholesale margins in 2004	Decree No. 459 of the Ministry of Health of the Republic of Lithuania, 12 August 2000
Discounts and Rebates		X		
Company profit control		X		
Country specific:				
Pharmaceutical Industry				
Sets manufacturer price freely	X		For non-reimbursable pharmaceuticals; free to change	Decree No. 459 of the Ministry of Health of the Republic of Lithuania, 12 August 2000
Notifies manufacturer price		X		
Negotiates manufacturer price	X		For reimbursable pharmaceuticals	
Is free to set price below fixed manufacturer price		X	No, a application to SAM has to be submitted to lower prices.	Decree No. VIII-994 of the Government of the Republic of Lithuania, 13 September 2005
Decides on application for reimbursement	X			Decree No. 159 of the Ministry of Health of the Republic of Lithuania, 5 April 2002
Negotiates reimbursement price		X	Has to submit information for process of setting base price of reimbursement	
Free to keep manufacturer price above reimbursement price	X		Patient has to pay the difference between the reimbursement amount and the PRP.	Decree No. VIII-994 of the Government of the Republic of Lithuania, 13 September 2005
Free to grant rebates / discounts to wholesalers	X			
Free to grant rebates / discounts to pharmacies		X	No direct discounts, as manufacturers do supply pharmacies via wholesale,	

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Can engage in marketing towards doctors	X		In line with code of conduct	- Law on Pharmaceutical Activities; No. I-1025, 31 January 1991; last amended on 29 September 2005; and - Law on Advertising; No. VIII-1871, 18 July 2000 - Code of Conduct, http://www.efa.lt/ekodeksas.html
Can engage in public advertising		X	Only for authorised OTC products	Decree No 298 of the Minister of Health of the Republic of Lithuania, 30 May 2000, http://www.vvkt.lt/t_aktai/isvedimas.php?temos_id=7&title=Vaist%F8+reklama
Can provide information toward patients		X	Only for OTC products	
Applies for switches and delisting	X			
Country specific:				
Distribution Chain				
Wholesaler				
Margins are fixed by statute	X		Maximum mark-up scheme for reimbursable pharmaceuticals based on manufacturer price	Decree No. 459 of the Ministry of Health of the Republic of Lithuania, 12 August 2000
Margins are subject to statutory discounts / rebates		X		
Free to grant discounts / rebates to pharmacies	X			
Pharmacists				
Margins are fixed by statute	X		Maximum mark-up scheme for reimbursable pharmaceuticals based on maximum wholesaler price	Decree No. 459 of the Ministry of Health of the Republic of Lithuania, 12 August 2000 Decree No. V-171 of the Ministry of Health of the Republic of Lithuania, 11 April 2002
Free to set retail price	X		For non-reimbursable pharmaceuticals; For reimbursable pharmaceuticals maximum margins apply: pharmacies may set PRP below maximum PRP or grant discounts to patients	
Obliged to inform patient on cheaper product	X			Decree No. 112 of the Ministry of Health of the Republic of Lithuania, 8 March 2002

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Obliged to substitute by a generic	X		INN prescribing is obligatory within the reimbursable segment; prescribing by brand name is only allowed with non-reimbursable pharmaceuticals	
Allowed to substitute by a generic	X		INN prescribing is obligatory within the reimbursable segment	Decree No. 112 of the Ministry of Health of the Republic of Lithuania, 8 March 2002
Obliged to substitute by a parallel import		X	No parallel imports	
Allowed to substitute by a parallel import		X	No parallel imports	
Therapeutic / analogous substitution is allowed		X		
Are subject to statutory discounts / rebates		X		
Claw back system exists		X		
May grant rebates to customers	X		As PRP are of maximum nature for reimbursable pharmaceuticals and prices for non-reimbursable pharmaceuticals are free.	
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			Decree No. 112 of the Ministry of Health of the Republic of Lithuania, 8 March 2002.
Are obliged to inform on co-payment / deductibles	X			Decree No. 112 of the Ministry of Health of the Republic of Lithuania, 8 March 2002.
Prescription habits are monitored	X			
Are subject to prescription guidelines	X		Treatment algorithms have been established for various diseases	Decree No. 422 of the Ministry of Health of the Republic of Lithuania, 14 August 2002.
Budgets are controlled		X	Doctors budgets were in place 2002/2003.	

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Allowed to prescribe INN	X		For reimbursable pharmaceuticals obligatory; for non-reimbursable pharmaceuticals prescription by INN or brand name is allowed	Decree No. 112 of the Ministry of Health of the Republic of Lithuania, 8 March 2002
Obliged to prescribe INN	X		For reimbursable pharmaceuticals	Decree No. 112 of the Ministry of Health of the Republic of Lithuania, 8 March 2002
Can oppose generic substitution		X		Decree No. 112 of the Ministry of Health of the Republic of Lithuania, 8 March 2002
Can oppose therapeutic substitution			Not applicable	
Can oppose substitution by parallel import			Not applicable	
Country specific:				
Patients				
Can shop for cheapest price of the product	X		For non-reimbursable products; prices may also differ for reimbursable pharmaceuticals; discounts may be granted by pharmacies to patients	
Pay a flat rate per prescription / pack		X		
Pay a certain percentage per prescription / pack or a deductible	X		Certain percentage according to underlying disease or social status	
Annual minimum co-payment		X		
Annual maximum co-payment		X		
May ask for substitution by a generic	X		INN prescribing is obligatory for reimbursed products; prescription by brand name is possible for non-reimbursable pharmaceuticals	Decree No. 112 of the Ministry of Health of the Republic of Lithuania, 8 March 2002
May oppose substitution by a generic		X	Only at on payment of price difference.	Decree No. 112 of the Ministry of Health of the Republic of Lithuania, 8 March 2002
May ask for substitution by a parallel import			No parallel imports in Lithuania	
Can oppose substitution by a parallel import			No parallel imports in Lithuania	

Tasks / Duties	Yes	No	Comment	Legal bases or agreement
Can oppose substitution only on payment of price difference			No parallel imports in Lithuania	
Has to pay the difference between reimbursement price and PRP	X		Even with 100% reimbursement category has to pay the difference between base price of reimbursement and the PRP	Decree No. VIII-994 of the Government of the Republic of Lithuania, 13 September 2005
Has access to full public information on prices and products	X		Has access to full information on base prices for reimbursement and maximum PRP for reimbursable pharmaceuticals	Decree No. VIII-994 of the Government of the Republic of Lithuania, 13 September 2005
Country specifics:				

N. a. = Not available

Source: ÖBIG 2006

LUXEMBOURG

17 Luxembourg

17.1 Pharmaceutical System

17.1.1 Regulatory Framework and Authorities

Nearly all inhabitants (working population and their families, retired persons) in Luxembourg are covered by compulsory health insurance. There are nine sickness funds. The system is funded through contributions by employees and employers. A major part of the population purchases complementary health insurance which is supported by tax relief.

Sickness funds are organised within an umbrella organisation, the Union of Sickness Funds (Union des Caisses de Maladie, UCM). It administrates the budgets of all sickness funds and - with consent of the Ministry of Health - can change social insurance contributions as well as patient co-payments. The scope of services reimbursed is the same for all sickness funds and is defined by the Ministry of Health (Ministère de la Santé)and the Ministry of Social Security (Ministère de la Sécurité Sociale).

The most relevant players in the pharmaceutical system in Luxembourg are:

- The Ministry of Health (Ministère de la Santé) is in charge of overall health policy and legislation.
- The Health-Directorate, Department for Pharmacy and Pharmaceuticals (Direction de la Santé, Division de la Pharmacie et des Médicaments) acts as advising body to the Ministry of Health. It is responsible for the authorisation of pharmaceuticals, the supervision of the practice of professional pharmacists, authorisation of new pharmacies and provides expertise on health care questions[777].
- The Ministry of Economy and Foreign Trade, Competition Direction (Ministère de l'Economie et du Commerce exterieur, Division de la Concurrence)[778] is in charge of pricing of pharmaceuticals.
- The Union of Sickness Funds (Union des Caisses de Maladie, UCM) is in charge of the reimbursement of pharmaceuticals.
- The Ministry of Social Security, Department of Medical Control (Ministère de la Sécurité Sociale, Contrôle medical) acts as advisory body to the UCM in reimbursement decisions.

[777] Act of 21 November 1980 on the organisation of the Direction of Health (amended)

[778] Act of 17 May 2004 on competition

Market authorisations for pharmaceuticals are granted by the Ministry of Health consulted by the Department for Pharmacy and Pharmaceuticals within the Health-Directorate. When authorised, pharmaceuticals are categorised into POM and OTC. The Department for Pharmacy and Pharmaceuticals within the Health-Directorate issues a list of authorised pharmaceuticals.[779]

Table 17.1: Luxembourg - Relevant Authorities and Market Players in the Pharmaceutical Sector 2006

Institution	Task	Contact details/URL	Responsible person
Ministère de la Santé, Direction de la Santé, Division de la Pharmacie et des Médicaments / Ministry of Health, Health-Directorate, Department for Pharmacy and Pharmaceuticals	Ministry of Health, Authorisation	Ministry of Health Villa Louvigny - 1er étage Allée Marconi L-2120 Luxembourg Luxembourg Tel.: +352 4781 Fax: +352 4679 62 Ministere-Sante@ms.etat.lu www.ms.etat.lu/	Ms. Mariette Backes-Lies Villa Louvigny - 1er étage Allée Marconi L-2120 Luxembourg Luxembourg Tel.: +352 4785 590 Fax: +352 2620 0140 Mariette.backes-lies@ms.etat.lu
Ministère de l'Economie et du Commerce exterieur, Division de la concurrence / Ministry of Economy and Foreign Trade, Competition Direction	Ministry of Economy and Foreign Trade, Pricing of Pharmaceuticals	Ministry of Economy and Foreign Trade 6, boulevard Royal L-2449 Luxembourg Luxembourg Tel.: +352 4781, +352 4784 174 Fax: +352 4604 48, +352 26 20 12 18 info@eco.public.lu, concurrence.luxembourg@eco.public.lu www.eco.public.lu/, www.concurrence.public.lu/	Mr. Guy Wetzel 6, boulevard Royal L-2449 Luxembourg Luxembourg Tel.: +352 4784 122 Fax: +352 2620 1218 or +352 4604 48 guy.wetzel@eco.etat.lu
Union des Caisses de Maladie (UCM)/ Union of Sickness Funds	Third Party Payer, Reimbursement of Pharmaceuticail	Union of Sickness Funds 125, route d' Esch L-1471 Luxembourg Luxembourg Tel.: +352 4983 311 Fax: +352 4983 32 ucm@secu.lu www.ucm.lu	Union of Sickness Funds 125, route d' Esch L-1471 Luxembourg Luxembourg Tel.: +352 4983 311 Fax: +352 4983 32 ucm@secu.lu www.ucm.lu

[779] "Liste des médicaments admis a la vente dans le Grand-Duche de Luxembourg"

Institution	Task	Contact details/URL	Responsible person
Ministère de la Sécurité Sociale, Contrôle medical / Ministry of Social Security, Department of Medical Control	Advices UCM in pharmaceutical reimbursement decisions	Department of Medical Control 125, route d'Esch L-1471 Luxembourg Tel : +352 261913 1 Fax: +352 40 78 62 www.mss.etat.lu, www.mss.etat.lu/admini/attrib1.htm	Department of Medical Control 125, route d'Esch L-1471 Luxembourg Tel : +352 261913 1 Fax: +352 40 78 62 www.mss.etat.lu, www.mss.etat.lu/admini/attrib1.htm
Groupement des Grossistes Répartiteurs Luxembourgeois en Produits Pharmaceutiques / Association of Pharmaceutical Wholesalers of Luxembourg	Wholesaler Association	Association of Pharmaceutical Wholesalers of Luxembourg 60, Rue de la Vallée L-2661 Luxembourg Luxembourg Tel.: +352 4507 07 Fax: +352 4563 46 Hanff@hanff.lu	Mr. Jules Clement 60, Rue de la Vallée L-2661 Luxembourg Luxembourg Tel.: +352 4507 07 Fax: +352 4563 46 Hanff@hanff.lu
Union des Pharmaciens Luxembourgeois / Union of Luxemburgish Pharmacists	Pharmacy Association	Union of Luxemburgish Pharmacists 70a Route D Arlon L-8008 Strassen Luxembourg Tel.: +352 2963 33 Fax: +352 2963 32 unaphalu@pt.lu	Mr. Theo Thiry President 70a Route D Arlon L-8008 Strassen Luxembourg Tel.: +352 2963 33 Fax: +352 2963 32 unaphalu@pt.lu
Collège Médical / Medical College	Medical Association, represents doctors, dentists and pharmacists	Collège Médical 90, boulevard de la Pétrusse L-2320 Luxembourg Luxembourg Tel.: +352 478 5542 Fax: +352 475 679 www.collegemedical.lu	Mr. Paul Linckels Administrative Secretary 90, boulevard de la Pétrusse L-2320 Luxembourg Luxembourg Tel.: +352 478 5542 Fax: +352 475 679 info@collegemedical.lu
Association des Médecins et des Médecins-Dentistes du G.D. de Luxembourg (AMMD) / Medical Association of Luxembourg	Medical Alliance	AMMD Rue de Vianden, 29 L-2680 Luxembourg Luxembourg Tel.: +352 4440 33 Fax: +352 4583 49 www.ammd.lu	Mr. Joe Wirtz President Rue de Vianden, 29 L-2680 Luxembourg Luxembourg Tel.: +352 444 033 Fax: +352 458 349

Institution	Task	Contact details/URL	Responsible person
Patiente Ver-driedung / Patients Association	Patient's Association	Patient's Association 18, rue Dicks L-1417 Luxembourg Luxembourg Tel.: +352 4914 571 Fax: +352 4914 58 www.patientevertriedung.lu/	Mr. René Pizzaferri President 18, rue Dicks L-1417 Luxembourg Luxembourg Tel.: +352 4914 571 Fax: +352 4914 58 Rene.pizzaferri@patientevertriedung.lu

Source: ÖBIG 2006

17.1.2 Market Players

17.1.2.1 Pharmaceutical Industry

There are no pharmaceutical manufacturers in Luxembourg. Most pharmaceuticals are imported from Belgium (87% in 2005[780]), the rest mainly from Germany, France and Austria[781].

17.1.2.2 Distribution

In Luxembourg there are four pharmaceutical wholesalers. The largest is CPL (Comptoir Pharmaceutique Luxembourgeois), followed by Hanff Frères, Mathis Prost and Prophac, which operates only a small pharmaceutical division.

Only pharmacies and hospital pharmacies may dispense pharmaceuticals. Self-dispensing doctors are not allowed. Selling pharmaceuticals via internet is forbidden.

780 Ministry of Health, personal communication, 16 May 2006

781 Association of Pharmaceutical Wholesalers of Luxembourg, written communication, 8 May 2006

Currently there are 87 pharmacies operating in Luxembourg (cf. Table 17.2). New pharmacies require authorisation by the Ministry of Health (on advice of the Department for Pharmacy and Pharmaceuticals within the Direction of Health). In general, around 5,000 inhabitants should be supplied by one pharmacy. There are plans to establish two additional pharmacies as this target threshold is exceeded at the moment (cf. Table 17.2). The final target is a number of 90 pharmacies.[782]

Table 17.2: Luxembourg - Pharmaceutical Distribution, 2006

Distribution of pharmaceuticals	2006
Wholesalers	4
Community pharmacies	87
Hospital pharmacies	7
Inhabitants per pharmacy	5,386

Source: Association of Pharmaceutical Wholesalers of Luxembourg, written communication, 19 April 2006, data gathering by OEBIG

17.1.2.3 Patients

In Luxembourg patients do not have a formal role in the decision making process of pharmaceutical pricing and reimbursement. They have access to the positive list via Internet[783] which includes information on retail prices and the level of co-payment. For most pharmaceuticals a co-payment of 20% of the pharmacy retail price has to be paid (cf. 17.2.1.3). Doctors are not obliged to inform patients on the level of co-payment.

Patients have no substitution right. If the doctor prescribes by brand, the pharmaceutical may not be substituted.

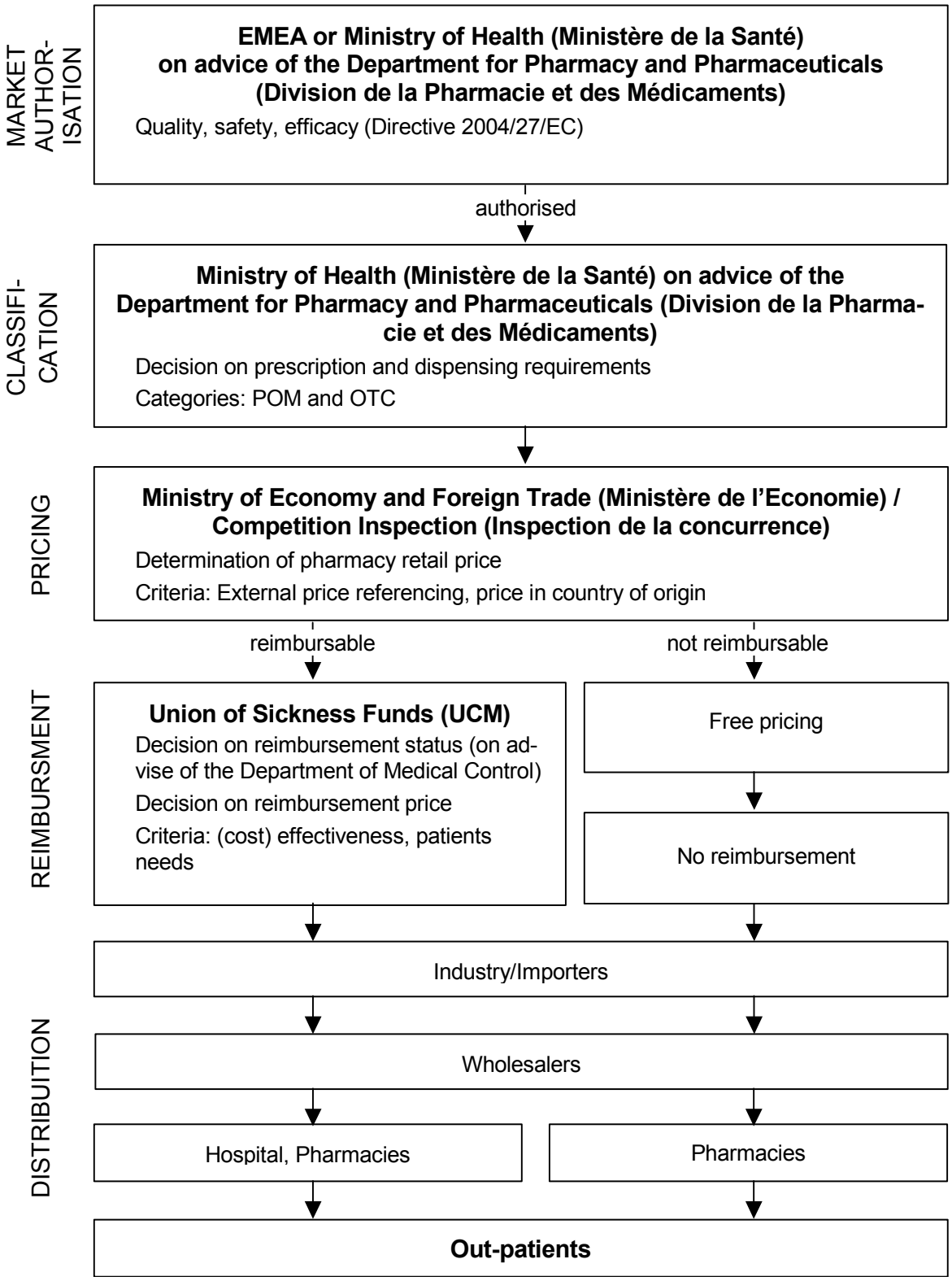
17.1.3 Overview of the Pharmaceutical System

Figure 17.1 gives an overview on the pharmaceutical system in Luxembourg.

782 Pharmacies' Association, personal communication 8 May 2006; UCM, personal communication 4 May 2005

783 Liste positive des médicaments valable au 1er mai 2006, http://www.secu.lu/legis/ucmmedicaments/fichier_listepos/liste_positve_assures_act.pdf

Figure 17.1: Luxembourg - Pharmaceutical System, 2006



Source: ÖBIG 2006

17.2 Pricing

17.2.1 Scope of Price Control

There is statutory pricing for all pharmaceuticals authorised and being brought on the market in Luxembourg. Market authorisation holders have to submit a price application to the Competition Direction in the Ministry of Economy and Foreign Trade, as the retail prices are subject to authorisation.

The price level which is determined is the pharmacy retail price; however, the manufacturer price is indirectly regulated via wholesale and pharmacy margins. The key criterion in pricing decision is country of origin or provenance of the (imported) pharmaceuticals, which entails different rules for pricing. As stated in section 17.1.2.1, pharmaceuticals in Luxembourg are imported from other countries, mostly from Belgium.

The legal basis is a decree on pricing, originally from 1988[784], in its updated version from 2004[785]. This Pricing Decree covers all rules of prices which are explicitly defined as maximum prices.[786]

Table 17.3 provides a concise overview of the pricing system in Luxembourg.

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784 Règlement grand-ducal du 13 décembre 1988 concernant les prix des spécialités pharmaceutiques et des médicaments préfabriqués, http://www.legilux.public.lu/leg/a/archives/1988/0661612/0661612.pdf#page=7

785 Règlement grand-ducal du 29 juillet 2004 concernant les prix des spécialités pharmaceutiques et des médicaments préfabriqués, http://www.legilux.public.lu/leg/a/archives/2004/1491708/1491708.pdf?SID=4d8177094c08f95d6c6e5364a631d865#page=2

786 Art. 2, Règlement grand-ducal du 29 juillet 2004 concernant les prix des spécialités pharmaceutiques et des médicaments préfabriqués, http://www.legilux.public.lu/leg/a/archives/2004/1491708/1491708.pdf?SID=4d8177094c08f95d6c6e5364a631d865#page=2

Table 17.3: Luxembourg - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	No	No	No
Statutory Pricing	At pharmacy retail level for all pharmaceuticals; indirectly at manufacturer level regulated due to wholesale and pharmacy mark-ups, differing due to the import country	At pharmacy retail level for all pharmaceuticals; indirectly at wholesale level regulated due to wholesale and pharmacy mark-ups, differing due to the import country	At pharmacy retail level for all pharmaceuticals
Price Negotiations	Not applicable	Not applied	Not applied
Price / volume agreements, discounts / rebates	Rebates to wholesalers allowed	Rebates to pharmacies not allowed	Rebates to patients allowed
Institution in charge of pricing	- Ministry of Economy and Foreign Trade, Competition Direction		
Legal Basis	- Decree of the Grand Duke of 29 July 2004 on the prices of pharmaceuticals ("Pricing Decree")[787]		

Source: ÖBIG 2006

17.2.1.1 Manufacturer Price

When the market authorisation holder applies for the price of a pharmaceutical, the price is set at the pharmacy retail level. Due to fixed wholesale and pharmacy margins, differing from country of origin or provenance, the price at the manufacturer/importer level is indirectly regulated.

17.2.1.2 Wholesale Price

For pharmaceuticals of Belgian or Luxembourgish origin or provenance, the wholesale margin is fixed at 15.21% of the purchase price, which equals to 13.20% of the selling price.[788].

17.2.1.3 Pharmacy Retail Price

As explained in 17.2.1, there is statutory pricing for all pharmaceuticals at pharmacy retail level. The Pricing Decree foresees external price referencing as the key method for determining the pharmacy retail price. Usually, it is the country of origin or provenance which is referred to, unless in case of countries which are not adhered to the EEA. In this case, the

[787] Règlement grand-ducal du 29 juillet 2004 concernant les prix des spécialités pharmaceutiques et des médicaments préfabriqués, http://www.legilux.public.lu/leg/a/archives/2004/1491708/1491708.pdf?SID=4d8177094c08f95d6c6e5364a631d865#page=2 (in the following quotations referred to as "Pricing Decree")

[788] Art. 6 of Pricing Decree

neighbouring countries of Luxembourg are taken as a reference. However, currently no pharmaceuticals are imported from countries from outside the European Economic Area.[789]

The pharmacy margin is, in general, 50.20% of PPP, which corresponds to 33.42 % of PRP. For Luxembourgish pharmaceuticals or pharmaceuticals imported from Belgium, the pharmacy margin amounts to 46.70% of PPP (i.e. 31.83 % of PRP).

The detailed regulations in the Pricing Decree, which is currently valid, are described in Table 17.1.

Table 17.1: Luxembourg - Pricing regulations in the Pricing Decree of 2004

Relevance	Regulation	Article
In general[1]	Pharmacy margin: 50.20% of PPP = 33.42% of PRP	Art. 4
Country of origin or provenance is B or LUX	In general: Wholesale margin: 15.21% of purchase price = 13.2% of selling price Pharmacy margin: 46.70% of PPP = 31.83% of PRP	Art. 6
	Pharmaceuticals of Belgian origin or provenance: PRP incl. VAT (3% in LUX) may not exceed 98.44% of the Belgian PRP incl. VAT (6% in B)	Art. 6
	Additionally Belgian margins are applied.	Art. 7
Country of origin or provenance is not B or LUX	In general: Net PRP in LUX is the net PRP in the country of origin or provenance, diminished by 0.62% In accordance with the Ministry of Economy and Foreign Trade, the prices may be increased by import and extraordinary distribution costs	Art. 8
	Imported pharmaceuticals from non-EEA Members: Net PRP in LUX is the lowest net PRP in one of the neighbouring countries of LUX, diminished by 0.62% In accordance with the Ministry of Economy and Foreign Trade, the prices may be increased by import and extraordinary distribution costs	Art. 8
	Country of origin or provenance is F: In addition, the net PRP may be increased by 5% if the French distribution margins do not exceed 63.81% (excl. tax)	Art. 8

Art. = Article, B = Belgium, EEA = European Economic Area, LUX = Luxembourg, PPP = pharmacy purchase price, PRP = pharmacy retail price

[1] if not overruled by other regulations in the Pricing Decree

Source: Règlement grand-ducal du 29 juillet 2004 concernant les prix des spécialités pharmaceutiques et des médicaments préfabriqués

[789] Ministry of Health, personal communication, 11 May 2006

17.2.1.4 Value Added Tax (VAT)

The value added tax rate for all pharmaceuticals amounts to 3%, the standard VAT being 15%.[790]

17.2.2 Price related Cost-containment Measures

17.2.2.1 Pharmaco-economic Evaluation

In Luxembourg pharmaco-economic evaluation does not play an important role. Only a few pharmaco-economic studies have been conducted.

17.2.2.2 Internal Price Referencing

There is no internal price referencing applied in Luxembourg.

17.2.2.3 External Price Referencing / Cross Country Referencing

As explained in section 17.2.1.3 with the overview on the Pricing Decree in Table 17.1, external price referencing is the key methodology for determining the pharmacy retail price. The price of the pharmaceutical in the country of origin or provenance is taken as reference and then decreased by a certain percentage (1.56% for Luxembourgish or Belgian pharmaceuticals, and 0.62% for products from other countries). In case of imports from outside the EEA, the lowest net PRP in one of the neighbouring countries of Luxembourg acts as reference price, which is then diminished by 0.62 %.

17.2.2.4 Price Freezes / Stops

There have been no prize freezes / stops in Luxembourg for more than a decade.

17.2.2.5 Margin Cuts

In recent years there have been no margin cuts in Luxembourg.

17.2.2.6 Discounts and Rebates

There is no mandatory or statutory system of discounts or rebates which the pharmaceutical industry, wholesalers or pharmacies in Luxembourg have to grant to the sickness funds. Concerning commercial discounts, wholesalers may not grant discounts towards pharmacies but it still happens. On the contrary, pharmacists are free to grant rebates to patients for OTC products.[791]

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790 European Commission - DG Taxation and Trade Union 2006

791 UCM, personal communication, 12 May 2006

17.2.2.7 Parallel Trade

Parallel trade plays no role in Luxembourg. Thus, there is no special authorisation procedure provided for parallel imports.

17.2.3 Co-Payment

There are product-specific co-payments for pharmaceuticals (cf. also Table 1.5), which the patients have to pay in the pharmacy, when getting the pharmaceutical, while the remaining part of the price is claimed back directly from the UCM by the pharmacy:

- There is no co-payment on pharmaceuticals for certain chronic or severe diseases, e.g. cancer (2001 around 24% of all pharmaceuticals[792]).
- For most pharmaceuticals (2001 around 64%[793]) a co-payment of 20% of the pharmacy retail price is applied.
- For pharmaceuticals which are considered of minor interest in the course of treatment, e.g. minor painkillers, patients have to pay 60% of the price out of pocket (2001 around 12%[794]).

For pharmaceuticals for which effectiveness/efficacy in relation to costs is not sufficiently proven patients have to pay the full price (negative list).[795] Approximately one quarter of pharmaceuticals (mainly OTC) are included in the negative list.[796]

In 2005 a threshold was implemented in legislation[797]: The expenses may not exceed 2.5% of the net income. Patients list their co-payment for the previous year and submit the list to the sickness fund, so they get the amount above the threshold reimbursed.

17.2.4 Information Transparency and Marketing

As to information transparency, the lists of authorised pharmaceuticals as well as of reimbursable pharmaceuticals (including prices and reimbursement status) may be accessed via Internet without cost (cf. 17.1.1, 17.3). Doctors on the other hand are not obliged to inform patients on the level of co-payment.

According to UCM[798], the Luxembourg legislation, which is in line with the EU provisions on advertising[799], advertising in media to the general public is not allowed for prescription phar-

792 ÖBIG 2001

793 ÖBIG 2001

794 ÖBIG 2001

795 UCM, written information, 10 May 2006

796 Martikainen / Rajaniemi 2002

797 Statuts de l'UCM, Chapitre 15, Art 154, http://www.secu.lu/legis/Statucm/statactuel/sommaire.htm

maceuticals, for pharmaceuticals not authorised in Luxembourg, and for pharmaceuticals containing narcotic, psychotropic and other addictive substances. Thus, public advertising is only allowed for OTC. Furthermore, advertising should not include information on prices of the pharmaceutical and information leading to erroneous self-diagnosis. However, in Luxembourg it is possible to make advertising for reimbursable pharmaceuticals (as long as they are OTC).

In general, doctors, pharmacies and pharmaceutical companies are allowed to inform patients about the characteristics of pharmaceuticals. Pharmaceutical industry may engage in marketing towards doctors.

17.3 Reimbursement

Pricing and reimbursement is a two step process in Luxembourg. First the pharmacy retail price of a pharmaceutical has to be fixed, then the market authorisation holders file an application for reimbursement with the Union of Sickness Funds (UCM).[800,801]

The decision on inclusion into the positive list[802] is taken by the UCM based on an assessment of the Department of Medical Control (Ministry of Social Security).[803]

There is also a negative list in place, which includes around one quarter of all pharmaceuticals on the market (pharmaceuticals whose effectiveness in relation to costs does not seem to be efficiently proved), mainly OTC.[804] Also generic pharmaceuticals which are more expensive than the original product are not reimbursed.

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798 UCM, personal information, 12 May 2006

799 Directive 2001/83/EC

800 Règlement grand-ducal du 12 décembre 2002 précisant les conditions et déterminant la procédure relatives à l'inscription d'un médicament sur la liste positive des médicaments pris

801 en charge par l'assurance maladie, http://www.legilux.public.lu/leg/a/archives/2002/1643112/1643112.pdf?SID=5638c2a37f80568b1926e87c7e96bab3#page=4 , application form: http://www.secu.lu/legis/ucmmedicaments/sommaire.htm

802 Liste positive des médicaments valable au 1er mai 2006, http://www.secu.lu/legis/ucmmedicaments/fichier_listepos/liste_positve_assures_act.pdf

803 Règlement grand-ducal du 12 décembre 2002 précisant les conditions et déterminant la procédure relatives à l'inscription d'un médicament sur la liste positive des médicaments pris en charge par l'assurance maladie, http://www.legilux.public.lu/leg/a/archives/2002/1643112/1643112.pdf?SID=5638c2a37f80568b1926e87c7e96bab3#page=4

804 Martikainen / Rajaniemi 2002; UCM, written information 10 May 2006; Code des assurances sociales (C.A.S.), Art. 23, http://www.secu.lu/legis/legis/legmal2.htm

17.3.1 Pharmaceutical Lists and Reimbursement Categories

In Luxembourg there is a positive list in place. Pharmaceuticals on the positive list may be reimbursed fully, at 80% or at 40%. The level of reimbursement depends on the disease which the pharmaceutical is used for, for details cf. to Table 17.4.[805] Most pharmaceuticals are in the 80% "normal" reimbursement category.

Table 17.4: Luxembourg - Reimbursement Categories, 2006

Category	Description	Reimburse-ment
Preferential rate	Pharmaceuticals for certain chronic or severe diseases, e.g. cancer	100%
Normal rate	All pharmaceuticals on the positive list, for which no other status is fixed	80%
Reduced rate	Pharmaceuticals which are considered to represent a minor interest in the course of treatment, e.g. minor painkillers	40%

Source: Bylaws of the UCM as of 1 January 2006, Art. 100-104[806]; UCM, written information on 10 May 2006

17.3.1.1 Reimbursement Price

The basis for the reimbursement price is the pharmacy retail price. The amount of reimbursement granted depends on the reimbursement category (cf. Table 17.4).

In general only three pharmaceuticals per prescription are reimbursed. With a written justification on the prescription by the doctor also more pharmaceuticals can be reimbursed (otherwise only the three most expensive products are remunerated). Moreover there are specific instructions when prescribing expensive pharmaceuticals.[807]

A pharmacy may dispense up to two packages of any particular pharmaceutical at a time. For some there are even tighter restrictions.[808]

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805 Bylaws of the Union of Sickness Funds of 1 February 1994, Art. 100.104, http://www.secu.lu/legis/Statucm/statactuel/stat2005_c.html#c8

806 Statuts de l'UCM, Texte coordonné applicable au 1er janvier 2006, http://www.secu.lu/legis/Statucm/statactuel/stat2005_c.html#c8

807 ÖBIG 2001, Martikainen / Rajaniemi 2002

808 Martikainen / Rajaniemi 2002

17.3.1.2 Selection Criteria

The Social Insurance Code[809] defines the criteria for inclusion of pharmaceuticals in the positive list. A prerequisite for eligibility is the setting of the pharmacy retail price. [810]

In practice, the cost-effectiveness of a pharmaceutical is the key criterion for the decision on reimbursement. In addition, pharmaceuticals may also be included into reimbursement in case of patient needs.

17.3.1.3 Pharmaceuticals on Positive List

The positive list, that was introduced in 2002, is published on the website of the UCM (cf. 17.3). It contains around 8,000 entries (i.e. each package size and each pharmaceutical strength counted separately).[811]

17.3.1.4 Generics

In Luxembourg generic substitution by pharmacists is not permitted when branded pharmaceuticals are prescribed. . In this case pharmacists strictly must deliver the original brand prescribed. Doctors however may prescribe generically (i.e. by using the INN name) In this case pharmacists have to sell the cheapest product to the patient.

17.3.1.5 Non-reimbursable Pharmaceuticals

Around one quarter of pharmaceuticals are excluded from reimbursement.[812] Most of them are OTC.

17.3.1.6 Appeal Procedure

The market authorisation holder may appeal in written form against the decision within 40 days after notification. The appeal, which is suspensive, is brought before the Administration Council.[813]

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809 Relevant articles are Art. 17, Art. 22 and Art. 23 of the CAS, http://www.secu.lu/legis/ucmmedicaments/dispositions_legales.htm

810 Art. 23 CAS, http://www.secu.lu/legis/ucmmedicaments/dispositions_legales.htm

811 Liste positive des médicaments valable au 1er mai 2006, http://www.secu.lu/legis/ucmmedicaments/fichier_listepos/liste_positve_assures_act.pdf

812 Martikainen / Rajaniemi 2002

813 Art. 2, Loi du 31 mai 2002 portant introduction d'une liste positive des médicaments pris en charge par l'assurance maladie et modifiant le Code des assurances sociales, (Mémorial A-2002-064 du 01.07.2002, p. 1569), http://www.secu.lu/legis/legis/chrononew/A_2002_064_listepos.htm

17.3.1.7 Delisting and Switches

The Ministry of Health is in charge of the switch process (POM to OTC). It receives applications from manufacturers asking to change the prescription status of a pharmaceutical. The Ministry of Health then evaluates the application and makes a decision. It follows the criteria of the EU guidelines for switches[814].

For competition reasons, authorisation holders sometimes ask for delisting of their pharmaceutical, which is possible.[815]

17.3.2 Reference Price System

There is no reference price system in Luxembourg.

17.3.3 Pharmaceutical Budgets

There are no pharmaceutical budgets in Luxembourg.

17.3.4 Other Volume Control Oriented Measures

17.3.4.1 Prescription Monitoring and other Doctors-related Measures

Doctors receive feedback on their prescribing habits by the UCM. In principle, the Ministry of Health has the power to issue financial claims on doctors for their prescribing habits. In fact however such measures are rarely applied.[816] The list of authorised pharmaceuticals issued by the Department for Pharmacy and Pharmaceuticals within the Health-Directorate contains prescription recommendations in some sections.

UCM provides doctors with internal prescribing guidelines. Doctors are encouraged to prescribe the most economical product out of several therapeutically similar alternatives, meaning they should preferably prescribe products from the positive list, and thereof the cheapest generic. But doctors are not obliged to do this[817].

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814 2006 EU guideline on changing the classification for the supply of a medicinal product for human use http://pharmacos.eudra.org/F2/eudralex/vol-2/C/switchguide_160106.pdf

815 UCM, personal communication, 12 May 2006

816 Martikainen / Rajaniemi 2002

817 Klepper 2006

17.3.4.2 Generics

The UCM has launched a campaign on generics promotion. For 7 active ingredients, UCM has published lists of interchangeable pharmaceuticals (i.e. original products and generics with pharmacy retail prices) on its website.[818] It is planned to extend the campaign to further ingredients.

17.4 Overview of the Reimbursement Market in Luxembourg

Tasks / Duties	Yes	No	Comment	Legal bases
Public Authorities				
Decide on prescription status	X			
Decide on manufacturer price		X	Fixing of prices at PRP level	Decree of the grand duke of 29 July 2004 on the prices of pharmaceuticals
Agree on manufacturer price		X	N.app.	
Fix wholesale margin	X		Fixing of prices at PRP level, in addition mark-up	Decree of the grand duke of 29 July 2004 on the prices of pharmaceuticals
Fix pharmacy retail price	X		Fixing of prices at PRP level, in addition mark-up	Decree of the grand duke of 29 July 2004 on the prices of pharmaceuticals
Decide on reimbursement status	X			Bylaws of the Union of Sickness Funds of 1 February 1994 (amended on 1 January 2006)
Agree on reimbursement price		X	N.app.	Bylaws of the Union of Sickness Funds of 1 February 1994 (amended on 1 January 2006)
Decide on reimbursement price	X			Bylaws of the Union of Sickness Funds of 1 February 1994 (amended on 1 January 2006)
Use Pharmaco-economic Guidelines		X	There are no specific pharmacoeconomic Guidelines.	
Use Internal reference pricing		X		
Use External reference pricing	X		Key methodology for fixing pharmaceuticals prices	Decree of the grand duke of 29 July 2004 on the prices of pharmaceuticals
Price freezes		X		

[818] Liste de médicaments génériques 2006, http://www.ucm.lu/actu_generiq.htm

Tasks / Duties	Yes	No	Comment	Legal bases
Margin cuts		X		
Discounts and Rebates		X		
Company profit control		X		
Country specific:				
Pharmaceutical Industry				
Sets manufacturer price freely		X	N.app.	
Notifies manufacturer price		X	N.app.	
Negotiates manufacturer price		X	N.app.	
Is free to set price below fixed manufacturer price	X			
Decides on application for reimbursement	X			
Negotiates reimbursement price		X		Bylaws of the Union of Sickness Funds of 1 February 1994 (amended on 1 January 2006)
Free to keep manufacturer price above reimbursement price		X	N.app.	
Free to grant rebates / discounts to wholesalers		X	N.app.	
Free to grant rebates / discounts to pharmacies		X		
Can engage in marketing towards doctors	X			
Can engage in public advertising	X		Only for OTC	
Can provide information toward patients	X		Only for OTC	
Applies for switches and delisting	X			
Country specific:				
Distribution Chain				
Wholesaler				
Margins are fixed by statute	X			Decree of the grand duke of 29 July 2004 on the prices of pharmaceuti-

Tasks / Duties	Yes	No	Comment	Legal bases
				cals
Margins are subject to statutory discounts / rebates		X		
Free to grant discounts / rebates to pharmacies		X	Although it is not allowed discounts are sometimes still granted	
Pharmacists				
Margins are fixed by statute	X			Decree of the grand duke of 29 July 2004 on the prices of pharmaceuticals
Free to set retail price		X		
Obliged to inform patient on cheaper product		X		
Obliged to substitute by a generic		X		
Allowed to substitute by a generic	X		Only if doctor has written prescription generically	
Obliged to substitute by a parallel import		X	Not applicable	
Allowed to substitute by a parallel import	X		Only if doctor has written prescription generically but plays no role	
Therapeutic / analogous substitution is allowed		X		
Are subject to statutory discounts / rebates		X		
Claw back system exists		X		
May grant rebates to customers	X			
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and alternatives	X			
Are obliged to inform on co-payment / deductibles		X		
Prescription habits are monitored	X		UCM give doctors feedback over their prescribing habits	
Are subject to prescription guidelines	X		Internal guidelines	
Budgets are con-		X		

Tasks / Duties	Yes	No	Comment	Legal bases
trolled				
Allowed to prescribe INN	X			
Obliged to prescribe INN		X		
Can oppose generic substitution		X	Not applicable	
Can oppose therapeutic substitution		X	Not applicable	
Can oppose substitution by parallel import		X	Not applicable	
Country specific:				
Patients				
Can shop for cheapest price of the product		X		
Pay a flat rate per prescription / pack		X		
Pay a certain percentage per prescription / pack or a deductible	X			
Annual minimum co-payment		X		
Annual maximum co-payment	X		2.5% of annual net income	Bylaws of the Union of Sickness Funds of 1 February 1994 (amended)
May ask for substitution by a generic	X		Only if doctor has written prescription generically	
May oppose substitution by a generic			Not applicable	
May ask for substitution by a paralle import			Not applicable	
Can oppose substitution by a parallel import			Not applicable	
Can oppose substitution only on payment of price difference			Not applicable	
Has to pay the difference between reimbursement price and retail price	X		No reference price	

Tasks / Duties	Yes	No	Comment	Legal bases
Has access to full public information on prices and products	X		Has access to the positive list including pharmacy retail prices and reimbursement status on the website of UCM	
Country specifics:				

Source: ÖBIG 2006

MALTA

18 Malta

18.1 Pharmaceutical System

18.1.1 Regulatory Framework and Authorities

The health care system in Malta is organised on the basis of a National Health Service (NHS). Besides that, there is a significant private sector.

The most relevant players in the pharmaceutical system of Malta are:

- the Ministry of Health, the Elderly and Community Care (MoH), which is responsible for the general health care planning as well as for the decision on the inclusion of pharmaceuticals on the positive list with the advice of the Drugs and Therapeutics Committee (DTC) under the MoH[819]
- the Health Care Procurement and Supplies Services (HPSS) under the Government Pharmaceutical Services (GPS) within the MoH, which is responsible for the procurement of pharmaceuticals as well as for the pricing of pharmaceuticals in the NHS system[820]
- the Medicines Authority (until 2003 used to be the Medicines Regulatory Unit, MRU), which is responsible for issuing market authorisation and classification of pharmaceuticals[821].

Public health care is funded through taxation. The Ministry of Finance is responsible for allocating resources to the health care system; while the MoH is in charge of administering the funds. Malta has a national social insurance, but their funds are used for other social services, such as pension funds.

Private health insurance can be purchased on a voluntary basis and is becoming increasingly popular, as it offers a greater choice of services and pharmaceuticals.

The health care system in Malta is organised on the basis of a National Health Service (NHS), providing services free at the point of delivery. Besides the NHS, there is a significant private sector.

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819 Medicines Act 2003 http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf, amended by Act III 2004 http://www.doi.gov.mt/EN/parliamentacts/2004/ACTIIIe.pdf

820 Medicines Act 2003 http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf

821 Legal Notice 387 by 2004 http://www.doi.gov.mt/EN/legalnotices/2004/08/LN387.pdf, amended by the Legal Notice 465 of 2004 http://www.doi.gov.mt/EN/legalnotices/2004/11/LN465.pdf, amended by the Legal Notice 72 of 2005 http://www.doi.gov.mt/EN/legalnotices/2005/03/LN72.pdf

With regard to pharmaceuticals, there is a public system (reimbursable pharmaceuticals dispensed to patients free of charge, purchased by the MoH via public tendering) and a private system (non-reimbursable pharmaceuticals purchased by the patients fully out-of-pocket in pharmacies). This distinction has of key importance, as there are different regulations on pricing, reimbursement and distribution of the pharmaceuticals (cf. 18.1.3) and will be referred to throughout this country profile.

The key authority for issuing market authorisations for pharmaceuticals (either imported or locally produced) is the Medicines Authority. The market authorisation procedure was harmonised to EU legislation in 2002. There is still a transitional period until the end of 2006 for pharmaceuticals, which had been authorised before 2002.

Besides issuing market authorisations, the Medicines Authority is responsible for controlling and assuring quality, safety and efficacy of all pharmaceuticals (either imported or locally produced).

Before the year 2003, the MRU was responsible for authorising pharmaceuticals, through the Certificate of Pharmaceutical Product, CPP, which had been developed by the WHO to insure the quality of traded pharmaceuticals. After September 2002 all pharmaceuticals with a valid CPP had to apply for a Provisional Market Authorisation (PMA) at the MRU/Medicines Authority. These pharmaceuticals are at the moment on a provisional list[822]. The list is regularly up-dated, since the PMA process is still ongoing. There are certain guidelines for granting a PMA[823], such as a completed application form, a completed EU type dossier[824] and a classification of the pharmaceuticals into three categories according to their authorisation status within the EU.

Once appropriate applications have been provided for a pharmaceutical with a PMA, they will be granted national market authorisation. These market authorisations have to be issued by the end of the derogation period, 31 December 2006. Since November 2004 only pharmaceuticals with a PMA or a national market authorisation may be on the market.

In absence of a marketing authorisation in Malta for a pharmaceutical containing an active substance that is essential for public health reasons, the Medicines Authority may grant a qualified licence[825] for that pharmaceutical, provided that this pharmaceutical has already been authorised in another EU Member State.

In the course of the market authorisation procedure the pharmaceutical is also classified according to its prescription status.

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822 Provisional Marketing Authorisation list http://medicinesauthority.gov.mt/pub/pma_list_draft_25.pdf

823 Guidelines for the granting of a provisional Marketing Authorisation http://medicinesauthority.gov.mt/pub/guidance_notes_re_requirements.pdf

824 as required by the EU Directive 2001/81/EC

825 Legal Notice 387 by 2004 http://www.doi.gov.mt/EN/legalnotices/2004/08/LN387.pdf, amended by the Legal Notice 465 of 2004 http://www.doi.gov.mt/EN/legalnotices/2004/11/LN465.pdf, amended by the Legal Notice 72 of 2005 http://www.doi.gov.mt/EN/legalnotices/2005/03/LN72.pdf

Table 18.1 contains an overview of the relevant stakeholders of Malta.

Table 18.1: Malta - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Ministry of Health, the Elderly, and Community Care	MoH	MoH Palazzo Castellana, 15 Merchants Street MT-Valetta CMR 02 Malta Tel.: +356 2122 4071 Fax: +356 2299 2655 www.sahha.gov.mt/pages.aspx?page=34	Mr. Saviour Gambin Palazzo Castellana, 15 Merchants Street MT-Valetta CMR 02 Malta Tel.: +356 2122 4071 Fax: +356 2299 2655 saviour.gambin@gov.mt
Health Care Procurement and Supplies Services (HPSS)	HPSS (under the GPS within the MoH)	HPSS St. Luke's Square MT-G'Mangia MSD 07 Malta Tel.: +356 2122 2014 Fax: +356 2124 3163 http://www.sahha.gov.mt/pages.aspx?page=200	Ms. Anna Debattista St. Luke's Square MT-G'Mangia MSD 07 Malta Tel.: +356 2122 2014 Fax: +356 2124 3163 anna.debattista@gov.mt
Medicines Authority (MA)	Medicines Authority	MA 198 Rue D´ Argens MT-GZR 003 Gzira Malta Tel.: +356 2343 9110 Fax: +356 2343 9158 info.mru@gov.mt http://medicines.authority.gov.mt	Ms. Patricia Vella-Bonanno 198 Rue D´ Argens MT-GZR 003 Gzira Malta Tel.: +356 2343 9112 Fax: +356 2343 9161 patricia.vella@gov.mt
Pharmacy Council	Pharmacy Council	Pharmacy Council 181, Melita Street MT-Valletta Malta Tel.: +356 2125 5538 Fax. +356 2125 5541 http://www.sahha.gov.mt/pages.aspx?page=89	Mr. Peter Fenech 181, Melita Street MT-Valletta Malta Tel.: +356 2125 5538 Fax. +356 2125 5541 pharmacy.council@gov.mt
Malta Chamber of Pharmacists	Association of Pharmacists	Malta Chamber of Pharmacists Sliema Road MT-Gzira GZR06 Malta Tel.: +356 312888 Fax: +356 343002 spizjar@synapse.net.mt www.synapse.net.mt	Ms. Mary-Ann Sant Fournier Sliema Road MT-Gzira GZR06 Malta Tel.: +356 312888 Fax: +356 343002 Mary-ann.sant-fournier@um.edu.mt or mfpb@maltanet.net

Institution	Task	Contact details/URL	Responsible person
Medical Association of Malta (MAM)	Medical Doctors' Association	MAM Sliema Road MT-Gzira GZR 06Malta Tel.: +356 21 3128 88 Fax: +356 21 3317 13 mfpb@maltanet.net www.mam.org.mt	Mr. Bryan Flores Martin President Sliema Road MT-Gzira GZR 06 Malta Tel.: +356 21 3128 88 Fax: +356 21 3317 13 mfpb@maltanet.net

Source: ÖBIG 2006

18.1.2 Market Players

18.1.2.1 Pharmaceutical Industry

Pharmaceuticals of the public system (NHS pharmaceuticals) are purchased through tendering by the HPPS under the MoH. This department is responsible for the purchase, the storage and the distribution of pharmaceuticals in line with EU legislation. The MoH, taking into consideration the recommendations of the DTC, decides which pharmaceuticals shall be purchased and thus be made available free of charge to the patients (cf. 18.3.1).

Malta has only one pharmaceutical company and relies almost entirely upon imports. International pharmaceutical companies act as importers in Malta. These importers act as purchasers and distributors both to the state and to private pharmacies or clinics[826].

18.1.2.2 Distribution

In the public system, NHS pharmaceuticals are dispensed to eligible patients in NHS facilities such as health centre dispensaries, dispensaries in out-patient departments and dispensaries of hospitals. The health centre dispensaries are restricted to eligible patients in their catchment area. This has been criticised in the last few years and reform plans have been made. No final agreement has yet been reached[827]. Public dispensaries can also deliver NHS pharmaceuticals via mail, whereas certain pharmaceuticals (e.g. antibiotics, pharmaceuticals with special restrictions to the temperature) are excluded from mail delivery.

In the private system pharmaceuticals are dispensed in 210 private pharmacies. Pharmacy chains are basically allowed, but nevertheless most of the pharmacies are owned by one pharmacist. Some pharmacies have build up a cooperation to obtain better price conditions. The Pharmacy Council, which is a statutory body, is responsible for granting pharmacy li-

826 Health in Transition of Malta, 1999 http://www.euro.who.int/document/e67136.pdf

827 ÖBIG 2005

cences[828]. Demographic and geographic criteria and the needs of the population are taken into account when the Pharmacy Council makes its decisions[829].

The distribution of pharmaceuticals over the internet as well as self-dispensing doctors are not allowed[830].

Table 18.2 gives an overview of the pharmaceutical distribution in Malta.

Table 18.2: Malta - Pharmaceutical Distribution, 2005

Actors of the pharmaceutical distribution	2005
Pharmaceutical Industry[1]	1
Wholesalers	90
Pharmacies	210
NHS dispensaries[2]	52
Inhabitants per pharmacy	1,904
Inhabitants per NHS dispensary	1,526

[1] Locally producing pharmaceutical company

[2] Dispensing of NHS pharmaceuticals to eligible patients: 8 health centre dispensaries, 41 dispensaries in out-patient departments, 3 dispensaries in public hospitals

Source: ÖBIG 2005

18.1.2.3 Patients

The role of patients is rather minor in the choice of pharmaceuticals. Furthermore patients are usually not informed on products and their prices. Eligible patients receive health care services as well as NHS pharmaceuticals free of charge (cf. 18.2.3).

In the private system, patients have to pay out-of-pocket for the services of general practitioner, specialists and pharmaceuticals. Pharmaceuticals can be purchased in private pharmacies.

18.1.3 Overview of the Pharmaceutical System

As already stated, two pharmaceutical systems exist next to each other: a public and a private system. There are different regulations on pricing, reimbursement and distribution for the public and the private system:

828 Members are from the Pharmacist's Association, the MoH an others http://www.sahha.gov.mt/pages.aspx?page=89

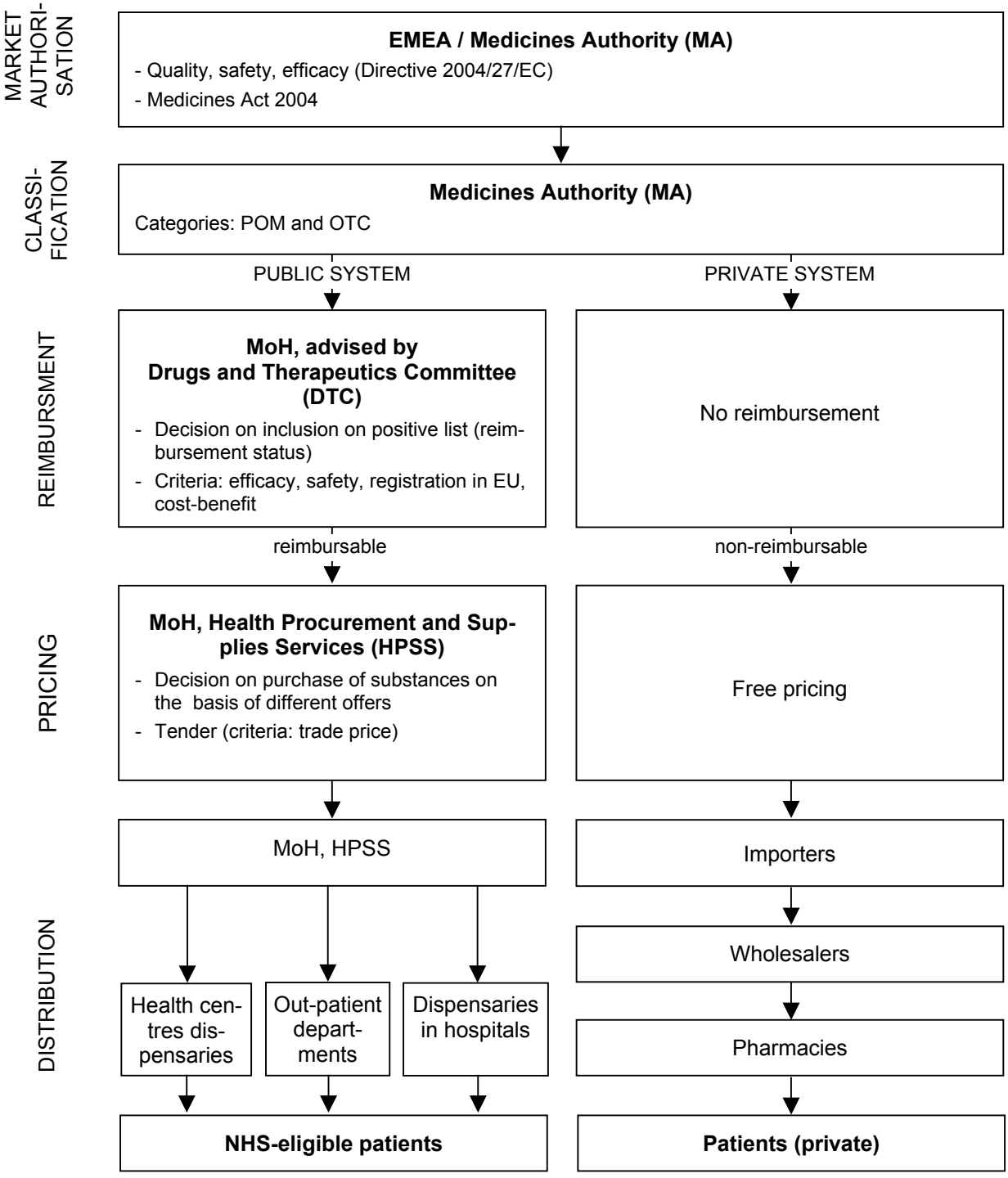
829 Legal Notice 31, 1984, http://docs.justice.gov.mt/lom/Legislation/english/SubLeg/458/16.PDF

830 Legal Notice 386, 2005 http://doi.gov.mt/EN/legalnotices/2005/11/LN386.pdf

- In the public system, the MoH runs a national formulary called “Essential Drugs List”. Pharmaceuticals on that list are fully reimbursed for NHS eligible patients. The MoH decides, on advice of the Drugs and Therapeutics Committee, which pharmaceuticals shall be added to the national formulary, and then purchases these products via public tendering. This public procurement process is handled by a MoH department, the HPSS. In the public system there is direct distribution, without any mark-ups, to the dispensaries where patients get the pharmaceuticals.
- All other pharmaceuticals fall under the private system. As there is only one pharmaceutical company in Malta, pharmaceuticals are mostly imported and then delivered via wholesalers to pharmacies where the patients buy these pharmaceuticals fully out-of-pocket, as they are not reimbursed at all. There is free pricing in the private system.

The information on the public and the private pharmaceutical system in Malta is displayed in Figure 18.1.

Figure 18.1: Malta - Pharmaceutical System, 2006



POM = Prescription-only Medicine, OTC = Over-the-Counter

Source: ÖBIG 2006

18.2 Pricing

18.2.1 Scope of Price Control

The pricing procedures depend on if the pharmaceutical is in the private or in the public system.

In the public system, the HPSS purchases pharmaceuticals to be listed on the national formulary (cf. 18.3.1) via a tendering process. Most of these pharmaceuticals are imported. The tendering process is mainly driven by the price. Each contract agreed through the tendering process is valid for a period of 3 years. Contracts can also be awarded for a one-year period in specific circumstances, such as when a very high price is granted. There are no mark-ups for wholesalers and (retail) dispensaries in the public system.

Table 18.3: Malta - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	*Public system:* Not applied *Private system:* All pharmaceuticals in the private system	*Public system:* Not applied *Private system:* Not applied	*Public system:* Not applied *Private system:* Not applied
Statutory Pricing	*Public system:* Not applied *Private system:* Not applied	*Public system:* Not applied *Private system:* All pharmaceuticals in the private system regulated via linear mark-up of 15%	*Public system:* Not applied *Private system:* All pharmaceuticals in the private system regulated via linear mark-up of 20%
Price Negotiations	*Public system:* Not applied *Private system:* Not applied	*Public system:* Not applied *Private system:* Not applied	*Public system:* Not applied *Private system:* Not applied
Public Procurement	*Public system:* Purchase via public tendering *Private system:* Not applied	*Public system:* Purchase via public tendering (trade price corresponds to wholesale price) *Private system:* Not applied	*Public system:* Purchase via public tendering, direct distribution to dispensaries without mark-ups *Private system:* Not applied
Price/volume agreements, discounts/rebates	No	No	No
Institution in charge of pricing	- MoH		
Legal Basis	- Medicines Act 2003		

Source: ÖBIG 2006

In the private system there is free pricing for manufacturers and importers and mark-ups for wholesalers and pharmacies.

Table 18.3 provides an overview of the pricing system in Malta, displaying the different provisions for the public and private system (in fact, pharmaceuticals in the public system are reimbursable and pharmaceuticals in the private system are non-reimbursable).

18.2.1.1 Manufacturer Price

As it has just been mentioned in section 18.2.1, in the public system pharmaceuticals are purchased through a tendering process. For pharmaceuticals in the private system there is free pricing for manufacturers and importers. This also includes parallel traded pharmaceuticals: thus there is also free pricing for parallel imports.[831]

18.2.1.2 Wholesale Price

In the public system, the HPSS is responsible for the purchase and distribution of pharmaceuticals to NHS dispensaries. The trade price, which is a key criterion in granting a tender, corresponds to the wholesale price.

In the private system, importers/wholesalers, which distribute pharmaceuticals private pharmacies, are granted a linear mark-up of 15% on the manufacturer price for locally produced pharmaceuticals or on the CIF price for imported pharmaceuticals. This mark-up is valid for POM as well as for OTC[832].

18.2.1.3 Pharmacy Retail Price

There is no pharmacy mark-up for NHS pharmaceuticals in the public system, as they are directly distributed to dispensaries for NHS eligible patients by the HPSS.

In the private system, there is a 20% linear mark-up on the wholesale price for pharmacies. This mark-up is also valid for POM as well as for OTC[833]. The pharmacy retail price is the same in all pharmacies throughout Malta, as the mark-ups are fully exhausted and no discounts are allowed (cf. 18.2.2.6).[834]

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831 Medicines Authority, written communication, July 2006

832 Medicines Act 2003 http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf, amended by Act III 2004 http://www.doi.gov.mt/EN/parliamentacts/2004/ACTIIIe.pdf

833 Medicines Act 2003 http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf, amended by Act III 2004 http://www.doi.gov.mt/EN/parliamentacts/2004/ACTIIIe.pdf

834 ÖBIG 2005; Pharmacy Chamber, personal communication, summer 2005

18.2.1.4 Value Added Tax (VAT)

At the moment there is no VAT on pharmaceuticals.

During the EU accession negotiations, Malta was asked to adjust its tax legislation with EU law. Therefore Malta negotiated a transitional period (until 2010) to allow pharmaceuticals to continue to be exempt from VAT. From 1 January 2010 on a VAT rate of 5% for pharmaceuticals shall be applied.

18.2.2 Price Related Cost-containment Measures

18.2.2.1 Pharmaco-economic Evaluation

Pharmaco-economic evaluations are not required, although economic criteria (e.g. data on cost-effectiveness) are taken into account in the tendering process as well as in the compilation of the national formulary (cf. 18.3.1).

18.2.2.2 Public Procurement

In the public system, the MoH operated by HPSS purchases NHS pharmaceuticals through public tendering, based on price considerations. The contract is then valid for a period of 3 years (c.f. 18.2.1).

18.2.2.3 External Price Referencing / Cross Country Referencing

External price referencing is not applied in Malta.

18.2.2.4 Price Freezes / Stops

There have been no price freezes in the last 5 years in Malta[835].

18.2.2.5 Margin Cuts

There have been no margin cuts.[836]

18.2.2.6 Discounts and Rebates

There is no mandatory/statutory system of discounts.

Pharmacies are not allowed to grant any rebates to patients, even not on voluntary basis[837].

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835 Medicines Authority, personal communication, March 2006

836 Pharmacy Chamber, personal communication, July 2006

837 Pharmacy Chamber, personal communication, summer 2005
Medicines Authority, personal communication, March 2006

18.2.2.7 Company Profit Controls

There are no company profit controls[838].

18.2.2.8 Parallel Trade

In Malta most of the pharmaceuticals are imported, as there is only one pharmaceutical company in Malta (cf. 18.2.1.1).

A pharmaceutical may be parallel imported in Malta provided that the importer obtains a licence to market the pharmaceutical. Up to now, 57 parallel import licences have been granted.[839] A list of pharmaceuticals that have obtained a license for parallel import is available on the website of the Medicines Authority[840]. The pharmaceuticals on that list are not necessarily already on the market.

The licensing process of parallel traded pharmaceuticals is regulated by the Medicines Authority[841]. A parallel import licence is granted for a period of 5 years. An application for the renewal of the parallel imported licence shall be submitted to the Medicines Authority no later than 3 months before the expiry of the previous license. Parallel importers need to keep records of the origin, imported quantities and batch numbers of the parallel imported pharmaceutical at any time. Upon request this information shall be submitted to the Medicines Authority[842].

Parallel trade plays a role in Malta, however, according to Medicines Agency, not a significant one, as the pharmaceuticals on the market are only slightly cheaper than the alternatives.[843] As any other medicine in the private system, there is also free pricing for parallel imported pharmaceuticals (cf. 18.2.1.1).

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838 Medicines Authority, personal communication, March 2006

839 Medicines Authority, written communication, July 2006

840 List of parallel licences issued, 2006 http://medicinesauthority.gov.mt/pub/pi_licences_full_list_19th_June_2006.pdf

841 Guideline to parallel importation of medicinal products http://monitor.isa/481044632/1208424T060320082313.txt.binXMysM0dapplication/mswordXsysM0dhttp://medicinesauthority.gov.mt/pub/guide_parallel.doc

842 Legal Notice No. 437 of 2004, http://medicinesauthority.gov.mt/pub/LN437.pdf

843 Medicines Authority, written communication, July 2006

18.2.3 Co-Payments

In Malta, most patients are eligible for free NHS pharmaceuticals, depending on the following criteria[844]:

Schedule II cards (pink card)

Pink cards are granted to patients entitled to free NHS pharmaceuticals on the national formulary (cf. 18.3.1) based on their household income level. The Department of Social Security issues the pink card in combination with a pink form stating the names of all eligible members of the household. The pink form is valid for one month, with patients over 60 able to extend their status for 6 months. Patients suffering from tuberculosis, leprosy or poliomyelities are also entitled for free prescription under Schedule II.

Schedule V cards (yellow card)

Irrespectively of the income, patients with the diagnosis listed in the Social Security Act[845] benefit from free pharmaceuticals. The diagnoses covered include malignant disease, cardiovascular disease, respiratory disease, collagen disease, endocrine disease, renal disease, digestive system disease, liver disease, central nervous system disease, schizophrenia, haemophilia, Paget's disease, glaucoma, HIV and others.

Other persons entitled to free NHS pharmaceuticals

There are certain population groups eligible for free NHS pharmaceuticals such as members of religious orders, patients in charitable facilities, members of the police and the armed force.

Patients who are eligible for free NHS pharmaceuticals need to have a prescription for receiving NHS pharmaceuticals. There is no prescription fee.

Patients, who are not eligible for free NHS pharmaceuticals, have to pay for pharmaceuticals the full price out-of-pocket. They can purchase those pharmaceuticals in private pharmacies. Patients also have to pay the full price for pharmaceuticals not included in the national formulary.

844 http://www.sahha.gov.mt/pages.aspx?page=8

845 Social Security Act, 2006 http://www.doi.gov.mt/EN/bills/2006/Bill%2059.pdf

18.2.4 Information Transparency and Marketing

In Malta prices of pharmaceuticals are hard to access by patients as there is no general public price database.

Patients can only access a list of pharmaceuticals with a marketing authorisation and the respective approved summary of product characteristics and package leaflet on the website of the Medicines Authority[846].

The regulations on the different requirements on the advertising of pharmaceuticals to the general public and the healthcare professionals are regulated by law[847] .

The advertising of pharmaceuticals is based on the system of self-regulation. The Advertising Committee within the Medicines Authority does not evaluate advertisements prior to their publication. Furthermore it investigates complains, monitors advertisements and provides advice to industry, healthcare professionals and other regulatory bodies. The Medicines Authority publishes guidelines on the advertising of pharmaceuticals for human use[848].

18.3 Reimbursement

In the private system there is no reimbursement. Patients have to pay the full price for the pharmaceuticals.

Only in the public system, NHS pharmaceuticals are reimbursable and are included on the positive list called “Essential Drugs List”, which is also referred to as the national formulary.

18.3.1 Pharmaceutical Lists and Reimbursement Categories

The national formulary was set upon the basis of the “Essential Drugs List” of the WHO and covers now a lot more pharmaceuticals. NHS pharmaceuticals are listed under their generic name. The list is regularly updated at meetings held by the DTC. The Director-General of Health ultimately decides whether to include a NHS pharmaceutical in the national formulary or not.

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846 Marketing Authorisation list http://medicinesauthority.gov.mt/pub/ma_licences_full_list_2nd_February_2006.pdf

847 Medicines Act 2003 http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf, amended by Act III 2004 http://www.doi.gov.mt/EN/parliamentacts/2004/ACTIIIe.pdf and Legal Notice 380, 2005 http://www.doi.gov.mt/EN/legalnotices/2005/11/LN380.pdf

848 Guidelines for the advertising of medicines for human use, 2004 http://medicinesauthority.gov.mt/pub/guidelines_for_advertising_may04.pdf

There are no reimbursement categories as such. Instead, patients are eligible for free NHS pharmaceuticals or must pay the full cost of their pharmaceuticals out-of-pocket (cf. 18.2.3).

18.3.1.1 Reimbursement Price

Reimbursable pharmaceuticals on the national formulary are fully reimbursed depending on the income level, the disease or other specific criteria of the patients (cf. 18.2.3).

18.3.1.2 Selection Criteria

The following criteria are crucial for including NHS pharmaceuticals on the national formulary[849]:

- clinical efficacy
- safety of the pharmaceutical
- whether the product is licensed in the EU
- a comparison of the pharmaceuticals with alternative treatments on the list
- a protocol for use of the pharmaceutical
- the cost and the cost-effectiveness of the pharmaceutical
- prioritisation of the allocation of the resources.

18.3.1.3 Pharmaceuticals on Positive List

In the private system there are around 2,300 pharmaceuticals (counting different pharmaceutical forms, excl. different pack sizes and dosages) authorised to be on the market. The number of authorised pharmaceuticals has decreased significantly since the implementation of the new market authorisation procedure in 2002 (cf. 18.1.1). Before 2002 there had been around 7,500 pharmaceuticals on the market[850].

In addition, in the public system there are around 3,200 active ingredients listed on the national formulary[851].

18.3.1.4 Generics

In general the MoH tends to favour generics because they have a lower price. Consequently are most of the NHS pharmaceuticals are generics. But also patients who are not eligible for free pharmaceuticals rather choose generics, since they have to pay the full price out-of-pocket.

There are no controls on the prices of generics, but strong competition has put prices down.

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849 PPR 2004

850 ÖBIG 2005

851 ÖBIG 2005

18.3.1.5 Non-reimbursable Pharmaceuticals

As it has already been mentioned in section 18.3, there is no reimbursement in the private . Patients have to pay the full price for healthcare services and for pharmaceuticals.

18.3.1.6 Appeal Procedure

The Maltese legislation[852] on the appeal procedure is in line with the EU Transparency Directive[853], meaning that the MoH decides within 90 days (180 days in the case of an application to have a product's status changed) from the date it receives the recommendations of the DTC.

18.3.1.7 Delisting

The MoH is free to remove a NHS pharmaceutical from the national formulary. This happens for instance if a manufacturer decides to discontinue to supply that pharmaceutical and no other source can be found. Alternatively, pharmaceuticals may also be deleted if their consumption is low or if an alternative therapy (with a better cost-effectiveness) is introduced.

18.3.2 Reference Price System

In Malta, there is no reference price system applied.

18.3.3 Pharmaceutical Budgets

In Malta there are no pharmaceutical (prescribing) budgets being applied for doctors or other health care providers.

Doctors working under the public system have to follow the national formulary when prescribing pharmaceuticals to patients covered by the NHS.

18.3.4 Other Volume Control Oriented Measures

18.3.4.1 Prescription Monitoring and Other Doctors-related Measures

In Malta there are no volume control oriented measures.

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852 Legal Notice 399, http://www.doi.gov.mt/EN/legalnotices/2003/12/LN399.pdf

853 EU Transparency Directive 89/105/EEC, http://dg3.eudra.org/F2/eudralex/vol-1/DIR_1989_105/DIR_1989_105_EN.pdf

18.3.4.2 Generics and Parallel Trade

In the private system generic substitution is on a voluntary basis allowed. There are certain limitations for generic substitution, such as that the pharmacist needs to obtain a permission for generic substitution from the prescribing doctor in each specific case. Doctors may also prescribe with the generic name.

With regard to parallel imported pharmaceuticals, there is "no reference to measures regarding parallel imported products"[854], they are thus dispensed as alternatives, but there is no obligatory substitution.

In general, parallel trade plays a role in Malta, but not a significant one (cf. 18.2.2.8). However, there are no figures on the market share of parallel imports of pharmaceuticals available.[855]

18.4 Overview of the Reimbursement Market in Malta

In order to give a broader picture of the pharmaceutical system in Malta, this overview displays not only the public system but also the private system.

Tasks / Duties	Yes	No	Comment	Legal bases
Public authorities				
Decide on prescription status	X		Medicines Authority	Legal Notice 387 by 2004 http://www.doi.gov.mt/EN/legalnotices/2004/08/LN387.pdf, amended by the Legal Notice 465 of 2004 http://www.doi.gov.mt/EN/legalnotices/2004/11/LN465.pdf, amended by the Legal Notice 72 of 2005 http://www.doi.gov.mt/EN/legalnotices/2005/03/LN72.pdf
Decide on manufacturer price	X		*Private system:* Free pricing *Public system:* HPSS via tendering	Medicines Act 2003 http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf
Agree on manufacturer price		X	N.app.	
Fix wholesale margin		X	*Private system:* Mark-up of 15% of the manufacturer price *Public system:* HPSS via tendering	Medicines Act 2003 http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf

854 Medicines Authority, written communication, July 2006

855 Medicines Authority, written communication, July 2006

Tasks / Duties	Yes	No	Comment	Legal bases
Fix pharmacy retail price		X	*Private system:* Mark-up of 20% of the whole-sale price *Public system:* HPSS via tendering	Medicines Act 2003 http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf
Decide on reimbursement status	X		*Private system:* No reimbursement *Public system:* MoH advised by DTC	Medicines Act 2003 http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf
Agrees on reim-bursement price		X	N.app.	
Decide on reimbursement price		X	N.app.	
Use Pharmaco-economic guide-lines		X	N.app.	
Use Internal reference pricing		X	N.app.	
Use External reference pricing		X	N.app.	
Price freezes		X	N.app.	
Margin cuts		X	*Private system:* No *Public system:* N.app.	
Discounts and Re-bates		X	N.app.	
Company profit control		X	N.app.	
Country specific:				
Pharmaceutical Industry				
Sets manufacturer price freely	X		*Private system:* Free pricing *Public system:* N.app.	Medicines Act 2003 http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf
Notifies manufacturer price		X	N.app.	
Negotiates manufacturer price		X	N.app.	
Is free to set price below fixed manu-facturer price	X			
Decides on application for re-imbursement		X	*Private system:* No reimbursement *Public system:* 100% reimbursement for eligible patients	

Tasks / Duties	Yes	No	Comment	Legal bases
Negotiates reimbursement price		X	N.app.	
Free to keep manufacturer price above reimbursement price		X	N.app.	
Free to grant rebates / discounts to wholesalers	X		No statutory system for discounts and rebates	
Free to grant rebates / discounts to pharmacies		X		
Can engage in marketing towards doctors	X			Medicines Act 2003 http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf, amended by Act III 2004 http://www.doi.gov.mt/EN/parliamentacts/2004/ACTIIIe.pdf and Legal Notice 380, 2005 http://www.doi.gov.mt/EN/legalnotices/2005/11/LN380.pdf
Can engage in public advertising	X			Medicines Act 2003 http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf, amended by Act III 2004 http://www.doi.gov.mt/EN/parliamentacts/2004/ACTIIIe.pdf and Legal Notice 380, 2005 http://www.doi.gov.mt/EN/legalnotices/2005/11/LN380.pdf
Can provide information toward patients	X			Medicines Act 2003 http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf, amended by Act III 2004 http://www.doi.gov.mt/EN/parliamentacts/2004/ACTIIIe.pdf and Legal Notice 380, 2005 http://www.doi.gov.mt/EN/legalnotices/2005/11/LN380.pdf
Applies for switches and de-listing		X	*Private system:* No reimbursement *Public system:* MoH decides to remove a pharmaceutical from the national formulary	
Promotional control		X	N.app.	
Country specific:				
Distribution chain				
Wholesaler				

Tasks / Duties	Yes	No	Comment	Legal bases
Margins are fixed by statute		X	*Private system:* Mark-up of 15% of the manufacturer price *Public system:* N.app.	Medicines Act 2003 http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf
Margins are subject to statutory discounts / rebates		X	N.app.	
Free to grant discounts / rebates to pharmacies		X		
Pharmacists				
Margins are fixed by statute		X	*Private system:* Mark-up of 20% of wholesale price *Public system:* N.app.	Medicines Act 2003 http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf
Free to set retail price	X		*Private system:* Free pricing *Public system:* N.app.	Medicines Act 2003 http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf
Obliged to inform patient on cheaper product		X	N.app.	
Obliged to substitute by a generic		X		
Allowed to substitute by a generic			*Private system:* Doctor needs to note it on the prescription *Public system:* Mainly generics available	
Obliged to substitute by a parallel import		X		
Allowed to substitute by a parallel import	(X)		There is no explicit reference to measures regarding parallel imports.	
Therapeutic / analogous substitution is allowed	X			
Are subject to statutory discounts / rebates		X	N.app.	
Claw back system exists		X	N.app.	
May grant rebates to customers		X	Not allowed	
Country specific:				
Doctors				

Tasks / Duties	Yes	No	Comment	Legal bases
Are obliged to inform patients on risks of treatment and treatment alternatives		X	N.app.	
Are obliged to inform on co-payment / deductibles		X	N.app.	
Prescription habits are monitored		X	N.app.	
Are subject to prescription guidelines		X	N.app.	
Budgets controlled		X	N.app.	
Allowed to prescribe INN	X			
Obliged to prescribe INN		X	N.app.	
Can oppose generic substitution	X		*Private system:* Doctors can appose *Public system:* N.app.	
Can oppose therapeutic substitution	X		*Private system:* Doctors can appose *Public system:* N.app	
Can oppose substitution by parallel import		X	N.app.	
Country specific:				
Patients				
Can shop for cheapest price of the product		X	The prices are the same throughout the country, as there are no discounts allowed to customers allowed and the mark-ups are fully utilised..	
Pay a flat rate per prescription / pack		X	N.app.	
Pay a certain percentage per prescription / pack or a deductible		X	N.app.	
Annual minimum co-payment		X	N.app.	
Annual maximum co-payment		X	N.app.	
May ask for substitution by a generic	X		*Private system:* Patient may ask for generic substitution *Public system:* Mainly generics available	

Tasks / Duties	Yes	No	Comment	Legal bases
May oppose substitution by a generic		X	N.app.	
May ask for substitution by a parallel import		X	*Private system:* N.app. (patient may ask for a cheaper product, no legal reference to substitution by a parallel import) *Public system:* N.app. (dispensing of NHS pharmaceuticals in NHS dispensaries, not in pharmacies)	
Can oppose substitution by a parallel import		X	N.app.	
Can oppose substitution only on payment of price difference		X	N.app.	
Has to pay the difference between reimbursement price and retail price		X	N.app.	
Has access to full public information on prices and products		X	N.app.	
Country specifics:				

N. app. = Not applicable, N. a. = Not available
Source: ÖBIG 2006

NETHERLANDS

19 Netherlands

19.1 Pharmaceutical System

19.1.1 Regulatory Framework and Authorities

The Dutch health care system is characterised by continuous debate and discussion about its structure and reform. Some reforms have helped to prepare the way for the new basic health insurance scheme, which was implemented on 1 January 2006.

Under the new Health Insurance Act[856], all patients are covered by health insurance and all insurance funds must provide the obligatory basic insurance package, but they also have the option of offering supplementary insurance.

In reviewing the reforms of the last decade, the shift of responsibility for purchasing care from government to insurance funds can be observed as a consistent trend. Secondly there has been a trend towards more competition among care providers. Thirdly, there has been a move towards combinations of market and non-market elements in health care.

The most relevant actors in the pharmaceutical system are:

- The Ministry of Health, Welfare and Sport (Volksgezondheid, Welzijn en Sport, VWS), who in charge of the overall pharmaceutical policy and decides on the maximum whole-sale price and the reimbursement status and price of pharmaceuticals
- The Medicines Evaluation Board (College ter Beoordeling van Geneesmiddelen, CBG), which is in charge of the evaluation of pharmaceuticals
- The Health Care Insurance Board (College voor Zorgverzekeringen, CVZ) which advises the Ministry of VWS on the reimbursement of pharmaceuticals

In accordance with the Pharmaceutical Supply Act[857] and the Decree on authorisation of pharmaceuticals[858], pharmaceuticals may only be brought on the market once the Medicines Evaluation Board (CBG) has issued a positive assessment of their quality, safety and effectiveness. As a part of this authorisation procedure, the legal status of a pharmaceutical is decided by the CBG. Pharmaceuticals are divided into two categories: prescription-only and non-prescription pharmaceuticals. Requirements for a pharmaceutical to be classified as

856 Wet van 16 juni 2005, houdende regeling van een sociale verzekering voor geneeskundige zorg ten behoeve van de gehele bevolking (Zorgverzekeringswet); http://www.st-ab.nl/1-05358-zvw.htm

857 Wet van 28 juli 1958, houdende nieuwe regelen nopens de geneesmiddelenvoorziening en de uitoefening der artsenijbereidkunst (Wet op de geneesmiddelenvoorziening); http://www.st-ab.nl/wetten/0658_Wet_op_de_Geneesmiddelenvoorziening_WOG.htm

858 Besluit van 8 september 1977, houdende regelen met betrekking tot de registratie van farmaceutische specialités en farmaceutische preparaten (Besluit registratie geneesmiddelen)

prescription-only (uitsluitend recept, UR) are described in an official regulation[859]. In the framework of the ongoing revision of the Pharmaceutical Law, the Dutch government plans to re-introduce the pharmacy-only category for certain non-prescription pharmaceuticals (cf. 19.1.2.2). The pharmacy-only category had been officially abolished on 1 January 1997.

The maximum wholesale prices of pharmaceuticals are set by the Ministry of VWS, according to the Law on pharmaceuticals' prices[860]. The National Health Tariffs Authority (College Tarieven Gezondheidszorg / Zorgautoriteit in oprichting, CTG/ZAio) Board, which consists of independent experts, advised by representatives of doctors, pharmacists and insurance funds, sets the dispensing fees for pharmacists which will be further discussed under section 19.2.1.3.

The Ministry of VWS also decides, based on the advice of the Pharmaceutical Care Committee (Commissie Farmaceutische Hulp, CFH) under the Health Care Insurance Board (College voor Zorgverzekeringen, CVZ), on the reimbursement of pharmaceuticals.

Table 19.1: Netherlands - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Repsonsible person
Ministerie van Volksgezondheid, Welzijn en Sport (VWS) / Ministry of Health, Welfare and Sport	Ministry of Health (decision on price and reim bursement)	VWS Postbus 20350 2500 EJ, Den Haag The Netherlands Tel.: +31 70 3407 911 Fax: +31 70 3407 834 www.minvws.nl	Mr. H. Hurts Postbus 20350 2500 EJ, Den Haag The Netherlands Tel.: +31 70 3407 911 Fax: +31 70 3407 834 The Netherlands hr.hurts@minvws.nl
College vor Zorgverzekeringen (CVZ) / Health Insurance Insurance Board	Third Party Payer (Advice on reimbursement)	CVZ Postbus 320 1110 AH, Diemen The Netherlands Tel.: +31 20 7978 555 Fax: +31 20 7978 500 www.cvz.nl	Mr. J. van Luijn PO Box 396 1180 BD, Amstelveen TheNetherlands Tel.: +31 20 3475 555 Fax: +31 20 6473 494 Jluijn@cvz.nl

859 Regeling UR-geneesmiddelen, 1997

860 Wet van 25 januari 1996, houdende regels omtrent de vaststelling van maximumprijzen voor geneesmiddelen (Wet Geneesmiddelenprijzen, WGP); http://www.st-ab.nl/wetten/0517_Wet_geneesmiddelenprijzen.htm

Institution	Task	Contact details/URL	Repsonsible person
College Ter Beoordeling van Geneesmiddelen (CBG) / Medicines Evaluation Board	Medicines Agency (Authorisation, Classification)	CBG/MEB Kalvermarkt 53 2511 CB, Den Haag The Netherlands Tel.: +31 70 3567 483 Fax: +31 70 3567 515 info@cbg-meb.nl , www.cbg-meb.nl/	Mr. A.A.W. Kalis Kalvermarkt 53 2511 CB, Den Haag The Netherlands Tel.: +31 70 3567 450 Fax: +31 70 3567 515 Aaw.kalis@cbg-meb.nl
Nederlandse Vereniging van de Research-georiënteerde Farmaceutische Industrie / (NEFARMA) Association of Research Based Pharmaceutical Industry	Association of Research Based Pharmaceutical Industry	Nefarma Koninginnegracht 37 2514 AD, Den Haag The Netherlands Tel.: +31 70 3132 222 Fax: +31 70 3132 230 www.nefarma.nl	Mr. C. de Visser Koninginnegracht 37 2514 AD, Den Haag The Netherlands Tel.: +31 70 3132 222 Fax: +31 70 3132 230 s.baaij@nefarma.com
Nederlandse Vereniging van de Farmaceutische Industrie van Zelfzorggeneesmiddelen en Gezondheidsproducten. (NEPROFARM) / Association of manufacturers of self-care pharmaceuticals	Association of manufacturers of self-care harmaceuticals	Neprofarm Huizermaatweg 354 1276 LK, Huizen The Netherlands Tel.: +31 35 6970 821 Fax: +31 35 6970 822 info@neprofarm.nl www.neprofarm.nl	Mr. B.J. Mauritz Huizermaatweg 354 1276 LK, Huizen The Netherlands Tel.: +31 35 6970 821 Fax: +31 35 6970 822 b.mauritz@neprofarm.nl
Bond van de generieke geneesmiddelenindustrie Nederland (BOGIN) / Federation of generic manufacturers	Association of generics manufacturers	Bogin Zurich toren Muzenstraat 89 2511 WB, Den Haag The Netherlands Tel.: +31 70 4262 237 Fax: +31 70 4262 428 www.bogin.nl info@bogin.nl	Mr. P.F. Bongers Zurich toren Muzenstraat 89 2511 WB, Den Haag The Netherlands Tel.: +31 70 4262 237 Fax: +31 70 4262 428

Institution	Task	Contact details/URL	Repsonsible person
Bond van Groothandelaren in het Pharmaceutische bedrijf (BG Pharma) / Association of Pharmaceutical Industry	Wholesale association	BG Pharma Adriaan Goedkooplaan 5 2502 LV, Den Haag The Netherlands Tel.: +31 70 3384 654 Fax: +31 70 3512 777 Bgpharma@verbondgroothandel.nl	Mr. L. Antonini Adriaan Goedkooplaan 5 2502 LV, Den Haag The Netherlands Tel.: +31 70 3384 654 Fax: +31 70 3512 777 Bgpharma@verbondgroothandel.nl
Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (KNMP) / Royal Dutch Pharmaceutical Society	Association of Pharmacists	KNMP Alexanderstraat 11 2500 GL, Den Haag The Netherlands Tel.: +31 70 3737 373 Fax: +31 70 3106 530 communicatie@knmp.nl www.knmp.nl	Mrs. M. van Weelden Alexanderstraat 11 2500 GL, Den Haag The Netherlands Tel.: +31 70 3737 373 Fax: +31 70 3106 530 Hoofdbestuur@knmp.nl
Koninklijke Nederlandse Maatschappij tot bevordering der Geneeskunst (KNMG) / The Royal Dutch Medical Association	Medical Doctors' Association	KNMG Lomanlaan 103 3526 XD, Utrecht The Netherlands Tel.: +31 30 2823 911 Fax: +31 30 2823 326 communicatie@fed.knmg.nl www.knmg.nl	Mr. P. Holland Lomanlaan 103 3526 XD, Utrecht The Netherlands Tel.: +31 30 2823 828 Fax: +31 30 2823 326 p.holland@fed.knmg.nl
Nederlandse Patienten Consumenten Federatie (NPCF) / Patient's and Consumers' Association	Patient's Association	NPCF Churchilllaan 11 3527 GV, Utrecht The Netherlands Tel.: +31 30 2970 303 Fax: +31 30 2970 606 npcf@npcf.nl www.npcf.nl	Mr. E. Visser Churchilllaan 11 3527 GV, Utrecht The Netherlands Tel.: +31 30 2970 303 Fax: +31 30 2970 606 evisser@npcf.nl
Vereniging van internationale handelaren / Dutch merchands association (DMA)	Parallel traders association	DMA Postbus 19 5570 AA, Bergeijk The Netherlands Tel: +31 497 556 064 Fax: +31 497 556 112 info@parallelhandel-dma.nl www.parallelhandel-dma.nl	DMA Postbus 19 5570 AA, Bergeijk The Netherlands Tel: +31 497 556 064 Fax: +31 497 556 112 info@parallelhandel-dma.nl www.parallelhandel-dma.nl

Source: ÖBIG 2006

19.1.2 Market Players

19.1.2.1 Pharmaceutical Industry

The requirements concerning licences and conditions for the production and import of pharmaceuticals are laid down in a Decree [861].

The Netherlands is not seen to have an extremely positive industrial climate. The interests of the research-based pharmaceutical industry are represented by Nefarma[862], which currently has more than 50 members. Manufacturers of self-medication pharmaceuticals are represented by Neprofarm[863], with 23 members. Finally, generic manufacturers are represented by BOGIN[864] (Bond van de Generieke Geneesmiddelenindustrie Nederland).

In 2004, the Netherlands counted 63 companies in the research-based pharmaceutical industry, which employs more than 15,000 people. In 2004, Nefarma members invested 15 to 20% of their annual worldwide turnover in the development of new pharmaceuticals. On the basis of figures from Statistics Netherlands (Centraal Bureau voor de Statistiek, CBS), the pharmaceutical industry has a surplus of € 0.8 billion on the balance of trade.

A Code of Behaviour for the Pharmaceutical Branch (Gedragscode Farmaceutische Bedrijfstak, GFB) has been in force since 2002. This code was drawn up in agreement with Bogin, Nefarma, and the umbrella organisation for pharmaceutical wholesalers (Bond van Groothandelaren in het Farmaceutische Bedrijf, BG Pharma). The GFB consists of a number of general codes of behaviour governing “socially responsible enterprise” and requires stringent self-regulation on a number of issues such as advertising, recall, the protection of intellectual property and environmental matters. If a company seems not adhere to the Code, it can be brought before a Supervisory Committee. This committee consists of independent legal officers and members of the pharmaceutical branch and has the right to impose an injunction, or issue a banning order or a reprimand. Companies have the right to appeal in court. Nefarma has its own internal disciplinary tribunal which should guarantee that the judgements passed by the bodies of self regulation are upheld.[865]

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861 Besluit van 8 september 1977, houdende regelen met betrekking tot de bereiding en aflevering van farmaceutische specialités an farmaceutische preparaten;

862 http://www.nefarma.nl

863 http://www.neprofarm.nl

864 http://www.bogin.nl

865 Nefarma 2004

19.1.2.2 Distribution

Provisions for the distribution of pharmaceuticals to patients are laid down in a Law[866].

Manufacturers and importers mainly deliver the pharmaceuticals to wholesalers, who take care of the supply to pharmacies and drugstores. The distribution of pharmaceuticals by wholesalers is multi-channel.

In the Netherlands prescription-only pharmaceuticals are mostly sold in pharmacies. Furthermore, there is dispensing of pharmaceuticals by

- Self-dispensing doctors in areas where the distance to the closest pharmacy is more than 4.5 kilometres.
- Polyclinic pharmacies: Since 1 April 2000 hospitals have also been allowed to run pharmacies in out-patient clinics, which may dispense pharmaceuticals also to out-patients.
- Drugstores, which have been allowed to sell non-prescription (OTC)pharmaceuticals for a long time already (since approximately 1850). Nowadays more than 80 percent of OTC products are sold through approximately 3,961 drugstores or drugstore departments within supermarkets. Prescription-only medicines are not allowed to be dispensed through drugstores. The dispensing of OTC products in a drugstore requires that the manager or a staff member has a special drugstore license.
- Other OTC outlets, which can be located in groceries, supermarkets, or on camping sites. If the distance to the nearest pharmacy, self-dispensing doctor or drugstore is three kilometres or more, a special license for the dispensing of a restricted range of OTC products can be granted. In 2001, the Netherlands counted 760 of these types of OTC outlets.
- Internet pharmacies, which are also allowed to dispense prescription-only medicines in the Netherlands. Currently there are four internet pharmacies active in the Netherlands.

With the drafting of the new Pharmaceutical Law, the government is currently discussing the retail of OTC products by outlets other than drugstores and pharmacies, e.g. in gas stations and supermarkets, without requiring special licenses.

In 2005 there were 2,322 POM dispensaries in the Netherlands, of which 1,732 pharmacies. A POM dispensary has to provide on average 7,000 inhabitants with pharmaceuticals (a pharmacy about 9,400 inhabitants), which is a high number of inhabitants per POM dispensary compared to other EU Member States.

There are no state licenses required to own a pharmacy, but in order to run a pharmacy profitably contracts with health insurance funds are necessary. In every pharmacy there always needs to be a responsible pharmacist present. This rule was under discussion during the drafting of the new Pharmacy Act, which is expected to come into force in 2006. Abolishment

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866 Wet van 28 juli 1958, houdende nieuwe regelen nopens de geneesmiddelenvoorziening en de uitoefening der artsenijbereidkunst; http://www.st-ab.nl/wetten/0658_Wet_op_de_Geneesmiddelenvoorziening_WOG.htm

of the rule would have allowed pharmacists to supervise more than one pharmacy at a time. Due to heavy resistance of, among others, the Royal Dutch Pharmaceutical Society (Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie, KNMP) this rule will be held.

In the Netherlands multiple ownership of pharmacies has been allowed since 1987. This has led to the development of (a few) pharmacy chains already in the early 1990s. Until 1999 the owner of a pharmacy had to be a pharmacist. Only in a few occasions foundations or health insurance funds were allowed to own pharmacies. Since 1999 it has been possible for non-pharmacists to own pharmacies and employ pharmacists for supervision of the pharmacy practices. This has led to an increase in the number of newly established pharmacies and in the number and size of pharmacy chains. The owners of the pharmacy chains are mainly wholesale companies (OPG, Brocacef (Phoenix), Alliance Unichem and Celesio).

Drugstores, which want to sell OTC products, have to apply for licences at the Ministry of VWS. Selling of OTC medicines in drugstores is only allowed if supervised by a qualified employee. In case the distance to the nearest OTC outlet (drugstore or pharmacy) is more than 3 kilometres, a drugstore does not need to have a qualified employee to receive a “special licence” for the selling of OTC products.

Since June 2002, self-service for a selected group of OTC products is allowed.

19.1.2.3 Patients

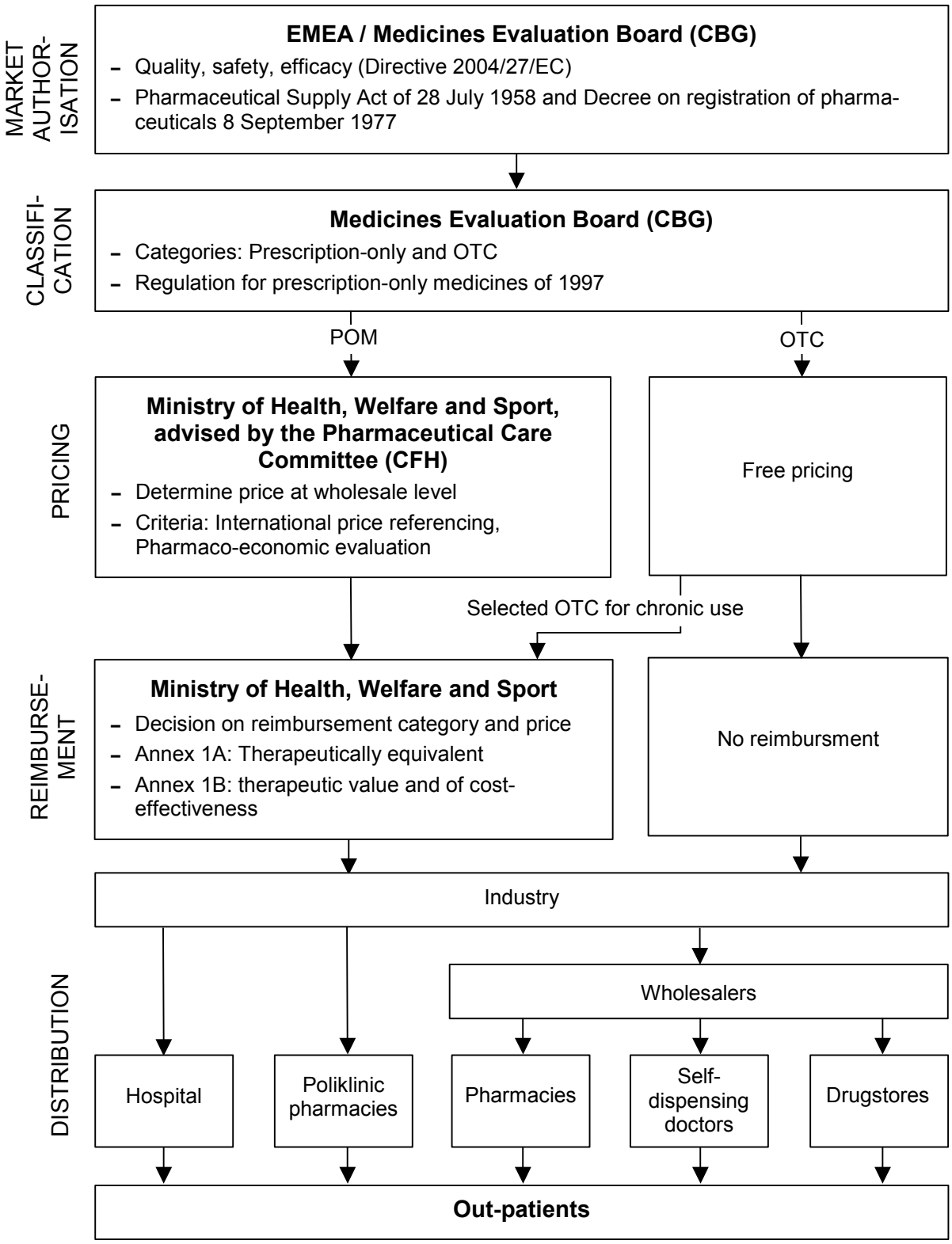
Patients do not have a formal role in decisions on the pricing and reimbursement of pharmaceuticals. Patients in the Netherlands are represented through the Dutch patients and consumers federation (Nederlandse Patienten en Consumenten Federatie, NPCF)

The main rights and duties of patients have been described in the Medical Treatment Agreement Law (Wet op de Geneeskundige Behandelingsovereenkomst, WGBO). This law however does not cover the services offered by pharmacists. In 1996 the Dutch Patients and Consumers Federation (NPCF) and the Pharmacist Association (KNMP) have formulated a „Modellregulation pharmacist - patient”. This regulation provides a protocol for the relation between a pharmacist and a patient, which is based on the WGBO. According to the regulations a patient is free to choose his/her pharmacy and he/she is obliged to provide the pharmacist with necessary information. In case a patient prefers not to follow the advice of the pharmacist, he/she has to discuss this with the pharmacist.

19.1.3 Overview of the Pharmaceutical System

Figure 19.1 shows an overview of the pharmaceutical system in Netherlands.

Figure 19.1: Netherlands - Pharmaceutical System, 2006



Source: ÖBIG

19.2 Pricing

19.2.1 Scope of Price Control

All prescription-only medicines (POM) dispensed by pharmacies are subject to the Law on pharmaceuticals' prices (Wet Geneesmiddelenprijzen, WGP)[867]. Since 1996, according to the WGP, the Ministry of VWS fixes the maximum wholesale price (pharmacy purchase price) of all POM, within 90 after having received of the application from the manufacturer. The Ministry is allowed to prolong this time period with 60 days in case of an extraordinary amount of applications. The WGP procedure is also used to set the prices of generics and parallel imported pharmaceuticals. Free pricing is allowed for OTC products. Prices of OTC products at pharmacy retail level are also officially free, but in practice OTC products are always sold at the prices mentioned in the price list ("taxe"). Except for a few supermarket-related drugstores, all drugstores sell OTC products at the recommended prices in the taxe. The "taxe" is a list containing recommended pharmacy purchase prices for all pharmaceuticals that are available on the Dutch market, which is monthly published by Z-Index[868]. The prices in the taxe are regularly updated by wholesalers and manufacturers, and must be equal to or below the maximum price defined under the WGP (cf. 19.2.1.2). In practice however, the actual prices pharmacies pay for pharmaceuticals are below those mentioned in the taxe.

Maximum prices are revised every six months, taking into account changes in the prices of pharmaceuticals in reference countries and fluctuations in the exchange rate of the euro and the British pound.

Wholesalers are not allowed to set their prices above the statutory maximum prices. The law also states that it is allowed to appeal against the decision of the Ministry concerning the maximum price of a pharmaceutical.

867 Wet van 25 januari 1996, houdende regels omtrent de vaststelling van maximumprijzen voor geneesmiddelen (Wet Geneesmiddelenprijzen, WGP); http://www.st-ab.nl/wetten/0517_Wet_geneesmiddelenprijzen.htm

868 http://www.zindex.nl

Table 19.2: Netherlands - Pharmaceutical Pricing System, 2006

	Manufacturer level	Wholesale level	Pharmacy level
Free Pricing	All pharmaceuticals	Non-prescription pharmaceuticals	Non-prescription pharmaceuticals
Statutory Pricing	Not applied	Maximum prices for prescription-only pharmaceuticals	Prescription-only pharmaceuticals via list prices and a fixed fee per prescription
Price Negotiations	Not applied	Not applied	Not applied
Price/volume agreements, discounts/rebates	No	No	Yes, clawback
Institution in charge of pricing	- Ministry of Health, Welfare and Sport (VWS) - Health Care Tariff Board (CTG)		
Legal Basis	- Wet van 25 januari 1996, houdende regels omtrent de vaststelling van maximumprijzen voor geneesmiddelen (Wet Geneesmiddelenprijzen, WGP) - Wet van 20 november 1980, houdende regelen met betrekking tot de tarieven van organen voor gezondheidszorg - Aanwijzingen tarievenbeleid en tarievenbudgetbeleid 1993 (apothekers en apotheekhoudende huisartsen)		

Source: ÖBIG

19.2.1.1 Manufacturer Price

Manufacturers are free to set their own prices when selling pharmaceuticals to wholesalers. In case a manufacturer delivers pharmaceuticals to a pharmacy directly, without intervention of a wholesaler, the manufacturer has to restrict the prices to the maximum wholesale prices (cf. 19.2.1.2), which can thus actually be considered as maximum “Pharmacy purchase prices”.

Prices of OTC products are officially free, but in practice OTC products are always sold at the prices mentioned in the taxe.

19.2.1.2 Wholesale Price

A maximum wholesale price (or pharmacy purchase price) was introduced in 1996, whereby the prices of reimbursable pharmaceuticals were cut by an average of 20%. The maximum wholesale price of all POM are calculated as the average wholesale price of comparable pharmaceuticals in four European countries, Belgium, France, Germany and the UK[869]. Maximum prices are revised every six months. Pharmaceuticals are considered comparable when they contain the same active ingredient, strength and pharmaceutical form. The prices are divided by pack size to get the price per unit and for each country an average price per unit is calculated. The mean of these averages becomes the maximum price per unit of the comparable pharmaceutical in the Netherlands. A maximum price can be determined if a

[869] Regeling referentieprijslijsten geneesmiddelen; http://www.farmatec.nl/prijsvorming/pdf/2006/2660802_vaststelling_regeling.pdf

comparable pharmaceutical is on the market in at least two of the four reference countries. Both patented pharmaceuticals and generics are treated in this way.

Wholesale margins are not fixed, but are based on individual agreements between the manufacturer or importer and the wholesaler, and vary from pharmaceutical to pharmaceutical. On average, most of the gross wholesale margins are said to be passed on to pharmacists and self-dispensing doctors in the form of discounts. Industry estimates suggest that wholesale margins are around 13-24% of the manufacturer price, or 7-8% of the reimbursement price (excluding VAT) [870]. Generic and parallel imported pharmaceuticals have slightly higher margins than branded pharmaceuticals.

19.2.1.3 Pharmacy Retail Price

On the basis of the Health Care Charges Act[871,872], the government specifies which maximum rates a pharmacy may charge to the person using the pharmaceutical or to the health insurance fund with whom the particular user is insured. This rate consists of two fees: a fixed fee for the services provided by the pharmacy (€ 6.10 for each prescription dispensed (2006)) and a purchase fee for the pharmaceutical supplied by the pharmacy.

The fixed fee is an amount that the pharmacy may charge per dispensed prescription. Starting point for determining the amount of the fixed fee per prescription are the pharmacy practice costs and the norm income for the established pharmacist as specified by the government. As of 1 January 2003, the National Health Tariffs Authority (College Tarieven Gezondheidszorg / Zorgautoriteit in oprichting (CTG/ZAio)) determined the fixed pharmacy fee to be € 6.10. The CTG applies annually an index-related adjustment of the pharmacy fees. The pharmacy fee did not change in 2004, in 2005 and in 2006.

The purchase fee is in fact the cost of the medicine as listed in the “taxe” (cf. 19.2.1). Pharmacists are reimbursed these costs albeit with some restrictions. For generics, reimbursement is based on the lowest priced generic that could theoretically supply the whole market; however, pharmacists are generally reimbursed at the full list price (i.e. price according to the taxe) because few manufacturers are able to supply the entire market. For parallel imports, reimbursement is based on the cheapest price per country of origin.

In practice, pharmacies can agree discounts for these list prices from their suppliers. These purchase benefits are periodically the subject of debate.

Self-dispensing doctors receive an annual subscription rate per registered nationally insured patient, irrespective of the number of prescription-only medicines that the person concerned consumes on a yearly basis. Since 1 January 2006 self-dispensing doctors receive, in addi-

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870 Tilson, L.; Barry, M. 2005

871 Wet van 20 november 1980, houdende regelen met betrekking tot de tarieven van organen voor gezondheidszorg; http://www.st-ab.nl/wetten/0814_Wet_tarieven_gezondheidszorg_Wtg.htm

872 Aanwijzingen tarievenbeleid en tarievenbudgetbeleid 1993 (apothekers en apotheekhoudende huisartsen)

tion to the basic amount of € 8.60 per patient, € 0.60 per patient younger than 65 and € 20.80 per patient older than 65 years of age.

19.2.1.4 Value Added Tax (VAT)

The VAT rate on all pharmaceuticals is set at 6%, while the standard VAT rate is set at 19%.

19.2.2 Price Related Cost-containment Measures

19.2.2.1 Pharmaco-economic Evaluation

Although unaffected by the new health insurance act, recent years have seen key changes to the application of pharmaco-economics. Pharmaco-economic studies have been required since January 2005 whenever the manufacturer claims the pharmaceutical is unique (Annex 1B, cf. 19.3.1) and should not, therefore, be clustered in an existing therapeutic reference price group.

If the CFH's therapeutic evaluation of the pharmaceutical (cf. 19.3.1.2) shows it to be clusterable in Annex 1A, then the pharmaco-economic data are no longer required.

The development of the Dutch pharmaco-economic guidelines has a 4-year history, starting with initial draft guidelines, which were drawn up by the Preparatory Committee on Guideline Development (Voorbereidingscommissie Richtlijnontwikkeling, VBR), a committee within the CVZ, in February 1998. A second draft was implemented in 2000, after comments were received from several actors in the pharmaceutical sector. The guidelines stipulate that a societal perspective should be adopted. Furthermore, regarding the methodology, a cost-utility study is preferred. In 2000 a manual was published and in 2002 a Pharmaco-economic Dossier Assessment form was designed. A three year transition period started in 2002. During this period, if the manufacturer claims that the new pharmaceutical has a therapeutic added value and cannot be clustered (i.e. is an Annex 1B pharmaceutical), results of pharmaco-economic research may be included in the submitted reimbursement dossier. Since February 2005, in such a situation inclusion of pharmaco-economic data regarding the new pharmaceutical is obligatory.

With input from various stakeholders, the guidelines were again updated in 2005[873], resulting in a total of 11 guidelines. The 11 guidelines formally took effect on 1 April 2006.

19.2.2.2 External Price Referencing / Cross Country Referencing

Maximum wholesale prices of all POM are calculated as the average wholesale price of comparable pharmaceuticals in four European countries, Belgium, France, Germany and the UK[874].

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873 Richtlijnen voor farmaco-economisch onderzoek, geactualiseerde versie, Amstelveen, College voor Zorgverzekeringen, 1 april 2006; http://www.cvz.nl/resources/FARM_richtlijnen_farmaco-economisch_onderzoek_2006_tcm28-19118.pdf

Maximum prices can only be calculated if at least two of the four countries have a comparable pharmaceutical on the market, i.e. a pharmaceutical with the same active ingredient, same strength and the same pharmaceutical form (including generics).

The prices are divided by the pack size to get the price per unit and for each country an average is calculated. The mean of these average prices becomes the maximum price per unit of the comparable pharmaceutical in the Netherlands.

19.2.2.3 Price Freezes and Price Cuts

Covenant 2004

In February 2004 a covenant was agreed between the Ministry of VWS, the Royal Dutch Pharmaceutical Society (KNMP), the Health Care Insurance Board (Colleg voor Zorgverzekeingen, CVZ) and the Dutch Federation for Generics Manufacturers (BOGIN). It was decided that the wholesale prizes of generics should decrease by an average of 40% of the list prices in January 2004. The prices of other pharmaceuticals were frozen.

Covenant 2005

In 2005, the 2004 covenant was extended for an additional year. This time the research-based pharmaceutical industry in the Netherlands (represented by Nefarma) also participated in the agreement. This time it was agreed that also the prices of branded pharmaceuticals for which generic alternatives are available should decrease by on average 40%. The prices of other pharmaceuticals remained frozen.

Covenant 2006 - 2007[875]

The agreements made within the 2005 covenant were extended for 2006 and 2007. Also, additional price cuts will take place in 2006 and in 2007: In 2006 the members of BOGIN and of Nefarma will lower the prices of their off-patent pharmaceuticals by on average 8.5%, this percentage has not yet been defined for 2007. The price freezes that were in place during the covenants of 2004 and 2005 were abolished; incidental price increases are now allowed.

19.2.2.4 Discounts and Rebates

Since 1991 a large part of the pharmacies' remuneration has been made up of discounts granted by the manufacturers or wholesalers. As the exceeding of the pharmaceutical budget has become an annually recurring problem, the Ministry of VWS introduced a clawback rule in 1998. Modelled after the British example, the then Minister of Health introduced a legal arrangement that obliged pharmacies to on-charge part of the realised purchase benefits on

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874 Regeling referentieprijslijsten geneesmiddelen; http://www.farmatec.nl/prijsvorming/pdf/2006/2660802_vaststelling_regeling.pdf

875 Convenant inzake het omzetten van kortingen en bonussen voor geneesmiddelen in structurele prijsverlagingen 2006/2007; http://www.minvws.nl/images/convenant_tcm10-78913.pdf

reimbursable pharmaceuticals as a price benefit (i.e. discount) to the patients and the health insurance companies. In 1998, this resulted in an effective discount rate of 2% of the list prices in the taxe (cf. 19.2.1) on an annual basis (the arrangement was introduced halfway through the year). In 1999, pharmacies were obliged to grant patients and health insurance companies an effective discount of 3% of the list prices. On 8 October 1999, the Minister of VWS concluded an agreement with the KNMP for the period of 1 January 2000 through 31 December 2002. The agreement provided for a phased increase of the fixed prescription fee in connection with an adjustment of the clawback from 3% to effectively 6% of the list prices in the taxe (cf. 19.2.1) (formally, the clawback was increased to 6.82% to a maximum of € 6.80 per dispensed prescription).

On 15 November 2002 the outgoing interim Minister of VWS, announced an adjustment of the clawback scheme with the objective of realising extra savings. Under this new scheme, 8% of pharmacy reimbursement was clawed back for single source pharmaceuticals (up to a maximum of € 9), and 40% of the official pharmacy purchase price in February 2003 was clawed back for multi-source pharmaceuticals (up to a maximum of € 20). The Ministry considers single-source pharmaceuticals to be prescription-only medicines that are produced by only one manufacturer (usually a pharmaceutical that is still patented). Pharmaceuticals that are supplied by more than one producer (including the original reference pharmaceutical) are considered to be multi-source.

The differentiated clawback was widely criticised and subjected to legal challenges at the Trade and Industry Appeals Tribunal (College van Beroep voor het Bedrijfsleven, CBB). In December 2003, the court ruled that it was unlawful, as the Ministry of Health had not put in place sufficient safety nets for pharmacists. This brought an end to the differentiated scheme.

The original clawback rule, according to which pharmacies are obliged to grant patients and health insurance companies a 6.82% discount on the list prices issued by the pharmaceutical manufacturers, with a maximum of € 6.80 per dispensed pharmaceutical, was reintroduced and still stands.

In addition, with the covenant concluded by the Ministry of VWS, the KNMP, the CVZ, and BOGIN in 2004 (and again in 2005 and in 2006, including Nefarma) (cf. 19.2.2.3), it was agreed that the wholesale prices of generics (and in 2005 also of branded pharmaceuticals with generic alternatives) should be cut by an average of 40% of the list price of January of the year in which the covenant came into force. This way, the covenant ensures that, rather than pharmacists obtaining large discounts on generics from manufacturers and wholesalers, these savings are passed directly to the insurance funds.

When the covenant was agreed, the government warned that if its budgetary goals were not met under the new system, it would retain the right to introduce the differentiated clawback with the necessary safety provisions. Based on the savings thus far, this is unlikely to be necessary.

19.2.2.5 Parallel Trade

Companies that want to parallel import pharmaceuticals from other EU Member States must apply for a licence for parallel wholesale.[876,877] In 2004, the Ministry of VWS and the CBG subsequently issued guidelines on parallel import of pharmaceuticals. Parallel importers now have to inform patent holders, in writing, of their intentions at least a month before they request authorisation for a parallel import. It is also compulsory to state the country of origin of the parallel import at that point.

The rules with relation to the pricing and reimbursement of parallel imported pharmaceuticals are the same as those for other (not imported) pharmaceuticals. In practice the prices of parallel imported are below those of the not imported pharmaceuticals.

Measured in numbers of prescriptions, the market share of parallel imported pharmaceuticals amounted to 7.4% in 2004. With regard to pharmaceutical expenditure, the share of parallel imported pharmaceuticals amounted to 16.3% in 2004.

Parallel import reached its peak in the mid-1990s. The increasing trend began in 1994, when pharmacists were allowed to negotiate purchasing advantages. The downward trend started during the second half of 1996 when, due to the introduction of legal maximum prices, the price difference between parallel imported pharmaceutical and branded pharmaceuticals produced in the Netherlands decreased.

19.2.3 Co-Payments

The Dutch population is cultured not to pay out-of-pocket for pharmaceuticals. In 2005 for instance, patient spending accounted for only 0.5% of the € 4.1 billion pharmaceutical expenditure. Including the payment for OTC pharmaceuticals, the proportion rose to 3.5%.

Under the reimbursement scheme, only pharmaceuticals listed in Annex 1A of the positive list (cf. 19.3) require patients to make a co-payment. Even in Annex 1A, patients receive reimbursable pharmaceuticals free of charge unless the pharmaceutical is priced above the maximum reimbursement level. As manufacturers tend to bring the price of their pharmaceuticals down to the reimbursement level to maintain market share by avoiding patients having to pay out-of-pocket, relatively few pharmaceuticals attract a co-payment.

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876 Wet van 28 juli 1958, houdende nieuwe regelen nopens de geneesmiddelenvoorziening en de uitoefening der artsenijbereidkunst (Wet op de geneesmiddelenvoorziening), article 2; http://www.st-ab.nl/wetten/0658_Wet_op_de_Geneesmiddelenvoorziening_WOG.htm

877 Besluit van 8 september 1977, houdende regelen met betrekking tot de bereiding en aflevering van farmaceutische specialités an farmaceutische preparaten

19.2.4 Information Transparency and Marketing

The EU's provisions on pharmaceutical advertising were implemented in the Netherlands[878]. In addition, the Dutch pharmaceutical manufacturers' associations Neprofarm and Nefarma have, in close cooperation, drafted a general code of conduct based in the EU provisions which deals with pharmaceutical advertising to the public as well as to health professionals. The section on public advertising, which is a stand-alone document, the Code on Public Advertising of Pharmaceuticals[879] (Code geneesmiddelenreklame, CGR), became effective at the beginning of 1995.

Only for OTC, advertising in all media is allowed. However, only indications suitable for self-medication may be mentioned in public advertising. A list of these indications is annexed to the Code on Public Advertising of Pharmaceuticals. All advertising control is officially in the hands of the self-regulatory Foundation for the Code on Public Advertising of Pharmaceuticals. Comparative advertising is allowed in the Netherlands and is regulated under Article 33 of the Code on Public Advertising of Pharmaceuticals.

It has been estimated that in the Netherlands, the pharmaceutical industry spends about 10% of its budget on marketing, including advertisements, folders and mail-shots. A further 12.5% of the budget goes to the provision of "scientific information and services". These include medical representatives, scientific publications, congresses, educational tools and continuing education courses. It is the aim of independent bodies, such as the "Farmacotherapeutisch Kompas"[880] and the "Geneesmiddelenbulletin"[881], to provide impartial information. The "Geneesmiddelenbulletin" Foundation publishes a monthly bulletin targeting everyone involved in the prescribing and provision of pharmaceuticals. Its intended purpose is to promote a more rational approach to pharmacotherapy. The bulletin was first published in 1967 under the auspices of the Directorate of Public Health at the former Ministry of Social Affairs and Public Health.

Characteristics, such as price and reimbursement status, of all pharmaceuticals available in Dutch pharmacies are published and kept up-to-date by Z-index[882]. The information published by Z-Index is not aimed at the general public. The Health Care Insurance Boars (CVZ) has launched a website for patients containing information per pharmaceutical on the actual retail prices, the reimbursement status, co-payment share and the availability of cheaper alternatives[883]. In addition, in February 2006 a public website containing information on self-medication has been launched[884]. On this website one can find detailed information on a large number of OTC.

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878 Besluit van 31 oktober 1994, houdende regels voor reclame voor geneesmiddelen

879 http://www.cgr.nl/sitedata/www.cgr.nl/uploads/misc/gedragscode/Gedragscode%20per%2001.10.05.pdf

880 http://www.cvzkompassen.nl/fk/

881 http://www.geneesmiddelenbulletin.nl/

882 www.zindex.nl

883 www.medicijnkosten.nl

884 www.zelfzorg.nl

19.3 Reimbursement

19.3.1 Pharmaceutical Lists and Reimbursement Categories

Until 1991, all prescribed pharmaceuticals were eligible for reimbursement. The reimbursement system changed greatly by the introduction of the reference price system and the positive list in 1991, and to a minor extent by the introduction of the new Health Insurance Act[885] and the accompanying Decree on Health Insurance[886] and Regulation on Health Insurance[887].

Manufacturers submit reimbursement applications for authorised pharmaceuticals to the Ministry of VWS. On the basis of input from the Pharmaceutical Care Committee (Commissie Farmaceutische Hulp, CFH) within the Health Care Insurance Board (CVZ), the Ministry of VWS determines within 90 days after receiving the application, whether a pharmaceutical will be included in the pharmaceutical reimbursement system (Geneesmiddelenvergoedingssysteem, GVS) or not. In 2004, the average duration of an assessment by the Pharmaceutical Care Committee was 164 days[888]. This included the shortened procedures, which are possible for generics or parallel imported pharmaceuticals and for new dosages of pharmaceuticals already included in Annex 1A. In the case of shortened procedures, the Ministry decides without input from the CVZ.

Reimbursable pharmaceuticals are listed on a positive list, which is divided into the following three categories:

- Annex 1A: Therapeutically interchangeable pharmaceuticals (including parallel imported pharmaceuticals) reimbursed according to a reference price system (cf. 19.3.2).
- Annex 1B: Unique pharmaceuticals (not reimbursed according to the reference price system, no reimbursement limit exists).
- Annex 2: Pharmaceuticals only reimbursed under specific circumstances, for example if prescribed by a specialist, if administered within a specialised health care centre (e.g. for cancer treatment), or after approval of the health insurance.

The CFH decides as to whether the pharmaceutical can be clustered with existing pharmaceuticals included in the therapeutic reference price system (Annex 1A), or is not interchangeable and cannot be clustered (Annex 1B).

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885 Wet van 16 juni 2005, houdende regeling van een sociale verzekering voor geneeskundige zorg ten behoeve van de gehele bevolking (Zorgverzekeringswet); http://www.st-ab.nl/1-05358-zvw.htm

886 Besluit van 28 juni 2005, houdende vaststelling van een algemene maatregel van bestuur als bedoeld in de artikelen 11, 20, 22, 32, 34 en 89, van de Zorgverzekeringswet (Besluit zorgverzekering); http://www.vgz.nl/bbcm/files/besluit%20zorgverzekering.pdf

887 Regeling van de Minister van Volksgezondheid, Welzijn en Sport van 1 september 2005, nr. Z/VV-2611957, houdende regels ter zake van de uitvoering van de Zorgverzekeringswet (Regeling zorgverzekering); http://www.cvz.nl/resources/FinBudgVerevZvw2006_regelingVWS_tcm28-17215.pdf

888 Nefarma 2004

19.3.1.1 Reimbursement Price

Under the reimbursement system (Geneesmiddelenvergoedingssysteem, GVS) reference reimbursement prices are set by the ministry of VWS for all Annex 1A pharmaceuticals according to the reference price system (cf. 19.3.2). Thus, only pharmaceuticals listed in Annex 1A of the positive list require patient co-payments if the pharmaceutical is priced above the maximum reimbursement price.[889]

For unique pharmaceuticals (Annex 1B), which cannot be clustered with other pharmaceuticals, the only cap on reimbursement prices are maximum wholesale prices set by the price referencing system as the average of wholesaler prices in Belgium, France, Germany and the UK (cf. 19.2.1.2). The reimbursement price of Annex 1B pharmaceuticals is based on the pharmacy retail price, which must not be above the maximum price set under the WGP. If a new pharmaceutical is added to the reimbursement list and is interchangeable with an Annex 1B pharmaceutical, the reimbursement price is based on the price of the pharmaceutical listed first.

Parallel imported pharmaceuticals and combination products are not included in the calculation of reimbursement prices. Although the reimbursement list has been updated on a continuous basis, reimbursement prices have not been recalculated since 1999.

A lot of health insurance companies are now, as this is allowed with the new health insurance legislation, offering the possibility to reimburse above the reimbursement limit as part of their additional insurance packages.

19.3.1.2 Selection Criteria

To be included in Annex 1A of the reimbursement list, a pharmaceutical must be therapeutically equivalent (i.e. same indications, same route of administration, and used by patients in the same age category) to one or more other pharmaceutical(s) already in the list.

Conditions for including a pharmaceutical in Annex 1B are based on an assessment of the therapeutic value and of cost-effectiveness. The CFH assesses pharmaceuticals' therapeutic value based on[890]:

- Therapeutic efficacy
- Therapeutic effectiveness
- Side-effects
- Experience with the pharmaceutical
- Applicability of the pharmaceutical
- Ease of use for the patient

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889 Besluit van 28 juni 2005, houdende vaststelling van een algemene maatregel van bestuur als bedoeld in de artikelen 11, 20, 22, 32, 34 en 89, van de Zorgverzekeringswet (Besluit zorgverzekering); http://www.vgz.nl/bbcm/files/besluit%20zorgverzekering.pdf

890 http://www.cvz.nl/resources/CFH_beoordelingscriteria_tcm28-15811.pdf

The assessment report is published on the internet[891]. If the therapeutic value of the pharmaceutical is too low, it will not be eligible for reimbursement.

19.3.1.3 Pharmaceuticals on Positive List

In 2005, approximately 11,440 prescription-only medicines (counted including different pharmaceutical forms (e.g. tablets) and dosages) were authorised, of which 9,960 were available on the market. Of these 9,960 prescription-only pharmaceuticals that are on the market, 99.6 percent is on the reimbursement list[892]. The reimbursement list is updated on a continuous basis. The positive list was frozen for a few years in the mid-1990s in order to contain increasing expenditures (i.e. no pharmaceuticals were added). This rendered several new expensive pharmaceuticals non-reimbursable during these years.

19.3.1.4 Generics

Regarding reimbursement, generics are subject to the same laws and regulations as branded pharmaceuticals. Nevertheless, in the reference price system which is applied to determine maximum reimbursement prices for pharmaceuticals, per reference price group only the cheapest generic is included.

Already since 2004, health insurance funds have been permitted to reimburse only one (the lowest priced generic) version of an active ingredient. In fact, the lowest price initiative has taken off in 2006. With the new Health Insurance Act[893], health insurance funds are more focussed than ever on cost-containment, and they are given more freedom in pharmaceutical matters. Currently reimbursement of only the cheapest generic is applied by the five biggest insurance funds, covering a total of 9 million people, for three pharmaceuticals (omeprazole, simvastatin and pravastatin). More pharmaceuticals are expected to be covered, which are likely to be those long out-of-patent and in large clusters.

19.3.1.5 Non-reimbursable Pharmaceuticals

Almost all OTC medicines, even if prescribed by a physician, are non-reimbursable. Until January 2004 OTC medicines that had been prescribed for chronic use were reimbursed. On 1 January 2005 reimbursement for five categories of self-medication pharmaceuticals for chronic use was reinstated. Of prescription-only medicines only 0.4% was not reimbursed in 2005[892].

19.3.1.6 Appeal Procedure

Manufacturers are allowed to appeal against any pricing decisions taken by the Ministry of Health. However, it is not possible to appeal against either the reimbursement recommendation by the CVZ to the Minister, or the contents of the assessment by the CFC.

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891 http://www.cvz.nl (CFH-rapporten)

892 ÖBIG 2006

893 Wet van 16 juni 2005, houdende regeling van een sociale verzekering voor geneeskundige zorg ten behoeve van de gehele bevolking (Zorgverzekeringswet); http://www.st-ab.nl/1-05358-zvw.htm

19.3.1.7 Delisting and Switches

Pharmaceuticals can be removed from Annexes 1A or 1B if alternatives show better efficacy, safety or cost-effectiveness. In 1996 the reimbursement list was screened and many pharmaceuticals were removed from it.

No set procedure is in place to switch pharmaceuticals from POM-to-OTC status. The Medicines Evaluation Board (CBG) is responsible for evaluating the status of pharmaceuticals, but only the market authorisation holder is permitted to apply for a change in status, as the legal status is part of the market authorisation. Under the new Pharmaceutical Law, which is likely to take effect in the second half of 2006, a clause will be included that will give the Minister of Health the authority to request the switching of certain categories of pharmaceuticals to OTC status.

Switching a pharmaceutical from prescription to OTC status has important implications for the reimbursement of the pharmaceutical. A switched pharmaceutical always loses its reimbursement status. All OTC medicines were removed from the reimbursement system in early 2004. Pharmaceuticals with the same composition as OTC that had prescription-only status on account of their indications were de-reimbursed at the same time.

On 1 January 2005, the Dutch Minister of Health reinstated reimbursement for five categories of self-medication pharmaceuticals for chronic use (cf. 19.3.1.5). As motivation, the Minister quoted the high expenses of these pharmaceuticals likely to be incurred by certain patients with a chronic illness. Chronic use should be interpreted as treatment of more than six months and should be indicated on the prescription.

19.3.2 Reference Price System

A reference price system was introduced in 1991. In this reference price system, Annex 1A pharmaceuticals are clustered into groups of similar interchangeable pharmaceuticals, including one (the cheapest) generic. Since June 2002, pharmaceuticals have been considered interchangeable if they are used for the same indications, have the pharmaceutical form and are used for patients in the same age category[894].

A maximum reimbursement price level or reference price is set for all pharmaceuticals in the group. The reference price is calculated using the cost of the defined daily dose (DDD) for each pharmaceutical in the group, unless the DDD is below or above the Dutch maximum advisable dose[895]. The reimbursement price is set as the price of the pharmaceutical equal to

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894 Regeling van de Minister van Volksgezondheid, Welzijn en Sport van 1 september 2005, nr. Z/VV-2611957, houdende regels ter zake van de uitvoering van de Zorgverzekeringswet (Regeling zorgverzekering), Article 2.40; http://www.cvz.nl/resources/FinBudgVerevZvw2006_regelingVWS_tcm28-17215.pdf

895 Regeling van de Minister van Volksgezondheid, Welzijn en Sport van 1 september 2005, nr. Z/VV-2611957, houdende regels ter zake van de uitvoering van de Zorgverzekeringswet (Regeling zorgverzekering), Article 2.41; http://www.cvz.nl/resources/FinBudgVerevZvw2006_regelingVWS_tcm28-17215.pdf

or directly below the average of the prices of all pharmaceuticals in the group. Under this system, at least one pharmaceutical in each group is fully reimbursed. Pharmaceuticals priced above the reference price are only partially reimbursed and the patient must pay the difference between the reimbursement price and the pharmacy retail price[896]. Manufacturers tend to lower their prices towards the reference price to avoid patients having to pay excessive co-payments.

With the new insurance system[897], some insurance funds are starting to reimburse just one pharmaceutical within a group of therapeutically equivalent pharmaceuticals. This has only been possible with the new legislation which was implemented on 1 January 2006, although preparations for these initiatives started at the end of 2005. The new insurance system allows for voluntary contracts to be drawn up between health insurance funds and physicians. For example, physicians agree to start 80% of new patients on off-patent simvastatin and, if this is achieved, the health insurance funds pay them a bonus. Although the aim of this agreement is to reimburse just one pharmaceutical, patients who really need another pharmaceutical on medical grounds will still have it reimbursed - the patient has the right to receive other pharmaceuticals within the cluster.

Legal cases, citing curtailment of physicians' prescribing freedom and patients not receiving optimal care, have been lodged against the one pharmaceutical per cluster initiatives. Judges have ruled in favour of the schemes so far, on the ground that prescribers (i.e. physicians) are using their own guidelines to stimulate prescriptions and are not, therefore, doing anything illegal. The more these systems are used, the stronger the opposition is expected to get.

But, if the insurance funds keep winning the legal cases and GPs accept and sign these contracts, expansion of these schemes is likely.

19.3.3 Pharmaceutical Budgets

Doctors are not subject to prescribing budgets.

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896 Besluit van 28 juni 2005, houdende vaststelling van een algemene maatregel van bestuur als bedoeld in de artikelen 11, 20, 22, 32, 34 en 89, van de Zorgverzekeringswet (Besluit zorgverzekering); http://www.vgz.nl/bbcm/files/besluit%20zorgverzekering.pdf

897 Wet van 16 juni 2005, houdende regeling van een sociale verzekering voor geneeskundige zorg ten behoeve van de gehele bevolking (Zorgverzekeringswet); http://www.st-ab.nl/1-05358-zvw.htm

19.3.4 Other Volume Control Oriented Measures

19.3.4.1 Prescription Monitoring and Other Doctors-related Measures

Although doctors are not subject to prescribing budgets, other mechanisms are in place to encourage them to prescribe rationally. These include treatment guidelines and the monitoring of prescribing patterns by practice. There is also a growing trend for insurance funds to encourage doctors to abide by a formulary and prescribe by active substance. A national network of doctors and pharmacists meets in local groups, pharmacotherapeutic forums (farmacotherapeutisch overleg, FTO) and interdisciplinary pharmacotherapeutic forums (farmacotherapeutisch transmuraal overleg, FTTO) to discuss the optimal use of pharmaceuticals. The aim of these groups is to promote rational prescribing and dispensing of pharmaceuticals, to achieve better pharmaceutical care and to establish collective agreement on this subject.

An electronic prescribing system (Elektronisch Voorschrijf Systeem, EVS) was introduced in 1999 and is used by the majority of doctors as a support tool in the treatment for patients. Although the EVS has improved the efficiency of prescribing, the savings in prescribing expenditures have not been as great as anticipated.

19.3.4.2 Generics and Parallel Trade

Generics had a market share of 19.1% by value and 46.6% by volume in 2004 (SFK 2005). Owing to the introduction of the Law on pharmaceuticals' prices (WGP)[898], the price difference between branded pharmaceuticals and generics decreased from 20% at the beginning of the 1990s to 5% in mid-2003.

If a prescription is not written by international non-proprietary name (INN), a pharmacy may substitute a pharmaceutical with a cheaper one if the prescribed pharmaceutical is more expensive than an equivalent generic or parallel imported pharmaceutical. The prescriber must approve the substitution by marking the prescription accordingly and the patient must also approve the substitution.

In 1996, the National Association of General Practitioners (GP), with the Ministry of Health, set up a project to encourage all GP to use the INN instead of using brand names when writing prescriptions. Generic prescribing was even made easier for GP by purpose-written software (EVS), which was introduced in 1998. This system allows the doctor to enter the brand name of the pharmaceutical and then receive a print-out of a generic prescription.

In the past, pharmacists were encouraged to dispense generics instead of the more expensive branded pharmaceuticals because they were allowed to keep one third of the difference between the price of the brand and that of the generic dispensed. This incentive was re-

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898 Wet van 25 januari 1996, houdende regels omtrent de vaststelling van maximumprijzen voor geneesmiddelen (Wet Geneesmiddelenprijzen, WGP); http://www.st-ab.nl/wetten/0517_Wet_geneesmiddelenprijzen.htm

moved in the covenant of February 2004, which has lead to a voluntary reduction in the price of generics. There is now little financial incentive for pharmacists to dispense generics. Nevertheless, pharmacists have agreed under the covenants of 2004, 2005 and 2006-2007 to continue to make optimum use of generics.

Therapeutic substitution, where a pharmacist may substitute the prescribed pharmaceutical with a therapeutically equivalent one but which has a different active substance, is also possible for certain groups of pharmaceuticals.

Parallel imports had a total market share of 16.3% by value and 7.4% by volume in 2004 (SFK 2005). The parallel import market has been declining over recent years. The decline has been caused by the fact that the WGP pricing system lowered priced closer to those in neighbouring EU Member States, reducing the price differentials between countries.

In the past, pharmacists were encouraged to use parallel imports because they received one third of the difference in the price between a brand and a parallel import (like it used to be in the case of generics). But this incentive was also removed when the covenant was agreed in 2004. Like in the case of generic substitution, pharmacists are allowed to substitute by a parallel imported pharmaceutical if the prescribing physician agrees. In case the physician prescribes by INN, the pharmacist may choose him- / herself to dispense a parallel imported pharmaceutical.

19.4 Overview of the Reimbursement Market in the Netherlands

Tasks / Duties	Yes	No	Comment	Legal bases
Public Authorities				
Decide on prescription status	X		Medicines Evaluation Board (CBG)	Regeling UR-geneesmiddelen, 1997
Decide on manufacturer price		X		
Agree on manufacturer price or reimbursement price		X		
Fix wholesale margin		X	But regulated maximum prices for POM at the wholesale level	
Fix pharmacy retail price		X		
Decide on reimbursement status	X			Besluit van 28 juni 2005, houdende vaststelling van een algemene maatregel van bestuur als bedoeld in de artikelen 11, 20, 22, 32, 34 en 89, van de Zorgverzekeringswet (Besluit zorgverzekering) Regeling van de Minister van VWS van 1 september 2005, nr. Z/VV-2611957, houdende regels ter zake van de uitvoering van de Zorgverzekeringswet (Regeling zorgverzekering)
Decide on reimbursement price	X			Besluit van 28 juni 2005, houdende vaststelling van een algemene maatregel van bestuur als bedoeld in de artikelen 11, 20, 22, 32, 34 en 89, van de Zorgverzekeringswet (Besluit zorgverzekering) Regeling van de Minister van VWS van 1 september 2005, nr. Z/VV-2611957, houdende regels ter zake van de uitvoering van de Zorgverzekeringswet (Regeling zorgverzekering)
Use Pharmaco-economic guidelines	X		Required since January 2005, only for unique pharmaceuticals (Annex 1B)	
Use Internal reference pricing		X		

Tasks / Duties	Yes	No	Comment	Legal bases
Use External reference pricing	X		When determining maximum wholesale price (Belgium, France, Germany, UK)	Wet van 25 januari 1996, houdende regels omtrent de vaststelling van maximumprijzen voor geneesmiddelen (Wet Geneesmiddelenprijzen)
Price freezes		X	Since the 2006-2007 covenant prices are incidentally allowed to increase	
Margin cuts			N.app.	
Discounts and Rebates	X		Towards wholesalers / Pharmacies Pharmacy clawback system is in place	
Company profit control		X		
Country specific:				
Decide on maximum wholesaler price	X			Wet van 25 januari 1996, houdende regels omtrent de vaststelling van maximumprijzen voor geneesmiddelen (Wet Geneesmiddelenprijzen)
Pharmaceutical Industry				
Sets manufacturer price freely	X			
Notifies manufacturer price	X		Prices are listed in the "taxe"	
Negotiates manufacturer price		X		
Is free to set price below fixed manufacturer price			N.app.	
Decides on application for reimbursement	X			
Negotiates reimbursement price		X		
Free to keep manufacturer price above reimbursement price	X		Very unusual	
Free to grant rebates / discounts to wholesalers	X			
Free to grant rebates / discounts to pharmacies	X			

Tasks / Duties	Yes	No	Comment	Legal bases
Can engage in marketing towards doctors	X			
Can engage in public advertising	X		Only for OTC, in line with royal decree and with the Code on Public Advertising	Besluit van 31 oktober 1994, houdende regels voor reclame voor geneesmiddelen
Can provide information toward patients	X			
Applies for switches and de-listing	X			
Country specific:				
Distribution Chain				
Wholesaler				
Margins are fixed by statute		X		
Margins are subject to statutory discounts / rebates			N.app.	
Free to grant discounts / rebates to pharmacies	X			
Pharmacists				
Margins are fixed by statute		X		
Free to set retail price	X		Government specifies maximum rates based on list price and fixed fee	Wet van 25 januari 1996, houdende regels omtrent de vaststelling van maximumprijzen voor geneesmiddelen (Wet Geneesmiddelenprijzen, WGP)
Obliged to inform patient on cheaper product		X		
Obliged to substitute by a generic		X		
Allowed to substitute by a generic	X		If the prescribing physician approves	
Obliged to substitute by a parallel import		X		
Allowed to substitute by a parallel import	X		If the prescribing physician approves	
Therapeutic / analogous substitution is allowed	X		Allowed for certain pharmaceuticals, if the prescribing physician approves	
Are subject to statutory discounts / rebates	X		Clawback system	

Tasks / Duties	Yes	No	Comment	Legal bases
Clawback system exists	X		6.82% up to maximum € 6.80 per dispensed pharmaceutical	
May grant rebates to customers	X			
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			
Are obliged to inform on co-payment / deductibles		X		
Prescription habits are monitored	X		Through an electronic prescribing system	
Are subject to prescription guidelines	X			
Budgets are controlled		X		
Allowed to prescribe INN	X			
Obliged to prescribe INN		X		
Can oppose generic substitution	X			
Can oppose therapeutic substitution	X			
Can oppose substitution by parallel import	X			
Country specific:				
Patients				
Can shop for cheapest price of the product		X		
Pay a flat rate per prescription / pack	X		In addition to the list price	
Pay a certain percentage per prescription / pack or a deductible		X		
Annual minimum co-payment		X		
Annual maximum co-payment	X		Differs per health insurance provider	
May ask for substitution by a generic	X			

Tasks / Duties	Yes	No	Comment	Legal bases
May oppose substitution by a generic	X			
May ask for substitution by a parallel import	X			
Can oppose substitution by a parallel import	X			
Can oppose substitution only on payment of price difference		X		
Has to pay the difference between reimbursement price and retail price	X			
Has access to full public information on prices and products	X			
Country specifics:				

N. app. = Not applicable

Source: ÖBIG 2006

POLAND

20 Poland

20.1 Pharmaceutical System

20.1.1 Regulatory Framework and Authorities

In 1999, a mandatory social health insurance scheme was established in Poland. In each of the 16 provinces self-administering, regional sickness funds were set up; furthermore, sickness funds for certain professions were installed. This system proved to be inefficient and therefore the National Health Fund (Narodowy Fundusz Zdrowia, NFZ) under the control of the Ministry of Health was established in 2003[899]. The NFZ is organised in 16 regional branches. The system is funded through contributions by employees (8.5 percent), whereas employers pay no contributions. The health insurance covers all working, unemployed and retired people and their families.

The most relevant players in the Polish pharmaceutical system are

- the Ministry of Health (Ministerstwo Zdrowia, MZ), responsible for the legal framework of the pharmaceutical market and for authorisation, pricing and reimbursement decisions. There are the following committees under the control of the MZ:
  - the Advisory Drug Committee[900]
  - the National Office for Registration of Medicinal Products, Medical Devices and Biocides (Urząd Rejestracji Produktów Leczniczych, URPL)[901]
    - Pharmaceutical Committee, appointed by the president of the URPL as its advisory body[902]
  - the Main Pharmaceutical Inspectorate (Główny Inspektorat Farmaceutyczny, GIF), holding supervision over production and import, as well as quality and distribution of pharmaceuticals[903]
- the National Health Fund (Narodowy Fundusz Zdrowia, NFZ)[904].

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899 Act of 23 January 2003 on the Common Insurance in the National Health Fund

900 It consists of three representatives appointed by the Minister of Health, Minister of Finance and Minister of Economy. Three representatives of the National Health Fund may take part as consultants; cf. Act of 5 July 2001 on prices, Art. 7.

901 Act of 6 September 2001 on pharmaceuticals, Art. 7-8, Official Journal 04.53.533, http://www.bip.urpl.gov.pl/page.aspx?id=61 (German)

902 Decree of the Minister of Health of 29 November 2002 on the President of the Office for Registration of Medicinal Products, Medical Devices and Biocides' advisory entities

903 Act of 6 September 2001 on pharmaceuticals, Art. 108-123, Official Journal 04.53.533, http://www.bip.urpl.gov.pl/page.aspx?id=61 (German); Decree of the Minister of Health of 2 December 2002 pursuant to Art. 112, section 4 of the Act of 6 September 2001 on pharmaceuticals, http://www.gif.gov.pl/en_statut.html

Applications for authorisation of pharmaceuticals have to be addressed to the URPL, which was founded in 2001. Market authorisations granted before the accession to the EU are still valid within a transitional period until the end of 2008. For branded pharmaceuticals the transitional period already ended on 31 December 2005. The list of products under the transitional regulation is quite extensive. The URPL is also in charge of classifying pharmaceuticals into prescription-only medicines (POM) and Over-the-Counter (OTC) medicines, advised - if necessary - by the Pharmaceutical Committee (which mainly consists of medical experts). The formal decisions are taken by the Ministry of Health on proposal of the URPL.

The manufacturers have to submit the applications for reimbursement of pharmaceuticals (cf. 20.3) as well as for prices (cf. 20.2.1.2) to the MZ. The formal decision (on inclusion into the positive list as well as on the maximum price) is thus taken by the MZ, consulted by the Ministry of Finance and based on the expertise of the advisory Drug Committee.[905]

Table 20.1: Poland - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Ministerstwo Zdrowina (MZ) / Ministry of Health	Pricing and Reimbursement	MZ ul. Miodowa 15 PL-00-952 Warsaw Poland Tel.: +48 22 6349 600 kancelaria@mz.gov.pl www.mz.gov.pl	Mr. Piotr Blaszczyk Director of the Drug Department ul. Miodowa 15 PL-00-952 Warsaw Poland Tel.: +48 22 6349 553 p.blaszczyk@mz.gov.pl
Narodowy Fundusz Zdrowia (NFZ) / National Health Fund	Third Party Payer	NFZ ul. Grójecka 186 PL-02-390 Warsaw Poland Tel.: +48 22 5726 000 Fax: +48 22 5726 333 www.nfz.gov.pl	Mr. Jerzy Miller Director ul. Grójecka 186 PL-02-390 Warsaw Poland Tel.: +48 22 57 26 013 (Secretary) Fax: +48 22 57 26 330

[904] Act of 27 August 2004 on health care services financed from public means (which replaced the Act of 23 January 2003 on the Common Insurance in the National Health Fund)

[905] Act of 5 July 2001 on prices, Art. 5-7, Regulation of the minister in charge of health on the bylaws of the Drug Management Team, Ministry of Health Journal 03.6.49

Institution	Task	Contact details/URL	Responsible person
Urzad Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych (URPL) / Office for Registration of Medicinal Products, Medical Devices and Biocides	Authorisation, Classification, Vigilance	URPL ul. Zabkowska 41 PL-03-736 Warszawa Poland Tel.: +48 22 4921 100 Fax: +48 22 4921 109 www.urpl.gov.pl/	URPL ul. Zabkowska 41 PL-03-736 Warszawa Poland Tel.: +48 22 4921 100 Fax: +48 22 4921 109 www.urpl.gov.pl/
Główny Inspektorat Farmaceutyczny (GIF) / The main Pharmaceutical Inspectorate	Pharmaceutical Inspection	GIF ul. Dluga 38/40 PL-00-238 Warszawa Poland Tel.: +48 22 8314 281 Fax: +48 22 8310 244 www.gif.gov.pl/	Ms. Dorota Duliban Pharmaceutical Inspector ul. Dluga 38/40 PL-00-238 Warszawa Poland Tel.: +48 22 8312 131 Fax: +48 22 8310 244
Stowarzyszenia Przedstawicieli Firm Farmaceutycznych w Polsce (SPFFwP) / Association of Pharmaceutical Companies Representatives in Poland	Association of the foreign Innovative Pharmaceutical Companies in Poland	SPFFwP ul. Pulawska 17 PL-02-515 Warsaw Poland Tel.: +48 22 8528 230 Fax: +48 22 8528 231 biuro@spff.pl www.spff.pl	Mr. Pavel Zelewski President ul. Pulawska 17 PL-02-515 Warsaw Poland Tel.: +48 22 8528 230 Fax: +48 22 8528 231
Polskie Stowarzyszenie Producentów Leków Bez Recepty (PASMI) / Polish Association of the Self-Medication Industry	Association of the OTC industry	PASMI Al. Jerozolimskie 158 PL-02-326 Warszawa Poland Tel.: + 48 22 8238 538 Fax: + 48 22 8238 538 www.pasmi.pl	Mr. Jerzy Strukowski Al. Jerozolimskie 158 PL-02-326 Warszawa Poland Tel.: + 48 22 8238 538 Fax: + 48 22 8238 538 jerzy.strukowski@pasmi.pl

Institution	Task	Contact details/URL	Responsible person
Polska Isza Przemyslu Farmaceutycznego i Wyrobów medycznych (POLFARMED) / Polish Chamber of Pharmaceutical Industry and Medical Equipment	Association of Generic Manufacturers	POLFARMED ul. Lucka 2/4/6 PL-00-845 Warsaw Poland Tel.: +48 22 6545 352 or +48 22 6545 351 Fax: +48 22 6545 420 Sekretariat@polfarmed.com.pl www.polfarmed.com.pl	POLFARMED ul. Lucka 2/4/6 PL-00-845 Warsaw Poland Tel.: +48 22 6545 352 or +48 22 6545 351 Fax: +48 22 6545 420 Sekretariat@polfarmed.com.pl www.polfarmed.com.pl
Zwiazek Pracodawców Hurtowni Farmaceutycznych (ZPHF) / Association of Polish Pharmaceutical Wholesalers	Polish Wholesale Association	ZPHF Al. Krakowska 28 PL- 05-090 Sekocin Nowy – Raszyn Poland Tel : + 48 22 720 1376 Fax: + 48 22 722 6668 taras@parafarmacja.com.pl	Mr. Andrzej Tarasiewicz President Al. Krakowska 28 PL- 05-090 Sekocin Nowy - Raszyn Poland Tel : + 48 22 720 1376 Fax: + 48 22 722 6668 taras@parafarmacja.com.pl
Naczelna Izba Aptekarska (NIA) / Polish Pharmaceutical Chamber	Association of Pharmacists	NIA ul. Dluga 16 PL-00-238 Warszawa Poland Tel.: +48 22 6359 285 or +48 22 6350 670 Fax: +48 22 8875 032 nia@nia.org.pl www.nia.org.pl	Mr. Andrej Wrobel President ul. Dluga 16 PL-00-238 Warszawa Poland Tel.: +48 22 6359 285 or +48 22 6350 670 Fax: +48 22 8875 032 nia@nia.org.pl
Polskie Towarzystwo Farmaceutyczne (PTFarm) / Polish Pharmaceutical Society	Pharmaceutical Society	PTFarm ul. Dluga 16 PL-00-238 Warszawa Poland Tel.: +48 22 8311 542 Fax: +48 22 8311 542 zarzad@ptfarm.pl www.ptfarm.pl	Mr. Jerzy Szewczynski ul. Dluga 16 PL-00-238 Warszawa Poland Tel.: +48 22 8311 542 Fax: +48 22 8311 542 zarzad@ptfarm.pl
Naczelna Izba Lekarska (NIL) / The Polish Chamber of Physicians and Dentists	Medical Association	NIL ul. Sobieskiego 110 PL-00-764 Warszawa Poland Tel.: +48 22 5591 300 or +48 22 5591 324 Fax: + 48 22 5591 323 sekretariat@hipokrates.org www.nil.org.pl	NIL ul. Sobieskiego 110 PL-00-764 Warszawa Poland Tel.: +48 22 5591 300 or +48 22 5591 324 Fax: + 48 22 5591 323 sekretariat@hipokrates.org www.nil.org.pl

Institution	Task	Contact details/URL	Responsible person
Stowarzyszenie Pacjentów Primum Non Nocere (SPPNN) / Polish Patients Association Primum Non Nocere	Patient's Association, Focus on Medical Malpractice Cases	SPPNN ul. 29 Listopada 10a / 8 PL-00-465 Warsaw Poland Tel.: +48 22 8406 547 pnn@poczta.neostrada.pl www.sppnn.org.pl	SPPNN ul. 29 Listopada 10a / 8 PL-00-465 Warsaw Poland Tel.: +48 22 8406 547 pnn@poczta.neostrada.pl www.sppnn.org.pl
HTA Consulting	Promotion of Evidence-based Health Care and Health Technology Assessment in Poland	HTA Consulting ul. Bożego Ciała 3 / 16 PL-31-055 Kraków Tel.: +48 12 421 88 32 Fax: +48 12 395 38 32 office@hta.pl www.hta.pl	Mr. Krzysztof Landa ul. Bożego Ciała 3 / 16 PL-31-055 Kraków Tel.: +48 12 421 88 32 Fax: +48 12 395 38 32 landa@hta.pl

Source: ÖBIG 2006

20.1.2 Market Players

20.1.2.1 Pharmaceutical Industry

In 2005 there were around 300 manufacturers in Poland. The biggest local producer is Polpharma with a market share of about 10 percent in volume and about 5 percent in value. Glaxo Smith Kline is the second largest producer. The local pharmaceutical industry is characterised by a large share of pharmaceuticals with non-EU-conform market authorisation. For these pharmaceuticals a transitional period until 2008 is applied (cf. 20.1.1).

20.1.2.2 Distribution

There were 663 pharmaceutical wholesalers in Poland in 2005 (number of licences). Market leaders are PGF (Polska Grupa Farmaceutyczna), Farmacol and Prosper holding a total market share of approximately 45 % of the wholesale market. Wholesalers are obliged to notify data on (structure and scale of) turnover to the Ministry of Health represented by the URPL.[906]

Pharmaceuticals - in general - are dispensed to patients in pharmacies. Pharmacy establishment is not linked to any geographic or demographic criteria. In 2005, there were approximately 11,000 community pharmacies in Poland. Pharmacies need not to be owned by a specially trained person, but have to be operated by a licensed pharmacist. The ownership is not restricted to one pharmacy, but since 2004 not more than 1% of all pharmacies in each of the 16 regions of Poland may be possessed by the same owner. However, the regulation has no retroactive validity[907].

Certain OTC products can also be sold in pharmacy stations and drugstores. For this purpose, the Ministry of Health issues a list of pharmaceuticals, which are allowed to be sold outside pharmacies. Doctors are not permitted to dispense pharmaceuticals. Self-service of pharmaceuticals is not allowed.[908]

20.1.2.3 Patients

In Poland patients do not have a formal role in the decision making process of pharmaceutical pricing and reimbursement. However as the official wholesale and retail prices represent maximum levels, prices may differ between pharmacies. So patients can “shop around” for the cheapest pharmaceutical. However, there are plans to change from maximum to fixed retail prices in the near future (cf. 20.2.1)[909].

Since 2006, (maximum) prices for reimbursable pharmaceuticals as well as information on co-payment can easily be accessed via internet (database on the website of the MZ[910]). The website also provides information on the cheapest pharmaceutical with the same active ingredient (based on the cost for Defined Daily Doses). Patients can ask for substitution by a generic and can oppose it as well. Pharmacies are obliged to inform patients about the opportunity of buying a cheaper than the prescribed pharmaceutical (unless the prescribing

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906 Act of 6 September 2001 on pharmaceuticals, Art. 78, Official Journal 04.53.533, http://www.bip.urpl.gov.pl/page.aspx?id=61 (German), Decree of the Minister of Health of 20 February 2003 (Official Journal 03.41.359)

907 PPR 2005

908 Act of 6 September 2001 on pharmaceuticals, Art. 70-71, Official Journal 04.53.533, http://www.bip.urpl.gov.pl/page.aspx?id=61 (German), AESGP 2005, PPR 2005

909 PPR 2005

910 http://www.mz.gov.pl

doctor excluded any such substitution by an annotation on the prescription).[911] Doctors are not obliged to inform patients on co-payment.

Co-payments in Poland are comparatively high. In 2003, 33% of expenditure for reimbursable pharmaceuticals were funded out-of-pocket[912]. With the exception of ten new chemical entities (ACE-inhibitors and Sartans) which were added to the reimbursement list in October 2005 no other new chemical entities have been included into reimbursement since 1999.[913]

The Polish Patients Association Primum Non Nocere (Stowarzyszenie Pacjentów Primum Non Nocere, SPPNN) - founded in 1998 - focuses on medical malpractice cases.

20.1.3 Overview of the Pharmaceutical System

Poland has the biggest pharmaceutical market within the new EU Member States. In 2004, pharmaceutical sales (at manufacturer level) amounted to PLN 13,269 million / € 2,931 million[914]. The Polish market is dominated by imported pharmaceuticals - they account for over 60% of total turnover - as well as by generics. Counted in pharmaceutical packages local industry has a market share of over two third.

Table 20.2 gives an overview of the pharmaceutical market in Poland.

Table 20.2: Poland - Pharmaceuticals, 2003 / 2005

Pharmaceuticals	2005
Authorised	8,089[1]
POM and hospital-only	5,905
Reimbursable	2,750[1]

POM = Prescription-only Medicines

[1] including different pharmaceutical forms and packages sizes

Source: ÖBIG 2005

Figure 20.1 gives an overview on the pharmaceutical system.

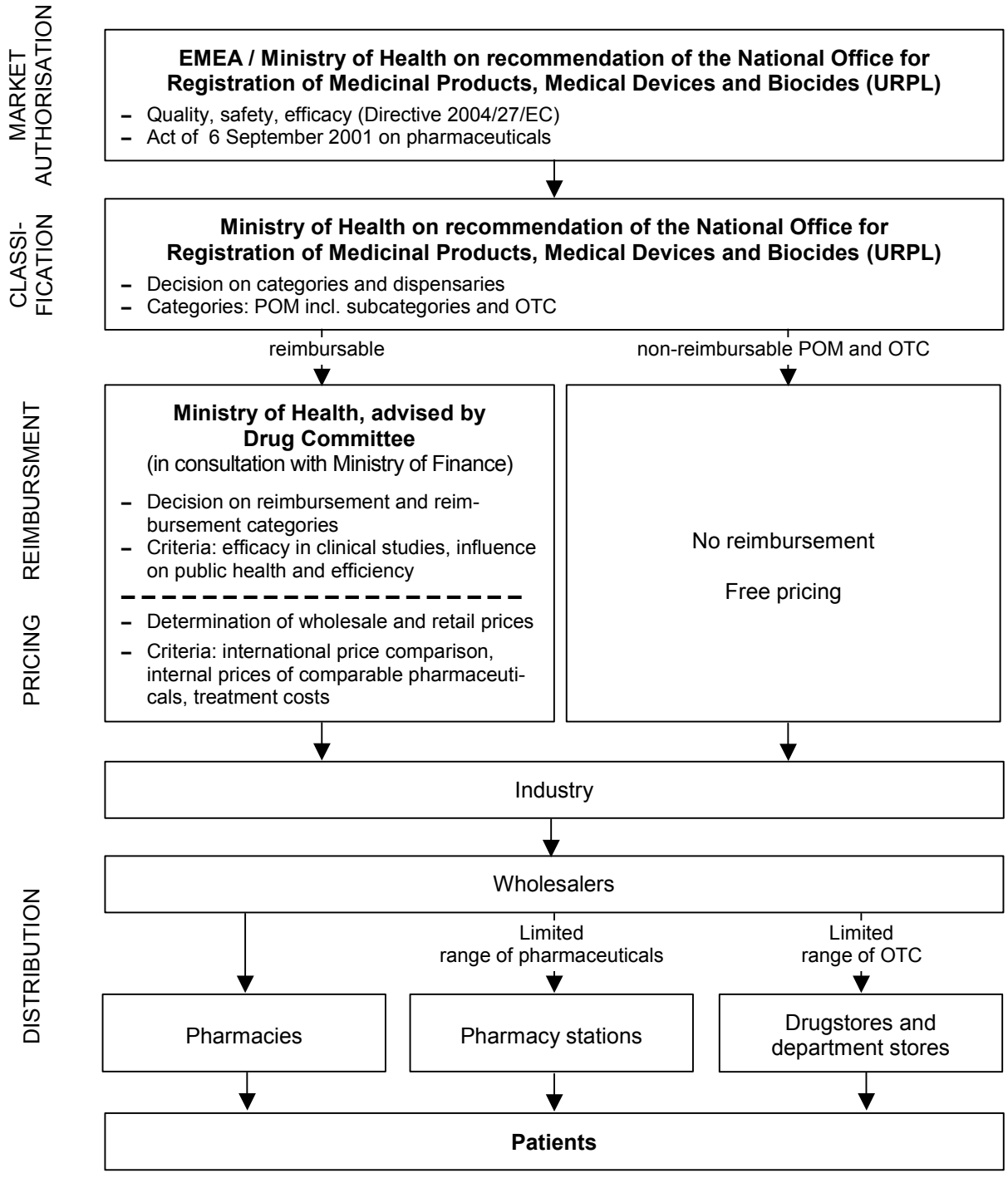
911 Act of 27 August 2004 on health care ser-vices financed from public means, Art. 38

912 PPR 2005, MZ

913 PPR 10/2005, PPR 11/2005, PPR 2005

914 AESGP 2005

Figure 20.1: Poland - Pharmaceutical System, 2006



EC = European Community, EMEA = European Medicines Agency, OTC = Over-the-Counter, POM = Prescription-only medicines, SAM = State Agency of Medicines, URPL = Urząd Rejestracji Produktów Leczniczych

Source: ÖBIG 2006

20.2 Pricing

20.2.1 Scope of Price Control

There is statutory pricing for reimbursable pharmaceuticals at wholesale level and free pricing for non-reimbursable pharmaceuticals (including all OTC products).

The pricing procedure in the reimbursement segment is the same for locally produced and imported pharmaceuticals, as well as for original pharmaceuticals and generics. The competent authority for setting the maximum wholesale prices is the MZ, advised by an advisory Drug Committee.

The reimbursement system (cf. 20.3) and the pricing procedure are very much linked: in the course of the application for reimbursement, pharmaceutical companies have to submit an application for price determination. This application has to include the proposed price including its justification, an international price comparison, the price of the pharmaceuticals of the same indication group in Poland, production costs and estimated volume of sales.[915] The advisory Drug Committee provides an assessment of the application with regard to the pricing and reimbursement decision. The MZ in consultation with the Ministry of Finance finally takes the decision on the maximum wholesale and retail prices.[916].

Generic prices are set in the same way. There are no specific regulations on how much the price difference between a generic (resp. a parallel import) and an original pharmaceutical has to be.

Table 20.3 provides an overview of the Polish pricing system.

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915 Act of 5 July 2001 on prices, Art. 6, Decree of the Minister of Health of 17 May 2002 on the scope of information and applications necessary to set official prices of pharmaceutical remedies and medical materials, procedure and time limits of submitting information and procedure and time limits of examination of applications and information (Official Journal 03.69.643)

916 Act of 5 July 2001 on prices, Art. 5-7, Regulation of the minister in charge of health on the bylaws of the Drug Management Team, Ministry of Health Journal 03.6.49

Table 20.3: Poland - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Non-reimbursable pharmaceuticals	Non-reimbursable pharmaceuticals	Non-reimbursable pharmaceuticals
Statutory Pricing	All reimbursable pharmaceuticals are indirectly regulated via maximum wholesale prices and a (maximum) mark-up for wholesalers	All reimbursable pharmaceuticals are regulated via maximum prices and a (maximum) mark-up	All reimbursable pharmaceuticals are regulated via maximum prices and a regressive (maximum) mark-up scheme
Price Negotiations	Between applicant and Ministry of Health	Not applied	Not applied
Price/volume agreements, discounts/rebates	Optional discounts/rebates	Optional discounts/rebates	Optional discounts/rebates
Institution in charge of pricing	Ministry of Health in consultation with Ministry of Finance		
Legal Basis	Act of 5 July 2001 on prices Announcement of the Minister of Health of 13 November 2003 -Regulation of the Minister of Health of 20 December 2004 on settlement of official wholesale and retail prices, Official Journal 04.275.2733, amended Decrees of the Minister of Health Act of 27 August on health care services financed from public means -Regulation of the Minister Health on the bylaws of the Drug Management Team, Ministry of Health Journal 03.6.49		

OTC = Over-the-Counter medicines

Source: ÖBIG 2006

Several changes concerning the pricing system are in discussion[917]:

- introduction of fixed (rather than maximum) statutory pharmacy retail prices for reimbursable pharmaceuticals
- regressive margin scheme (rather than fixed, cf. 20.2.1.2) for wholesalers
- introduction of a fixed fee for pharmacists for dispensing generics

[917] PPR 4/2006; Ministry of Health, written communication 16 May 2006

20.2.1.1 Manufacturer Price

The manufacturer price of reimbursable pharmaceuticals is indirectly regulated by maximum prices at wholesale level and a maximum wholesale mark-up. The proposed wholesale price has to be indicated in the application for reimbursement[918] (cf. 20.3.1).

In order to increase the price of a pharmaceutical on the reimbursement list a complete new application has to be filed with the MZ[919]. For price decreases applications are also necessary on which a decision has to be taken by the MZ within 30 days.

20.2.1.2 Wholesale Price

In Poland, maximum prices are determined at wholesale level.[920] The maximum statutory wholesale margin on reimbursable pharmaceuticals amounts to 8.91% of the wholesale price, equalling a maximum mark-up of 9.78 % on the manufacturer price[921]. Margins for non-reimbursable pharmaceuticals are not regulated. However, the average wholesale margin amounts to 14.5% of the wholesale price.

20.2.1.3 Pharmacy Retail Price

Also maximum prices are determined at pharmacy level.[922] The maximum pharmacy mark-ups for reimbursable pharmaceuticals are regulated in a regressive scheme (cf. Table 20.4), which has not been modified since 2001.

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[918] Act of 5 July 2001 on Prices, Art. 6 and Art. 7; Act of 27 August on health care services financed from public means, Art. 39

[919] Decree of the Minister of Health of 17 May 2002 on the scope of information and applications necessary to set official prices of pharmaceutical remedies and medical materials, procedure and time limits of submitting information and procedure and time limits of examination of applications and information (Official Journal 03.69.643)

[920] Act of 5 July 2001 on Prices, Art. 5

[921] Act of 5 July 2001 on prices, Art. 7, section 3, subsection 8; Announcement of the Minister of Health of 13 November 2003

[922] Act of 5 July 2001 on Prices, Art. 5

Table 20.4: Poland - Pharmacy Mark-up Scheme, 2006

PPP from…to…in PLN / €	Pharmacy mark-up in % of the PPP in PLN / €
up to PLN 3.60 / € 0.79	40%
from PLN 3.61 / € 0.80 to PLN 4.80 / € 1.06	PLN 1.44 / € 0.32
from PLN 4.81 / € 1.06 to PLN 6.50 / € 1.43	30%
from PLN 6.51 / € 1.44 to PLN 9.75 / € 2.15	PLN 1.95 / € 0.43
from PLN 9.76 / € 2.16 to PLN 14.00 / € 3.09	20%
from PLN 14.01 / € 3.10 to PLN 15.55 / € 3.43	PLN 2.80 / € 0.62
from PLN 15.56 / € 3.44 to PLN 30.00 / € 6.62	18%
from PLN 30.01 / € 6.63 to PLN 33.75 / € 7.45	PLN 5.40 / € 1.19
from PLN 33.76 / € 7.46 to PLN 50.00 / € 11.04	16%
from PLN 50.01 / € 11.05 to PLN 66.67 / € 14.72	PLN 8.00 / € 1.77
from PLN 66.68 / € 14.73 to PLN 100.00 / € 22.09	12%
from PLN 100.00 / € 22.09 on	PLN 12.00 / € 2.65

PPP = Pharmacy Purchase Price (wholesale price)

Source: Price Act of 2001[923] as quoted in ÖBIG 2005

As mentioned, margins of non-reimbursable pharmaceuticals are not regulated; the average pharmacy margin amounts to 23% of the pharmacy retail price[924].

Due to the fact that pharmacy mark-ups for non-reimbursable pharmaceuticals are not regulated and for reimbursable pharmaceuticals of maximum nature and not fully utilized, pharmacy retail prices may vary between pharmacies. Therefore patients have the chance to shop for the cheapest pharmaceutical.

20.2.1.4 Value Added Tax (VAT)

The standard value-added tax (VAT) in Poland is 22%, and the VAT on pharmaceuticals is 7%.

20.2.1.5 Hospital Price

Hospitals usually purchase pharmaceuticals on the basis of tenders. Maximum wholesale prices for pharmaceuticals used in NFZ contracting hospitals may be regulated by the MZ. A list of pharmaceuticals, which fall under this regulation, has been issued in September 2005, covering 14 active ingredients.[925]

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923 Act of 5 July 2001 on Prices, Art. 7, section 3, subsection 9

924 JWC Publishing Company, personal communication, 2005

925 Decree of Minister of Health of 1 September 2005 pursuant to Act of 5 July 2001 on prices, Art. 5

20.2.2 Price Related Cost-containment Measures

20.2.2.1 Pharmaco-economic Evaluation

In Poland, there are guidelines for pharmaco-economic studies[926]. In the future pharmaco-economic analyses shall play a more important role in the assessment of pharmaceuticals before the decision on reimbursement.[927]

20.2.2.2 Internal Price Referencing

Poland has a reference price system (cf. 20.3.2), in which the reference price is calculated on the basis of the cheapest generic pharmaceutical in a cluster: Clusters are either formed for pharmaceuticals with the same active ingredient (INN), pharmaceutical dosage and way of administration or for therapeutic groups (products must have the same indication, proof of clinical efficacy, the same portfolio of side-effects and the same way of administration, but since 2005 no longer the same mechanism of action).

Internal price referencing is also applied during the price setting process as well as the reimbursement decision process as one of several criteria.[928]

20.2.2.3 External Price Referencing / Cross Country Referencing

In the decision on reimbursement and pricing cross country referencing is applied as one of several criteria (besides manufacturing costs, efficacy of the pharmaceutical, volume of supplies, importance of the pharmaceutical in the control of diseases etc.).[929] Table 20.1 gives the details.

Table 20.5: Poland - Cross Country Referencing, 2005/2006

Pharmaceuticals targeted	Reimbursable pharmaceuticals
Timing	Before reimbursement and pricing decision
Actors in charge	Advisory Drug Committee
Reference Countries	In general, all other EU Member States. However, preference is given to countries with a similar GDP to Poland, although these countries are not specifically identified
Price Level	Manufacturer price
Methodology	There is no explicit methodology stated. If a price/pharmaceutical is not available in the country, the country is left out

GDP = Gross Domestic Product

Source: Information gathering by ÖBIG

926 http://www.ispor.org/PEguidelines/countrydet.asp?c=16&t=1

927 PPR 10/2005, PPR 2005

928 Act of 5 July 2001 on Prices, Art. 7, section 3, subsection 2

929 Act of 5 July 2001 on prices, Art. 7

20.2.2.4 Price cuts

There have not been any statutory price cuts/freezes during the last years in Poland.

20.2.2.5 Margin Cuts

In 2003, the statutory wholesale margin on reimbursable pharmaceuticals was decreased from 9.91% to 8.91% of the wholesale price.[930] This margin cut was the only change.

20.2.2.6 Discounts and Rebates

There is no mandatory/statutory system of discounts or rebates applied to the pharmaceutical industry, wholesalers or pharmacies in Poland. Manufacturers may grant rebates or discounts to wholesalers on an optional basis. The same applies to wholesalers' discounts towards pharmacies.

20.2.2.7 Parallel Trade

Parallel import of a pharmaceutical in Poland is subject to an authorisation by the MZ. Parallel import licenses are granted for a period of 5 years.[931]

Pharmacists are allowed to substitute by a parallel traded pharmaceutical. In addition patients can ask for substitution by a parallel import and may as well oppose it.

20.2.3 Co-Payments

For pharmaceuticals on the basic list (one of the reimbursement lists, cf. 20.3.1), patients have to pay a flat rate of € 0.80 (PLN 3,20) for pharmaceutical specialities and € 1.24 (PLN 5,00) for magistral preparations. There is an upper limit of this flat rate of € 1,06 (PLN 4,25) for pharmaceutical specialities and € 3,17 (PLN 12,75) for magistral preparations.[932] These limits are revised each year taking into consideration the price index of consumer goods and services of the corresponding period of the previous year.[933]

For pharmaceuticals on the supplementary list (another reimbursement list, cf. 20.3.1), patient co-payment is 30 or 50% of the pharmacy retail price, depending on the reimbursement category (but no flat rate has to be paid).

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930 Announcement of the Minister of Health of 13 November 2003

931 Act of 6 September 2001 on pharmaceuticals, Art. 21a, Official Journal 04.53.533, http://www.bip.urpl.gov.pl/page.aspx?id=61 (German), http://www.paralleltrade.pl/ustawa_prawo_farmaceutyczne.php?lang=en (English)

932 Please note that exchange rate used for all calculations was: € 1 = PLN 4,0230 (Annual rate 2005 as published by the Austrian National Bank, http://www.oenb.at/de/stat_melders/datenangebot/zinssaetze/wechselkurse/wechselkurse.jsp)

933 Act of 27 August 2004 on health care services financed from public means, Art. 36, section 3, amended (1 September 2005)

Furthermore, patients are obliged to pay the difference between the reference price and the pharmacy retail price of pharmaceuticals included in reference price clusters if they do not choose the cheapest product within the reference group.

Persons suffering from contagious or mental diseases and persons suffering from certain chronic diseases receive pharmaceuticals free of charge, at the flat rate mentioned above or at partial cost according to different rules than being in place for the basic or supplementary list (cf. 20.3.1). Moreover, several patient groups including blood donors, soldiers and war veterans have special entitlements to pharmaceuticals. Thus one and the same product may be reimbursed on different conditions depending on patient characteristics (e.g. having a chronic condition, being a war veteran, etc.).

For hospital in-patients there are no co-payment charges on pharmaceuticals necessary in the course of treatment.

The share of co-payments in Poland on pharmaceutical expenditure is comparably high (cf. 20.1.2.3).

20.2.4 Information Transparency and Marketing

Since 2006, prices of reimbursable pharmaceuticals in Poland may be accessed free of charge through an internet database on the website of the MZ.[934] The database also contains information on the ATC code, brand name, pharmaceutical form, dosage, pack size and name of the manufacturer. Moreover, information on co-payment and prices of comparable pharmaceuticals (cheapest pharmaceutical with the same active ingredient by Defined Daily Dose) is given. Doctors are not obliged to inform patients on (the level of) co-payment.

Advertising of pharmaceuticals is subject to several restrictions.[935] The main Pharmaceutical Inspectorate is in charge as control authority.[936] The law is in line with the EU provisions on pharmaceutical advertising.

The Polish legal framework concerning pharmaceuticals is complex, as regulations are spread over several acts. One of the intentions of the current MZ, besides a more effective

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934 http://www.mz.gov.pl/

935 Act of 6 September 2001 on pharmaceuticals, Art. 52-64, Official Journal 04.53.533, http://www.bip.urpl.gov.pl/page.aspx?id=61 (German), Resolution of Ministry of Health concerning the advertising on pharmaceuticals of 2002, No. 230 pos. 1936

936 Act of 6 September 2001 on pharmaceuticals, Art. 62-64, Official Journal 04.53.533, http://www.bip.urpl.gov.pl/page.aspx?id=61 (German)

implementation of the European Transparency Directive[937], is creating a single act outlining the reimbursement system (rather than two currently[938]).[939]

Regarding criteria for reimbursement and pricing decisions there are complaints by (foreign) pharmaceutical industry that the timeframe is not met and that procedures for accessing reimbursement remain intransparent and in breach with European legislation (also cf. 20.2.1 and 20.2.2.3).[940]

20.3 Reimbursement

Patients are provided with pharmaceuticals on the basis of prescriptions issued by health insurance doctors, health insurance paramedics or doctors / paramedics who have a contract with the NFZ which authorises her / him to issue prescriptions. In 2004, expenditure for reimbursement of pharmaceuticals amounted to 20% of total NFZ expenditure.

The application for reimbursement has to include the proposed price as well as a rationale for the application, an international price comparison, the price of the pharmaceuticals of the same indication group in Poland, manufacturing and treatment costs, data on efficacy and cost efficiency as well as the proposed reimbursement category.[941] Applications for reimbursement and for price determination have to be submitted separately but much of the information required is the same. In principle, the decision on reimbursement precedes the pricing decision. The legal timeframe for the reimbursement decision is 90 days[942]. If procedures for reimbursement and pricing decisions run parallel, the timeframe amounts to 180 days[943]. This is in line with the EU Transparency Directive.[944]

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937 Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance system, http://pharmacos.eudra.org/F2/eudralex/vol-1/new_v1/890105en.pdf#search='89/105/EECeudra'

938 Act of 27 August 2004 on health care services financed from public means, Act of 5 July 2001 on Prices, Official Journal 01.97.1050

939 PPR 4/2006, Ministry of Health, written communication 16 May 2006

940 PPR 2005, US Department of Commerce - International Trade Administration 2004

941 Act of 27 August 2004 on health care services financed from public means, Art. 39, Decree of the Minister of Health of 21 December 2004 on the detailed scope of information contained in applications to place a medicine or medicinal product on the lists, procedure of submitting applications and procedure and time limits of their examination (Official Journal 04.276.2741)

942 Act of 27 August 2004 on health care services financed from public means, Art. 39, section 6

943 Act of 27 August 2004 on health care services financed from public means, Art. 39, section 7

944 Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance system, http://pharmacos.eudra.org/F2/eudralex/vol-1/new_v1/890105en.pdf#search='89/105/EECeudra'

With the exception of 10 new chemical entities (ACE-inhibitors and Sartans) which were added to the reimbursement list in October 2005, no other new chemical entities have been included to reimbursement since 1999. [945]

20.3.1 Pharmaceutical Lists and Reimbursement Categories

Table 20.6 gives an overview of the 3 main reimbursement lists for

- essential pharmaceuticals
- complementary pharmaceuticals
- pharmaceuticals for chronic diseases.

Table 20.6: Poland - Reimbursement Lists, 2006

Reimbursement Lists	Description
Basic list	Pharmaceuticals as well as magistral preparations are reimbursed at 100% (up to the reference price). Patients have to pay a flat rate of € 0.76 for pharmaceutical specialities and € 1.20 for magistral preparations.
Supplementary list	Pharmaceuticals are reimbursed at 70% or 50%. The amount of reimbursement is calculated based on the reference price of the pharmaceutical.
Special reimbursement list	Reimbursement for pharmaceuticals for severe or chronic diseases such as cancer or osteoporoses at 100%, 70%, or 50%.

Source: ÖBIG 2006

Pharmacies are reimbursed by the NFZ on the basis of a reimbursement report submitted every 2 weeks to the regional office of the NFZ.

20.3.1.1 Reimbursement Price

For pharmaceuticals on the basic list patients have to pay a flat rate of € 0.76 for pharmaceutical specialities and € 1.20 for magistral preparations plus - if applicable - the difference between the reference price and the pharmacy retail price. For pharmaceuticals on the supplementary list patients have to pay 30% to 50% of the pharmacy retail price or 30% to 50% of the reference price plus - if applicable - the difference between the reference price and the pharmacy retail price. The same applies for pharmaceuticals on the special reimbursement list (also cf. 20.2.3).

[945] PPR 10/2005, PPR 11/2005, PPR 2005

20.3.1.2 Selection Criteria

As mentioned above, the Advisory Drug Committee provides an assessment with regard to the (pricing and) reimbursement decision taking into account several criteria e.g.

- international price comparisons,
- price comparisons with other pharmaceuticals with the same active ingredient,
- manufacturer costs,
- treatment costs,
- volume of supplies,
- drug efficacy.[946]

20.3.1.3 Pharmaceuticals on Positive List

The MZ is responsible for issuing the positive list. The positive list includes prescription-only medicines, OTC products are excluded. It is made public by decrees and - since 2006 - can be accessed via internet at the website of the MZ. It should be updated every 6 months.[947] In 2005, 2,750 pharmaceuticals were included in the positive list, which corresponds to one third of all authorised pharmaceuticals (cf. Table 20.2).

20.3.1.4 Generics

In Poland the market share of generic pharmaceuticals is high. In 2004 it amounted to 60% by value and 85% by volume.[948] However, there are neither specific rewards for pharmacists for dispensing generics nor specific incentives for doctors to prescribe generic pharmaceuticals.

20.3.1.5 Non-reimbursable Pharmaceuticals

Solely POM may be included in the positive list, so all OTC are excluded. However, the OTC sector has been growing in recent years and accounts for around 25% of the pharmaceutical market in value. One reason for this trend have been switches from prescription to non-prescription status (cf. 20.3.1.7).[949]

20.3.1.6 Appeal Procedure

The authorisation holder may appeal (negative) reimbursement decisions by filing an application of re-examination with the MZ within 14 days after receiving the decision (concerning pricing decisions the competent authority is the MZ as well as the Ministry of Finance).

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946 Act of 5 July 2001 on prices, Art. 7

947 Act of 27 August 2004 on health care services financed from public means, Art. 36, section 6

948 Catholic University Leuven. 2006

949 PPR 2005

20.3.1.7 Delisting and Switches

Pharmaceutical industry may apply for switches and delisting. Decisions on switches (from prescription status to non-prescription status) are made by the MZ on an assessment by the URPL.[950]

20.3.2 Reference Price System

Poland has a reference price system, in which the reference price is calculated on the basis of the cheapest available pharmaceutical in a cluster (including parallel imports).[951] Clusters are formed:

- For pharmaceuticals with the same active ingredient (INN), dosage, way of administration and package size; reference price equals the price of the cheapest available pharmaceutical.
- For therapeutic groups (pharmaceuticals must have the same indication, proof of clinical efficacy, the same portfolio of side-effects and the same way of administration, but since 2005 no longer the same mechanism of action); reference price is calculated on the basis of the price of the pharmaceutical with the cheapest DDD

Criteria for forming therapeutic groups are laid down by decree through the MZ.[952] They are criticized by several institutions for not being sufficiently transparent and objective.

In spring 2005, there were 221 reference price groups with pharmaceuticals with the same active ingredient and 23 therapeutic (reference price) groups.

In case of pharmaceuticals which belong to a reference price group patients - additionally to co-payments (also see 20.2.3, 20.3.1 and 20.3.1.1) - are obliged to pay the difference between the reference price (which is determined as explained above) and the actual pharmacy retail price of the pharmaceutical they buy. If applicable pharmacists however are obliged to inform patients about the possibility of buying a product with the same active ingredient that is cheaper than the one they have chosen.

Pharmacists are allowed to substitute within one INN group whereas therapeutic substitution is not allowed. The prescribing doctor can exclude substitution by an annotation on the prescription. The possibility of substitution also applies to pharmaceuticals not included in the

950 AESGP 2005, PPR 2005

951 Act of 27 August 2004 on health care services financed from public means, Art. 38, Regulation of the Minister of Health of 17 December 2004 on setting price limits of pharmaceuticals dispensed free of charge, at a flat rate or at partial cost (Official Journal 04.274.2727, amended)

952 Regulation of the Minister of Health of 17 December 2004 on criteria of qualification of pharmaceuticals which have different international names, but a similar therapeutic effect, to the group with the common price limit (Official Journal 04.266.2646)

reimbursement lists unless the price of the substituting pharmaceutical is higher than the reference price set for a group the concerned pharmaceutical belongs to.

20.3.3 Pharmaceutical Budgets

In Poland, there are no prescribing budgets for doctors or other forms of budget controls.

20.3.4 Other Volume Control Oriented Measures

20.3.4.1 Prescription Monitoring and Other Doctors-related Measures

Currently, there are no activities regarding prescription monitoring or similar measures in Poland. Doctors are permitted to prescribe a maximum of 5 items on each prescription form and generally not more than 2 packages per item using the smallest package size included in the reimbursement list.[953] However, the introduction of a monitoring system is planned for the future.[954]

20.3.4.2 Generics and Parallel Trade

Pharmacies are obliged to inform patients about the possibility of generic substitution and to offer them the cheapest pharmaceutical within the reference price group. Doctors are not specifically obliged to inform patients of generic substitution. However, guidelines for rational prescribing are published by the Polish Medical Association. Doctors may also oppose generic substitution by writing a note on the prescription. Patients may oppose to it by paying the difference between the reference price and the pharmacy retail price of the original pharmaceutical. The same is true for parallel imported pharmaceuticals. However, doctors cannot oppose substitution by a parallel import. Doctors are allowed to prescribe INN (but not obliged).

953 PPR 2005

954 Ministry of Health, written information, 26 April 2006

20.4 Overview of the Reimbursement Market in Poland

Tasks / Duties	Yes	No	Comment	Legal bases
Public Authorities				
Decide on prescription status	X			Act of 6 September 2001 on pharmaceuticals, Art. 23, Official Journal 04.53.533 Inner bylaws of the National Office for Registration of Medicinal Products, Medical Devices and Biocides
Decide on manufacturer price		X	Proposed price has to be given as part of an application for reimbursement.	Act of 5 July 2001 on Prices, Art. 7, Official Journal 01.97.1050 Act of 27 August on health care services financed from public means, Art. 39
Agree on manufacturer price		X		
Fix wholesale margin	X		Maximum margin, also a maximum wholesale price is fixed.	Act of 5 July 2001 on Prices, Art. 7 Official Journal 01.97.1050 Announcement of the Minister of Health of 13 November 2003 on wholesale and retail margin, Official Journal of the Minister of Health 03.11.108 Regulation of the Minister of Health of 20 December 2004 on settlement of official wholesale and retail prices, Official Journal 04.275.2733, amended
Fix pharmacy retail price	X		Maximum price, additionally there is a regressive (maximum) mark-up scheme	Act of 5 July 2001 on Prices, Art. 7 Official Journal 01.97.1050 Regulation of the Minister of Health of 20 December 2004 on settlement of official wholesale and retail prices, Official Journal 04.275.2733, amended
Decide on reimbursement status	X		Different reimbursement categories (see 20.3.1)	Act of 27 August 2004 on health care services financed from public means, Art. 34-39, 43-46 Act of 5 July 2001 on Prices, Official Journal 01.97.1050 Regulation of the Minister of Health of 17 December on the list of basic and supplementary pharmaceuticals and amounts of payment for supplementary pharmaceuticals (Official Journal 04.274.2725, amended) 17 December on the list of diseases and list of pharmaceuticals which are prescribed on account of these diseases free of charge, at a flat rate or at partial cost (Official Journal 04.275.2730, amended)

Tasks / Duties	Yes	No	Comment	Legal bases
Decide on reimbursement price	X		Calculated on basis of retail price	Act of 27 August 2004 on health care services financed from public means, Art. 34-39, 43-46 Regulation of the Minister of Health of 17 December on the list of basic and supplementary pharmaceuticals and amounts of payment for supplementary pharmaceuticals (Official Journal 04.274.2725, amended) 17 December on the list of diseases and list of pharmaceuticals which are prescribed on account of these diseases free of charge, at a flat rate or at partial cost (Official Journal 04.275.2730, amended)
Use Pharmaco-economic guidelines	X		Guidelines for pharmaco-economic studies have been developed.	
Use Internal reference pricing	X		Reimbursement decision. Clusters are either formed for pharamcetuicals with the same active ingredient (INN), dosage and way of administration or for therapeutic groups.	Act of 5 July 2001 on Prices, Official Journal 01.97.1050 Decree on qualification criteria for medicines with different INN, but similar therapeutic action, into a group of medicinal products with the same reference price, Official Journal 03.83.768
Use External reference pricing	X		Before reimbursement decision, manufacturer price, only one of several criteria.	Act of 5 July 2001 on Prices, Art. 7, Official Journal 01.97.1050 Regulation of the Minister Health on the bylaws of the Drug Management Team, Ministry of Health Journal 03.6.49
Price freezes		X		
Margin cuts	X		In 2003 (wholesale margin on reimbursable pharmaceuticals)	Act of 5 July 2001 on Prices, Art. 7, Official Journal 01.97.1050 Announcement of the Minister of Health of 13 November 2003 on wholesale and retail margin, Official Journal of the Ministry of Health
Discounts and Rebates		X		
Company profit control		X		
Country specific:				
Pharmaceutical Industry				

Tasks / Duties	Yes	No	Comment	Legal bases
Sets manufacturer price freely		X	For pharmaceuticals included in the reimbursement system prices are negotiated.	
Notifies manufacturer price		X		
Negotiates manufacturer price	X		Between applicant and Ministry of Health.	Act of 27 August 2004 on health care services financed from public means, Art. 39 Act of 5 July 2001 on Prices, Art. 6-7, Official Journal 01.97.1050 Regulation of the Minister Health on the bylaws of the Drug Management Team, Ministry of Health Journal 03.6.49
Is free to set price below fixed manufacturer price		X	N. app. (as there is no statutorily *fixed* manufacturer price)	Act of 27 August 2004 on health care services financed from public means, Art. 39 Act of 5 July 2001 on Prices, Art. 6, Official Journal 01.97.1050
Decides on application for reimbursement	X			Act of 27 August 2004 on health care services financed from public means, Art. 39 Decree of 2002 on the information's scope and application necessary to establishing official price, Official Journal 02.69.643.
Negotiates reimbursement price	X		The price is fixed by the way of negotiation between applicant and the Ministry of Health	Regulation of the Minister Health on the bylaws of the Drug Management Team, Ministry of Health Journal 03.6.49
Free to keep manufacturer price above reimbursement price			N.app.	
Free to grant rebates / discounts to wholesalers	X			Act of 5 July 2001 on Prices, Official Journal 01.97.1050
Free to grant rebates / discounts to pharmacies		X		
Can engage in marketing towards doctors	X		In line with code of conduct	Act of 6 September 2001 on pharmaceuticals, Art. 62-64, Official Journal 04.53.533.
Can engage in public advertising	X		There are restrictions regarding the way of advertising. POM cannot be subject to advertisement activity.	Act of 6 September 2001 on pharmaceuticals, Art. 62-64, Official Journal 04.53.533.

Tasks / Duties	Yes	No	Comment	Legal bases
Can provide information toward patients	X			
Applies for switches and delisting	X			
Country specific:				
Distribution Chain				
Wholesaler				
Margins are fixed by statute	X		For reimbursable pharmaceuticals	Act of 5 July 2001 on Prices, Art. 7, Official Journal 01.97.1050 Announcement of the Minister of Health of 13 November 2003 on wholesale and retail margins
Margins are subject to statutory discounts and rebates		X	Discounts and rebates are facultative.	
Free to grant rebates and discounts to pharmacies	X			Act of 5 July 2001 on Prices, Official Journal 01.97.1050
Pharmacists				
Margins are fixed by statute	X		Maximum regressive mark-up scheme	Act of 5 July 2001 on Prices, Art. 7, Official Journal 01.97.1050
Free to set retail price		X	Official retail prices represent the price maximum. Pharmacists may set prices lower than the price maximum so patients can “shop around” for the cheapest pharmaceutical.	Act of 27 August 2004 on health care services financed from public means, Art. 38 Act of 6 September 2001 on pharmaceuticals, Art. 95, Official Journal 04.53.533
Obliged to inform patient on cheaper product	X			Act of 27 August 2004 on health care services financed from public means, Art.38
Obliged to substitute by a generic	X		Unless the prescribing doctor states that substitution is not allowed.	Act of 27 August 2004 on health care services financed from public means, Art.38
Allowed to substitute by a generic	X			Act of 6 September 2001 on pharmaceuticals, Official Journal 04.53.533 Decree of 2002 on issuing pharmaceuticals from the pharmacy, Official Journal 02.183.1531 Act of 27 August 2004 on health care services financed from public means, Art.38

Tasks / Duties	Yes	No	Comment	Legal bases
Obliged to substitute by a parallel import		X		
Allowed to substitute by a parallel import	X			Act of 6 September 2001 on pharmaceuticals, Official Journal 04.53.533
Therapeutic substitution is allowed		X		
Claw back system exists		X		
Are subject to statutory discounts and rebates		X		
May grant rebates to customers	X			
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X		A doctor shall provide the patient with clear information about his/her health, diagnosis, recommended or possible methods of diagnostics and treatment, predictable consequences of application or negligence thereof, and the results of treatment and prognosis.	Act of 1997 on professions of doctors and dentists, Official Journal 97.28.152
Are obliged to inform on co-payment / deductibles		X	Facultative	
Prescription habits are monitored		X		
Are subject to prescription guidelines		X		
Budgets are controlled		X		
Allowed to prescribe INN	X			Act of 1997 on professions of doctors and dentists, Official Journal 97.28.152
Obliged to prescribe INN		X		

Tasks / Duties	Yes	No	Comment	Legal bases
Can oppose generic substitution	X			Act of 1997 on professions of doctors and dentists, Official Journal 97.28.152 Act of 27 August 2004 on health care services financed from public means, Art.38
Can oppose therapeutic substitution		X	N.app.	
Can oppose substitution by parallel import		X		
Country specific:				
Patients				
Can shop for cheapest price of the product	X			
Pay a flat rate per prescription / pack	X		For pharmaceuticals on the basic list. Does not apply for certain groups as war veterans or blood donors.	Act of 27 August 2004 on health care services financed from public means, Art.36, Art. 43-47 Act of 2003 on Public Health Insurance with National Health Fund, Official Journal 03.45.391 Act of 2003, on Provision for war and military veterans and their families, Official Journal 83.13.68
Pay a certain percentage per prescription / pack or a deductible	X			Act of 27 August 2004 on health care services financed from public means, Art.36, Art. 43-47 Act of 2003 on Public Health Insurance with National Health Fund, Official Journal 03.45.391 Act of 2003, on Provision for war and military veterans and their families, Official Journal 83.13.68
Annual minimum co-payment		X		
Annual maximum co-payment		X		
Can ask for substitution by a generic	X			Act of 27 August 2004 on health care services financed from public means
Can oppose substitution by a generic	X			Act of 27 August 2004 on health care services financed from public means
Can ask for substitution by a parallel import	X			Act of 6 September 2001 on pharmaceuticals, Official Journal 04.53.533 Act of 27 August 2004 on health care services financed from public means

Tasks / Duties	Yes	No	Comment	Legal bases
Can oppose substitution by a parallel import	X			Act of 6 September 2001 on pharmaceuticals, Official Journal 04.53.533 Act of 27 August 2004 on health care services financed from public means
Can oppose substitution only on payment of price difference	X			Act of 6 September 2001 on pharmaceuticals, Official Journal 04.53.533. Act of 27 August 2004 on health care services financed from public means
Has to pay the difference between reimbursement price and retail price	X		Difference between reference price / reimbursement price and retail price	Act of 27 August 2004 on health care services financed from public means
Has access to full public information on prices and products	X		Website of the Ministry of Health (maximum prices)	
Country specifics:				

N.app. = Not applicable, N.a. = Not available

Source: ÖBIG 2006

PORTUGAL

21 Portugal

21.1 Pharmaceutical System

21.1.1 Regulatory Framework and Authorities

The Portuguese health care system is organised as a national health service (Service National de Sáude, SNS), financed through general taxation, which provides health coverage to 75% of the population. The rest of the Portuguese are covered by one of the subsystems, funded mainly by contributions of employers and employees. Within the SNS, there is a strong regional structure with 5 regional health administrations.

In the pharmaceutical system, the most important players are as follows:

- The Ministry of Health (Ministério da Saúde), which
  - is in charge of the overall strategic framework of pharmaceuticals,
  - is the supervising authority of the Medicines Agency INFARMED and
  - acts as purchaser of pharmaceuticals for hospitals via public tendering.
- The Medicines Agency (Instituto Nacional da Farmácia e do Medicamento, INFARMED), being in charge of market authorisation (pharmaceuticals) and registration (medical devices), vigilance, monitoring of the market, distribution and reimbursement of pharmaceuticals. In fact, INFARMED is the key authority regarding pharmaceuticals in Portugal, covering all relevant tasks except pricing of pharmaceuticals. INFARMED was established in 1993.
- The Directorate-General Enterprise (Direcção-Geral da Empresa, DGE) which is responsible for the pricing of pharmaceuticals. The DGE was created in 2003,[955] substituting the former Directorate-General of Commerce and Competition (Direcções-Gerais do Comércio e da Concorrência, DGCC) within the Ministry of Health.

Table 21.1 gives an overview on the relevant authorities and market players in the pharmaceutical system in Portugal.

[955] Decreto-Lei n.º 186/2003, de 20 de Agosto, http://www.dgcc.pt/76.htm

Table 21.1: Portugal - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Direccao Geral da Saude / Ministry of Health	Ministry of Health	Direccao Geral da Saude Av. Alvares Cabral, n° 25 P-1250-015 Lisboa Portugal Tel.: +351 21 3824 660 Fax: +351 21 3824 659 www.dgsaude.pt/	Ms. Ana Couto Av. Alvares Cabral, n° 25 P-1250-015 Lisboa Portugal Tel.: +351 21 3824 660 Fax: +351 21 3824 659 anadi-niz@dgsaude.minsaude.pt
Direcção-Geral da Impresa (DGE) / Directorate-General Enterprise	Ministry of Ecconomy (Price Regulation)	DGE 72, av. Visconde Valmor P-1093 Lisboa Portugal Tel.: +351 1793 3166 Fax: +351 1796 5158 www.dgcc.pt/	Ms. Paula Santos 72, av. Visconde Valmor P-1093 Lisboa Portugal Tel.: +351 1793 3166 Fax: +351 1796 5158 paula.santos@dgempresa.min-economia.pt
Instituto Nacional da Farmácia e do Medicamento (INFARMED) / The National Pharmacy and Medicines Institute	Medicines Agency	INFARMED Parque de Saude de Lisboa Av. do Brasel 53 P-1749-004 Lisboa Portugal Tel.: +351 21 7987 179 Fax: +351 21 7987 155 www.infarmed.pt	Mr. Jesus Maria Vasca President Parque de Saude de Lisboa Av. do Brasel 53 P-1749-004 Lisboa Portugal Tel.: +351 21 7987 241 Fax: +351 21 7987 155 vasco.maria@infarmed.pt
Associação Portuguesa da Indústria Farmacêutica (APIFARMA) / Portuguese Association of Pharmaceutical Industry	Association of pharmaceutical industry	APIFARMA Rua Pêro da Covilhã, 22 P-1400-297 Lisboa Portugal Tel.: +351 21 3031 780 Fax: +351 21 3031 798 www.apifarma.pt/	Mr. João Gonçalves da Silveira Rua Pêro da Covilhã, 22 P-1400-297 Lisboa Portugal Tel.: +351 21 3031 780 Fax: +351 21 3031 798 apifar-ma.board@mail.telepac.pt
Associacão Portuguesa de Genericos (APOGEN) / Portuguese Association of Generic Industry	Association of generic industry	APOGEN Avenida 25 de Abril 672 - 2º P-2750-512 Cascais Portugal Tel.: +351 21 4826 651 Fax: +351 21 4826 652 apogen@apogen.pt www.apogen.pt/	APOGEN Avenida 25 de Abril 672 - 2º P-2750-512 Cascais Portugal Tel.: +351 21 4826 651 Fax: +351 21 4826 652 apogen@apogen.pt www.apogen.pt/

Institution	Task	Contact details/URL	Responsible person
Associacao de Grossistas de Produtos Quimicos e Farmaceuticos (GROQUIFAR) / Association of Wholesalers of Pharmaceuticals and Chemical Products	Association of Wholesalers	GROQUIFAR Av. António Augusto Aguiar Nº 118 - 1º P-1050-019 Lisboa Portugal Tel.: +352 13 1938 60 Fax: +352 13 1938 69 www.groquifar.pt	Mr. José Diniz Av. António Augusto Aguiar Nº 118 - 1º P-1050-019 Lisboa Portugal Tel.: +352 13 1938 606 Fax: +352 13 1938 69 groquifar@mail.telepac.pt
Associacao Portuguesa de Armazenistas de Medicamentos de Exportacao e Importacao (APAMEI) / Portuguese Association of Exporters and Importers of Pharmaceuticals	Association of Parallel Importer	APAMEI Ruo de Montijo, Lote 5 Lugar de Trajouce P-2785 Sao Domingos de Rana Portugal Tel.: +351 21 4480 850 Fax: +351 21 4480 859	Mr. Jose Manuel Miranda Ruo de Montijo, Lote 5 Lugar de Trajouce P-2785 Sao Domingos de Rana Portugal Tel.: +351 21 4480 850 Fax: +351 21 4480 859
Ordem dos Farmaceuticos / Association of Pharmacists	Association of Pharmacists	Ordem dos Farmaceuticos Rua da Sociedade Farmaceutica 18 P-1100 Lisboa Portugal Tel.: +351 13 1913 70 Fax: +351 13 1913 99 www.ordemfarmaceuticos.pt/	Mr. João Silveira President Rua da Sociedade Farmaceuti-ca 18 P-1100 Lisboa Portugal Tel.: +351 13 1913 70 Fax: +351 13 1913 99 dirnacio-nal@ordemfarmaceuticos.pt
Associação Nacional das Farmácias (ANF) / Association of Pharmacies	Association of Pharmacies	ANF Rua Marechal Saldanha 1 P-1200 Lisboa Portugal Tel.: +351 21 3400 653 Fax: +351 21 3400 759 www.anf.pt/	Mr. João Cordeiro President Rua Marechal Saldanha 1 P-1200 Lisboa Portugal Tel.: +351 21 3400 653 Fax: +351 21 3400 759 anf@anf.pt

Institution	Task	Contact details/URL	Responsible person
Ordem dos Médicos / Medical Doctors Association	Medical Doctors Association	Ordem dos Médicos Av. Almirante Gago Coutinho 151 P-1700 Lisboa Portugal Tel.: +351 18 4271 11 Fax: +351 18 4271 99 www.ordemdosmedicos.pt/	Mr. Marquez Av. Almirante Gago Coutinho 151 P-1700 Lisboa Portugal Tel.: +351 18 4271 11 Fax: +351 18 4271 99 pwg@ordemmedicos.pt
Associacao Portuguesa dos Farmaceuticos Hospitalares (APFH) / Association of Hospital Pharmacists	Association of Hospital Pharmacists	APFH Rua Padre Estevao Cabral 120 P-3000-316 Coimbra Portugal www.apfh.pt/	Ms. Maria Aida Magalhães Ferreira Batista Serviços Farmacêuticos Centro Hospitalar de V. N. de Gaia P-4430 Vila Nova de Gaia Portugal aida.batista@apfh.pt
Associacao Portuguesa para a Defesa do Consumidor (DECO) / Association for the Defense of Consumers	Consumers Association	DECO Av. Defensores de Chaves 22 P-1000 Lisboa Portugal Tel.: +351 13 5739 08 Fax: +351 13 5778 51 www.deco.pt	Mr. Manuel Ataide Ferreira Av. Defensores de Chaves 22 P-1000 Lisboa Portugal Tel.: +351 13 5739 08 Fax: +351 13 5778 51 info@deco.proteste.pt
Associcao Portuguesa de Direito do Consumo (APDC)/ Association for the Right of Consumers	Consumers Association	APDC Rua Vilaca da Fonseca 5 Villa Cortez P-3030-321 Coimbra Portugal Tel.: +351 23 9404 733 Fax: +351 23 9404 738 www.apdconsumo.pt/	Mr. Mário Frota Rua Vilaca da Fonseca 5 Villa Cortez P-3030-321 Coimbra Portugal Tel.: +351 23 9404 733 Apd.ccedc@mail.telepac.pt or cedc@apdconsumo.pt

Source: ÖBIG 2006

2005 was a year of major reforms, with changes concerning the pricing procedure of pharmaceuticals[956] (cf. 21.2.1), reimbursement classes[957] (cf. 21.3.1) and distribution of OTC products[958] (cf. 21.1.2.2).

956 Decreto-Lei n. º 134/2005, de 16 de Augusto, http://dre.pt/pdf1s/2005/08/156A00/47634765.pdf and Portaria n.º 618-A/2005, de 27 de Julho, http://www.dgcc.pt/47.htm#17

957 Decreto-Lei n. º 129/2005, de 8 de Augusto, http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_IV/decreto_lei_129_2005.pdf

The reforms continue in 2006, as the latest agreement between the government and the pharmaceutical industry signed in February 2006[959] will lead to new legislation in pricing (cf. 21.2.1.1) and limit pharmaceutical expenditure to a ceiling with penalties in case of over-spending (cf. 21.2.2.7). This agreement is the fourth in a serie of agreements signed since the mid-1990s (first agreement from 1997 to 1999, second agreement from 2001 to 2003, and the third agreement signed in January 2005, which failed). In addition, a liberalisation in the pharmacy sector is expected for 2006 (cf. 21.1.2.2).

21.1.2 Market Players

21.1.2.1 Pharmaceutical Industry

Portugal is not a very important pharmaceutical producer. According to IMS data, the Portuguese pharmaceutical market accounts for 3% of the respective EU market.

However, the key data (Apifarma 2006) of the research-oriented industry show a modest increase:

- The sales volume amounted to € 470.7 million in 2005 (estimate), which corresponds to an increase of 13% compared to the previous year. In 2001, the sales were € 317.2 million.
- In 2005, nearly 3,400 staff were employed in the pharmaceutical industry, among those around 1,000 with a superior education. The respective data for 2001 were 2,900 staff and 600 highly trained people.
- In 2005, investment amounted to € 58,5 million, compared to € 39,6 million in 2001.
- 130 pharmaceutical companies are represented as members in the association of the research-oriented industry Apifarma (Associação Portuguesa da Indústria Farmacêutica).

Since 1997, Apifarma has regularly signed framework agreements with the Ministry of Health, committing both parties to reforms: The industry was targeted by cost-containment measures like price freeze, price cuts and repayments, while the government promised to shorten procedure time and to pay the hospital debts. The latest (fourth) protocol, which followed the 2005 agreement which had failed, was signed on 10 February 2006[960] (cf. 21.1.1) and is valid from 1 January 2006 to 31 December 2009.

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958 Lei n.º 38/2005, de 21 de Junho, http://www.apifarma.pt/uploads/Legisla%C3%A7%C3%A3o_upload/Geral/lei%2038-05.pdf Decreto-Lei n. º 134/2005, de 16 de Augusto, http://dre.pt/pdf1s/2005/08/156A00/47634765.pdf and Portaria n.º 827/2005, de 14 de Setembro, http://dre.pt/pdf1s/2005/09/177B00/55745576.pdf

959 Protocolo entro o Ministério da Saúde e a Indústria Farmacêutica (2006 - 2009), http://www.apifarma.pt/uploads/PROTOCOLOAPIF-FINAL.pdf

960 Protocolo entro o Ministério da Saúde e a Indústria Farmacêutica (2006 - 2009), http://www.apifarma.pt/uploads/PROTOCOLOAPIF-FINAL.pdf

Manufacturers have to apply to the INFARMED for market authorisation (Autorização de Introdução no Mercado, AIM), which is in line with Community law.[961] An expert committee at INFARMED then decides on the prescription status of the authorised pharmaceutical (cf. Figure 21.1). There are prescription-only medicines (POM) and non-prescription pharmaceuticals (Medicamentos Não Sujeitos a Receita Médica, MNSRM)[962]. The prescription status has consequences on the pricing of the pharmaceuticals (cf. 21.2). Normally, OTC products are not reimbursable (cf. 21.3.1.5), unless in exceptional circumstances which have to be justified on grounds of public health.

For imports of pharmaceuticals from non-EU Member States, a prior authorisation from the INFARMED is needed, while pharmaceuticals from EU Member States can be imported without restrictions.[963] With regard to parallel trade, Portugal is a major exporter due to its low prices (see also 21.3.4.2).

21.1.2.2 Distribution

Pharmaceutical wholesale, which is regulated by a decree-law[964], is operated within a multi-channel system in Portugal. Like the pharmaceutical industry and retailers, wholesalers have to licence with INFARMED. Currently, more than 300 wholesalers are registered, however only 130 are active. There are only 11 full-line wholesalers. The market leaders Alliance Unichem, Codifar and OCP-Portugal have a common market share of nearly 50%.

Apart from a limited service within hospitals for dispensing POM without any co-payment to out-patients, until recently pharmacies had been the only outlets allowed to dispense pharmaceuticals to the public. The Portuguese pharmacy sector is characterised as follows:

- There are around 2,750 pharmacies in Portugal, which corresponds to 3,900 inhabitants per pharmacy.
- Pharmacy establishment is statutorily regulated. There should be at least one pharmacy per 4,000 inhabitants.
- A pharmacy must be owned by a pharmacist.
- Pharmacy chains are not allowed.
- However, pharmacies may run so-called Postos Farmacêuticos Móveis (PFM) to guarantee provision of the population in rural areas with pharmaceuticals. There are around 300 “Postos” in Portugal.
- Distance selling and internet pharmacies are not allowed. In Portugal, there are no self-dispensing doctors.

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961 Medicines Act: Decreto-Lei nº 72/91, de 8 de Fereveiro (ESTATUTO DO MEDICAMENTO)

962 Decreto-Lei n.º 209/94, de 6 de Agosto, http://www.dgcc.pt/anexos/decreto-lei%20209-94%20(274%20KB).pdf

963 Decreto-Lei n.º 272/95 de 23 de Outubro de 1995, http://www.iapmei.pt/acessivel/iapmei-leg-03.php?lei=2414

964 Decreto-Lei n.º 135/95, de 9 de Junho, http://www.iapmei.pt/iapmei-leg-03.php?lei=193

However, the monopoly of the pharmacies fell recently with allowing the sale of OTC products outside pharmacies, in so-called sales outlets for non-prescription pharmaceuticals (Locais de venda de MNSRM). According to the new legislation[965], these outlets may be established under the following conditions:

- The outlet has to possess adequate facilities (e.g. storage space).
- It has to be technically supervised by a pharmacist or a pharmacy technician (who could be technically responsible for up to 5 sales outlets within an area of 50 kilometres, but is not allowed to act as technical director of a community pharmacy simultaneously).
- The outlet has to comply with the pharmacovigilance rules established by law.
- To start, the outlet has to pay a one off tax of € 1,000 to the INFARMED.

At the end of April 2006, 126 sales outlets for OTC products were registered in Portugal[966].

The Portuguese Competition Authority (Autoridade Concorrência, AC), has recommended several measures to liberalise the pharmacy sector (among those are the abolishment of geographic and demographic restrictions for the establishment of a new pharmacy).[967] It is expected that at least the liberalisation of pharmacy establishment will be implemented this year.[968]

21.1.2.3 Patients

Concerning the pricing and reimbursement process, patients are not involved in this process. With regard to prescription medicines, patients have a minor role in the choice of having them prescribed.

Due to the liberalisation in the retail sector in 2005, patients can now purchase OTC products outside pharmacies, in special sales outlets (cf. 21.1.2.2). Information on where to find pharmacies and sales outlets for OTC products is provided on the website of INFARMED[969]. On that website, patients can also access information and data on authorised and reimbursable pharmaceuticals (cf. 21.2.4). There is a protocol between the industry association Apifarma and several patient organisations on mutual co-operation on the exchange of information and experience.

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965 Decreto-Lei n.º 134/2005, de 16 de Agosto, http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_II/TITULO_II_CAPITULO_VI/decreto_lei_134_2005.pdf and Portaria n.º 827/2005, de 14 de Setembro, http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_II/TITULO_II_CAPITULO_VI/portaria_827-2005.pdf

966 Lista de estabelecimentos de venda de medicamentos não sujeitos a receita médica (MNSRM), http://www.infarmed.pt/portal/page/portal/INFARMED/LICENCIAMENTO_DE_ENTIDADES/LOCAIS_DE_VENDA_MNSRM/LISTA_DAS_ENTIDADES_REGISTADAS_PARA_VENDA_DE_MNSRM

967 http://www.autoridadedaconcorrencia.pt/vImages/recomendation2006_01.pdf

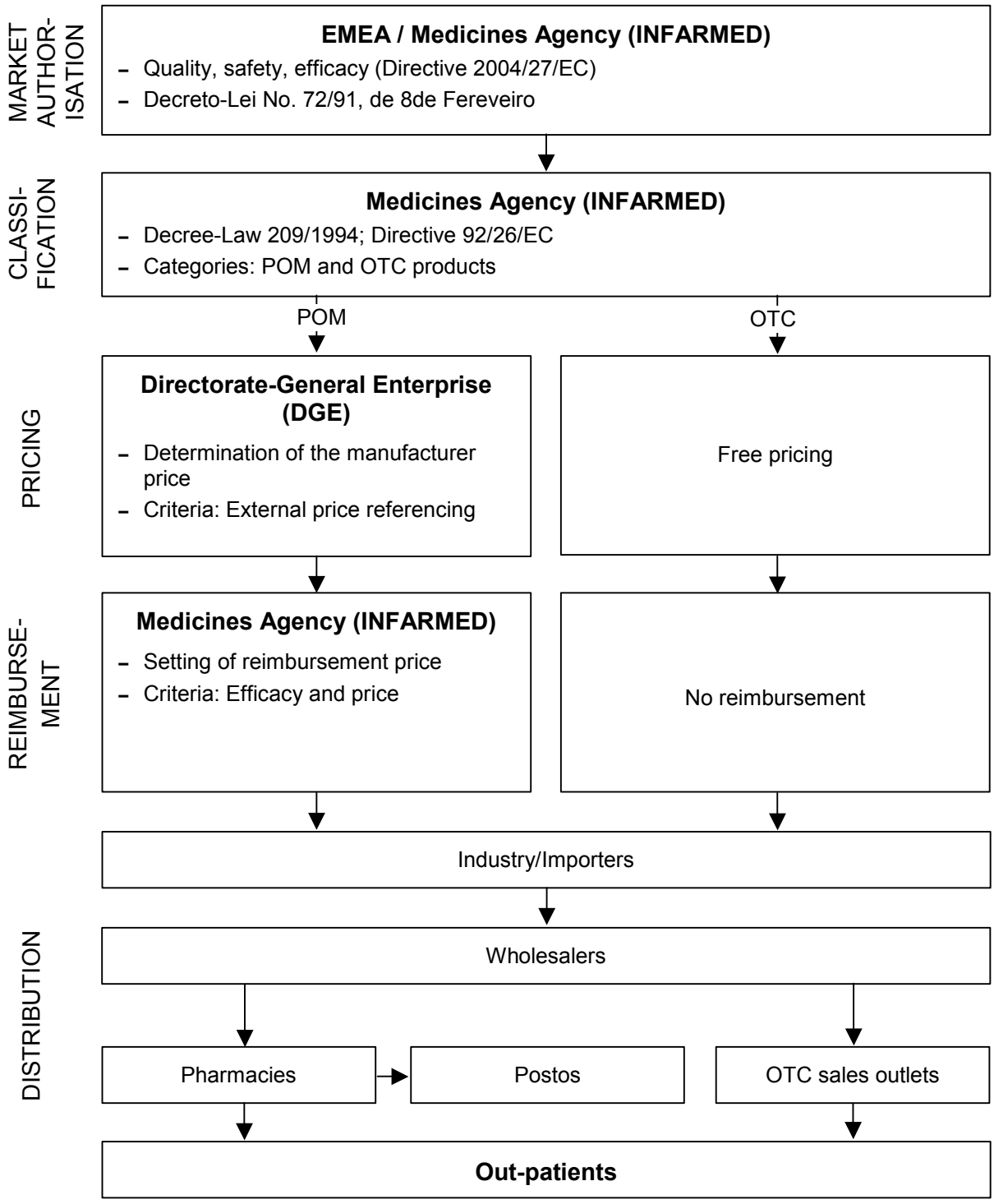
968 Ordem dos Farmacêuticos / ANF 2006

969 www.infarmed.pt

21.1.3 Overview of the Pharmaceutical System

Figure 21.1 gives an overview on the current pharmaceutical system in Portugal.

Figure 21.1: Portugal - Pharmaceutical System, 2006



POM = Prescription-only Medicines, OTC = Over-the-Counter

Source: ÖBIG 2006

21.2 Pricing

21.2.1 Scope of Price Control

Recently, there have been major reforms in the pricing system in Portugal, with the liberalisation of OTC prices at wholesale and pharmacy level[970]: Since September 2005, there are no longer wholesale and pharmacy margins for OTC products. Manufacturers continue to be allowed to set freely the price of OTC products. Thus, with the 2005 reforms, there is now free pricing for OTC products at all price levels.

In the prescription segment, manufacturer prices of pharmaceuticals are statutorily fixed, and the wholesale and pharmacy prices are regulated via linear margins, which were reduced as one of the reform measures in 2005 (cf.21.2.2.5).

All these provisions (statutory pricing at all price levels for POM) only concern the out-patient sector. In the hospital sector, no maximum prices are set. Most commonly used pharmaceuticals in hospitals are centrally purchased by the Ministry of Health via public procurement tendering. Neither the DGE nor INFARMED are involved.

Table 21.2: Portugal - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	OTC products	OTC products	OTC products
Statutory Pricing	POM	POM via a linear mark-up	POM via a linear mark-up
Price Negotiations	Not applied	Not applied	Not applied
Price/volume agreements, discounts/rebates	Yes	No	No
Institution in charge of pricing	Directorate-General Enterprise (Direcção-Geral da Empresa, DGE)		
Legal Basis	- Enactment: Portaria n.º 29/90, de 13 de Janeiro - Enactment: Portaria n.º 577/2001, de 7 de Junho - Enactment: Portaria n.º 914/2003, de 1 de Setembro - Decree-Law: Decreto-Lei n.º 134/2005, de 16 de Augusto - Enactment: Portaria n.º 618-A/2005, de 27 de Julho - Framework Agreement between Ministry of Health and pharmaceutical industry for 2006 to 2009: Protocolo entro o Ministério da Saúde e a Indústria Farmacêutica (2006-2009)		

POM = prescription-only medicines, OTC = Over-the-Counter

Source: ÖBIG 2006

970 Decreto-Lei n.º 134/2005, de 16 de Augusto, http://dre.pt/pdf1s/2005/08/156A00/47634765.pdf and Portaria n.º 618-A/2005, de 27 de Julho, http://www.dgcc.pt/47.htm#17

In Portugal, the pricing and reimbursement procedure is a two step process: First, the maximum manufacturer price for POM (reimbursable and non-reimbursable pharmaceuticals) is statutory fixed by the DGE. In a second step, applications for reimbursement are processed by INFARMED, which can propose the applicant to lower the price in order to obtain reimbursement status (cf. 21.3.1.1).

21.2.1.1 Manufacturer Price

The prices of all POM are statutorily fixed by the DGE. This is irrespective from the reimbursement status of the pharmaceuticals, and concerns, as the underlying regulation[971] states, original products as well as copy brands. For generics special rules are applied (see below).

The methodology used by the DGE to calculate the manufacturer price (Preço de Venda ao Armazenista, PVA) of new pharmaceuticals is the external price referencing: The 1990 Enactment provides that the PVA is strictly based on the lowest manufacturer price of identical or similar pharmaceutical specialities containing the same active ingredient, found in the reference countries. This Enactment defines three reference countries: Spain, France and Italy (cf. 21.2.2.3).

There are precise rules on how to carry out the price comparisons, in particular how to proceed if identical or similar pharmaceuticals are not on the market in the reference countries. The detailed information on the methodology to apply is provided in Table 21.3 under section 21.2.2.3.

However, the latest agreement[972] between the government and the industry association Apifarma, signed on 10 February 2006, provides for modifications in the pricing methodology. The two key changes are the inclusion of Greece as a fourth reference country in the price comparison and the calculation to an average of manufacturer price instead of the lowest price.

The applying manufacturer has to deliver the prices of the pharmaceuticals in the reference countries. However, the DGE may check the information provided via published sources.

Separate full applications are needed for every pharmaceutical form and dosage.

The DGE has, according the EU Transparency Directive 89/105/EEC[973], 90 days to decide. If there is no response within 90 days, the manufacturer may apply the price, which s/he has asked for. The time period may be suspended pending a request for further documentary evidence.

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971 Portaria n.º 29/90, de 13 de Janeiro, http://www.dgcc.pt/anexos/portaria%2029-90%20(503%20KB).pdf

972 Protocolo entro o Ministério da Saúde e a Indústria Farmacêutica (2006 - 2009), http://www.apifarma.pt/uploads/PROTOCOLOAPIF-FINAL.pdf

973 Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance system, http://pharmacos.eudra.org/F2/eudralex/vol-1/new_v1/890105en.pdf#search='89/105/EECeudra

The applications to obtain a manufacturer price are the same for an innovative new chemical entity, for a “me too” drug and for a line extension.

There are special pricing regimes for generics, targeting at retail level (cf. 21.2.1.3). According to an enactment of 2001[974], the pharmacy retail price of a generic brought on the Portuguese market will have to be at least 35% inferior of the pharmacy retail price of a reference pharmaceutical, with the same pharmaceutical form and equal dosage. The original product on the Portuguese market is taken as reference pharmaceutical. In case that the presentation of the generic has no direct correspondence with the one of the reference pharmaceuticals, then the comparison will be made with a presentation of the reference pharmaceutical which is most approximate. The criteria for carrying out the price comparison are the same as for prescription pharmaceuticals.

Regarding generics for which a homogeneous group under the reference price system already exists, an enactment of 2003[975] established that the respective pharmacy retail price will be equal or inferior to the reference price of this group (cf. 21.3.2).

Furthermore, in its most recent agreement[976] with the industry association Apifarma from February 2006, the Portuguese Ministry of Health commits itself to develop any legislative actions necessary to promote generics according to the following principles:

- For generics with a pharmacy retail price of less than € 10.-, the price difference of 20% (instead of 35%, see above) shall be applied.
- Generics will be subject to price cuts between 3% - 5% depending on their market share. Once a generic has more than 50% of the active ingredient market share, price reductions of up to 70% could be introduced. However, price decreases will be carried out in 10% steps per year.
- A mechanism to reduce the price when a generic enters a homogenous group (cf. 21.3.2) should be introduced, in order to facilitate the inclusion of generics into reimbursement (demonstrating of the economic advantage, cf. 21.3.1.2).

Usually, the prices of POM should be revised annually. However, no revisions took place in 2004 and 2005. The agreement[977] between the government and the industry association Apifarma as of February 2006 establishes annual price revisions, which should start not before 31 July 2006 (cf. 21.2.2.5). In the course of the revision, the prices of pharmaceuticals on the market will be amended from 31 July 2006 according to the new methodology.

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974 Portaria n.º 577/2001, de 7 de Junho, http://www.dgcc.pt/anexos/portaria%20577-2001%20(105%20KB).pdf

975 Portaria n.º 914/2003, de 1 de Setembro, http://www.dgcc.pt/anexos/portaria%20914-2003%20(71,1KB).pdf

976 Protocolo entro o Ministério da Saúde e a Indústria Farmacêutica (2006 - 2009), http://www.apifarma.pt/uploads/PROTOCOLOAPIF-FINAL.pdf

977 Protocolo entro o Ministério da Saúde e a Indústria Farmacêutica (2006 - 2009), http://www.apifarma.pt/uploads/PROTOCOLOAPIF-FINAL.pdf

For OTC products there is free pricing. In fact, the prices of OTC products would officially have to be approved by the DGE, which is, however, a mere formality. In reality, OTC manufacturers notify the price to the DGE, and apply it after one month in case that no objection had been given.

21.2.1.2 Wholesale Price

From 15 September 2005 on, there is a linear wholesale mark-up of 7.45% of the net pharmacy retail price POM.[978] The wholesale price of OTC products is free; before mid-September 2005, OTC prices were also subject to the linear wholesale mark-up, which was fixed at a higher level (cf. 21.2.2.6).

For generics, the same margin rules are applied: No statutorily fixed margins for OTC generics, while prescription-only generics are subject to the maximum mark-up of 7.45% of the net pharmacy retail price.

21.2.1.3 Pharmacy Retail Price

A new legislation, in force since 15 September 2005[979], establishes that the pharmacy retail price of POM is subject to a linear mark-up of 19.15% of the net pharmacy retail price. Before this enactment, the pharmacy margin was higher (cf. 21.2.2.6) and regarded all pharmaceuticals. Now, there is free pricing of OTC products at pharmacy level.

As explained under section 21.2.1.1, the pharmacy retail price of new generics has to be at least 35% inferior of the pharmacy retail price of a reference pharmaceutical, which is an original product with the same pharmaceutical form and equal dosage.[980] In addition, according to the latest framework agreement[981] between the government and the industry, a price difference of 20% will be applied for generics with a pharmacy retail price of less than € 10.-. As generics in the prescription segment are subject to the same mark-ups as original products at wholesale and retail level, this corresponds, in fact, to a price determination of the manufacturer price of a generic. In case that a generic enters a homogenous group of identical pharmaceuticals (same active substance, dosage and pharmaceutical form), the pharmacy retail price will be determined on the basis of the reference price of that group (equal or lower, cf. 21.3.2).[982]

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978 Portaria n.º 618-A/2005, de 27 de Julho, http://www.dgcc.pt/47.htm#17

979 Portaria n.º 618-A/2005, de 27 de Julho, http://www.dgcc.pt/47.htm#17

980 Portaria n.º 577/2001, de 7 de Junho, http://www.dgcc.pt/anexos/portaria%20577-2001%20(105%20KB).pdf

981 Protocolo entro o Ministério da Saúde e a Indústria Farmacêutica (2006 - 2009), http://www.apifarma.pt/uploads/PROTOCOLOAPIF-FINAL.pdf

982 Portaria n.º 914/2003, de 1 de Setembro, http://www.dgcc.pt/anexos/portaria%20914-2003%20(71,1KB).pdf

21.2.1.4 Value Added Tax (VAT)

The VAT on pharmaceuticals is 5%, thus lower than the standard rate of 19%.

In addition, there is the so-called INFARMED tax, which is a sales tax of 0.4% of the net pharmacy retail price.

21.2.2 Price Related Cost-containment Measures

21.2.2.1 Pharmaco-economic Evaluation

Pharmaco-economic evaluations play a role in the application for reimbursement (cf. 21.3.1.2). It is thus a task of the Medicines' Agency INFARMED to assess pharmaco-economic evaluations supplied by the manufacturers.

Methodological guidelines (Orientações Metodológicas para Estudos de Avaliação Económica de Medicamentos) on how to carry out and present studies on the cost-effectiveness of pharmaceuticals have been developed and were published in November 1998. The guidelines are accessible on the INFARMED website[983].

21.2.2.2 Internal Price Referencing

The prices of similar pharmaceuticals already on the Portuguese market (and an economic advantage of the new pharmaceutical) are one criterion in the decision on inclusion into re-imbursement (cf. 21.3.1.2). Since 2003, a reference price system is in place (cf. 21.3.2).

21.2.2.3 External Price Referencing / Cross Country Referencing

When manufacturer prices of POM in the out-patient sector are statutorily set by the DGE, the price calculation is strictly based on external price referencing (cf. 21.2.1.1).

An enactment of 1990[984] describes in detail the methodology to be applied: It defines three reference countries (Spain, France and Italy), and explicit rules apply in case of the non-existence of similar and identical pharmaceutical specialities in one or two of the reference countries or a later launching in these markets. The decree states that the comparison should be based on identical active substances and pharmaceutical forms, concerning both the dosage and the pack size, and it establishes rules to be applied if dosages and pack sizes differ. The provisions on the methodology to be applied by the DGE when calculating the manufacturer price on the basis of external price referencing are presented in Table 21.3.

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983 Orientações Metodológicas para Estudos de Avaliação Económica de Medicamentos, http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/AVALIACAO_ECONOMI-CA_E_COMPARTICIPACAO/AVALIACAO_DE_COMPARTICIPACAO/Orien_Metodologicas_EAEM.pdf

984 Portaria n.º 29/90, de 13 de Janeiro, http://www.dgcc.pt/anexos/portaria%2029-90%20(503%20KB).pdf

Table 21.3: Portugal - External Pricing Methodology Applied for Pricing POM at Manufacturer Level, 2006

Condition	Consequence
Regarding reference countries	
Identical or similar pharmaceutical specialities exist in only 1 of the 3 reference countries	The lowest PVA in that country is applied in Portugal
Identical or similar pharmaceutical specialities exist in 2 or 3 reference countries	Either the lowest PVA in those countries is applied in Portugal; Or, if the difference between the average and the lowest PVA is more than 30%, the lowest PVA plus one third of the average of the 2 lowest PVA is applied in Portugal
No identical speciality exists in the reference countries, but it exists in the Portuguese market	The highest PVP applied at the time for this similar pharmaceutical in Portugal is taken
An identical or similar speciality only exists in the country of origin	The PVA at launch in that country is applied but the situation will be reassessed annually
An identical or similar speciality is subsequently marketed in any of the 3 reference countries	The Portuguese launch price would be revised towards this price (upwards or downwards) in 10% steps each year
Regarding the pharmaceutical speciality	
In principal, the active substance and pharmaceutical form must be identical, concerning both the dosage and the pack size	-
Differing of the pack size	The closest and smallest one is considered
Differing of the dosage	The calculation must be made on the base of the closest one

PVA = Preço de Venda ao Armazenista = manufacturer price, PVP = Preço de Venda ao Público = pharmacy retail price

Source: Portaria n.º 29/90, de 13 de Janeiro; information gathering by ÖBIG

As stated in section 21.2.1.1, the latest agreement[985] between the government and the industry association Apifarma, signed in February 2006, establishes changes in the methodology of setting prices: The price of a new POM will be formed through comparison with the average price of original products in four reference countries: Spain, France, Italy and Greece. In the agreement, the Ministry of Health expressed its commitment to develop legislation to implement the new principles of the pricing procedure. At the time of submitting this report, no legislation to implement the changes has entered in force yet. However, the revision of the price of the new pharmaceuticals, starting not before 31 July 2006, shall already be based on the new methodology.

985 Protocolo entro o Ministério da Saúde e a Indústria Farmacêutica (2006 - 2009), http://www.apifarma.pt/uploads/PROTOCOLOAPIF-FINAL.pdf

21.2.2.4 Price Freezes / Stops

The first agreement between the pharmaceutical industry (represented by the association Apifarma) and the government (Ministry of Health) for the years 1997 to 1999 established a price freeze for 1997. For 1998 and 1999, inflation-linked price increases were allowed (up to 75% of the inflation rate of the year 1997 and a price freeze for the rest of 1998; and up to 80% of the inflation rate of the year 1998 and a price freeze for the rest of 1999).

The third agreement between Apifarma and the Ministry of Health, signed on 18 January 2005 (which eventually failed), provided a freeze of pharmaceutical prices for the year 2005.

21.2.2.5 Price Revisions / Price Cuts

The prices of POM should be revised annually, and, as a consequence, be adjusted (upwards or downwards). As described in Table 21.3, the Portuguese launch price of a pharmaceutical with no identical or similar pharmaceutical in the reference countries would be revised and adjusted in 10% steps annually to the price of that pharmaceutical if it had been marketed in any of the reference countries meanwhile. For example, if the price in Portugal was fixed at € 100:- and the pharmaceutical was later launched in France (or in Spain or in Italy) at € 70.- the Portuguese manufacturer price would become € 90.- in the first annual revision, € 81.- in the second, € 72.90 in the third and € 70.- in the fourth.

However, price revisions were stopped temporarily in 2004. As a consequence, no revisions took place in 2004 and 2005.

At the beginning of 2005, price cuts affected 168 pharmaceuticals (52 active ingredients) due to an enactment by INFARMED on 27 July 2004. The INFARMED decision is based on a decree-law[986], stating that pharmaceuticals may be excluded from reimbursement if, among others, they were considered as too expensive. Thus, INFARMED called on manufacturers of 168 pharmaceuticals (mainly antibiotics, anxiolytics, anti-hypertensives and cardiovascular pharmaceuticals) to cut their prices or else face removal from the reimbursement list ("Prontuário", cf. 21.3.1). By 14 February 2005, only pharmaceuticals at the new price were allowed for dispensing. In the majority of the cases, the manufacturers cut their prices, only a few opted for voluntary delisting (cf. 21.3.1.6).

Further price cuts took place in the second half of the year 2005, based on the same legislation[987], which reduced the wholesale and pharmacy mark-ups (cf. 21.2.2.6): On 15 September 2005, the pharmacy retail prices of all pharmaceuticals reimbursed by the SNS (including generics) were cut by 6%. Additionally, for new pharmaceuticals launched after 15 September 2005, the manufacturer price, calculated on the basis of external price referencing according to the enactment from 1990[988] (cf. 21.2.2.3), should be cut by 3%. This would also

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986 Decreto-Lei nº 129/2005, de 11 de Agosto, http://www.apifarma.pt/uploads/Decreto_Lei_n_129-05_Altera_o_Decreto_Lei_n_118_92_Re.pdf

987 Portaria n.º 618-A/2005, de 27 de Julho, http://www.dgcc.pt/47.htm#17

988 Portaria n.º 29/90, de 13 de Janeiro, http://www.dgcc.pt/anexos/portaria%2029-90%20(503%20KB).pdf

have an impact on the wholesale and pharmacy retail prices, as the wholesale and pharmacy margins will be based on the lower prices. However, the latest framework agreement was signed in February 2006 under the condition that price cuts would be suspended.

In the most recent agreement[989] between the Ministry of Health and Apifarma, signed on 10 February 2006, annual price revisions were re-introduced according to the following principles:

- No price adjustment applieswhere the comparison with the average of the reference countries results in an increase of pharmacy retail price in Portugal
- No price adjustment shall be required where the pharmacy retail price in Portugal and the amount resulting from the comparison with the average of the reference countries is equal to or less than 2.5% of pharmacy retail price in Portugal
- If the application of the new methodology results in a price reduction, this reduction shall be effected in stages.

The revisions should not start before 31 July 2006. Pharmaceutical with a pharmacy retail price of less than € 15.- shall be excluded from the revision. In addition, pharmaceuticals included in homogenous groups (cf. 21.3.2) are also excluded for the years 2006 and 2007; at the end of 2007, a re-examination is planned.

Pharmacies are not allowed to grant discounts to consumers; this provision is under discussion and may be revoked due to recommendations by the Competition Authority (cf. 21.1.2.2).

21.2.2.6 Margin Cuts

On the basis of an enactment of 1990[990], the wholesale and pharmacy mark-ups for all pharmaceuticals (POM and OTC products) had been, for 15 years, fixed as 8% and 20% of the net pharmacy retail price respectively. In 2005, a new legislation[991] reduced the mark-ups by 0.55% (wholesale) and 0.85% (pharmacies) respectively. The same legislation limited the regulation of wholesale and pharmacy retail prices to POM (cf. 21.2.1.2 and 21.2.1.3), while the pricing of OTC products is now free at all price levels.

In addition, the wholesale and pharmacy retail prices were implicitly reduced by the price cut of 3% at manufacturer price level applied on new pharmaceuticals launched after 15 September 2005 - which was, however, suspended in 2006 (cf. 21.2.2.5).

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989 Protocolo entro o Ministério da Saúde e a Indústria Farmacêutica (2006 - 2009), http://www.apifarma.pt/uploads/PROTOCOLOAPIF-FINAL.pdf

990 Portaria n.º 29/90, de 13 de Janeiro, http://www.dgcc.pt/anexos/portaria%2029-90%20(503%20KB).pdf

991 Portaria n.º 618-A/2005, de 27 de Julho, http://www.dgcc.pt/47.htm#17

21.2.2.7 Discounts and Clawbacks

All four framework agreements signed by the Portuguese Ministry of Health and the pharmaceutical industry association Apifarma established limits of public pharmaceutical expenditure and industry re-payments in case of excess:

- With regard to the first agreement (for the years 1997 to 1999), re-payments of PTE 18 million / € 89,783 million were, according to the industry, made. The repayments were offset to the outstanding debts of (public) hospitals to the suppliers.
- The payback arrangement included in the framework agreement for the years 2001 to 2003 was abandoned in 2003, mostly because of reforms like the introduction of the reference price system in March 2003 (cf. 21.3.2) and the rising debts of the hospitals.
- The third agreement, signed on 18 January 2005, provided that any excess spending above the pharmaceutical expenditure growth rate (established at 8% for 2004 and 5% for 2005) will be fully compensated by the industry. R&D projects ensured eligibility of companies on their contributions.
- The latest agreement[992] between the Ministry of Health and Apifarma, signed on 10 February 2006, limits the growth rates of reimbursable pharmaceuticals in the out-patient sector (plus a special arrangement for hospital pharmaceuticals) to 0% in 2006 and to the foreseen nominal growth rate in the GDP in 2007. In case of excess, re-payments by the industry are provided equal to 69.6% of the increase, up to € 35 million (2006) and € 45 million (2007) respectively. According to the agreement, the goals of the limits for 2008 and 2009 will be set in mutual agreement.

The other distribution actors (wholesale, pharmacies) have not been targeted by discounts and/or clawbacks to the SNS.

21.2.2.8 Company Profit Controls

The profits of the pharmaceutical industry are indirectly influenced by the payback arrangements in the out-patient sector (cf. 21.2.2.7) and in hospitals (maximum growth of 4% over the sales volume carried out in 2005). [993]

Portugal has a commercialisation tax (the so-called INFARMED tax, cf. 21.2.1.4), corresponding to 0.4% of the net pharmacy retail price.

There are no controls over promotional expenses of the actors.

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992 Protocolo entro o Ministério da Saúde e a Indústria Farmacêutica (2006 - 2009), http://www.apifarma.pt/uploads/PROTOCOLOAPIF-FINAL.pdf

993 Protocolo entro o Ministério da Saúde e a Indústria Farmacêutica (2006 - 2009), http://www.apifarma.pt/uploads/PROTOCOLOAPIF-FINAL.pdf

21.2.2.9 Parallel Trade

In general, Portugal is, due to its low price level, a major parallel exporter of pharmaceuticals.[994]

21.2.3 Co-Payments

There is no prescription fee in Portugal.

Patients have to pay a product-specific percentage co-payment, based on a law of 1992[995], which was modified in the course of the reform on reimbursement in October 2005.

As of today, there are co-payment rates of 5%, 30%, 60% and 80% (for further information on the criteria for pharmaceuticals to be given a certain reimbursement rate cf. 21.3.1). In the out-patient sector, pharmaceuticals are no longer free of co-payment, as it had been before the decree-law of August 2005, entering in force on 10 October 2005[996], which reduced the 100% reimbursement rate to 95%.

Till 10 October 2005, 10% lesser co-payments had been applied to generics (i.e. rates of 0%, 20%, 50% and 70%). The mentioned decree-law also abolished the different rates for original products and generics, as the expected results on generic penetration had not shown up.

Pensioners are granted co-payment rates, which are 15% less than the co-payments of the respective pharmaceutical. The exemption criterion, which had been an income threshold (less than the minimum wage), was changed by the new decree-law of 2005[997] to the total annual income. Currently, there are discussions to abolish the special rates for pensioners totally.

For non-reimbursable pharmaceuticals, which are mostly OTC products, patients in Portugal have to pay the full price out-of-pocket. In addition, patients have to cover the difference bet ween the reference price and the actual pharmacy retail price for pharmaceuticals, which fall under the reimbursement system (cf. 21.3.2).

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994 Tilson, L.; Barry, M. 2005

995 Decreto-Lei nº 118/1992, de 25 de Junho, http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_IV/105-DL_118_92.pdf and Decreto-Lei nº 48/99 de 16 de Fevereiro de 1999, http://www.iapmei.pt/iapmei-leg-03.php?lei=2437

996 Decreto-Lei nº 129/2005, de 11 de Agosto, http://www.apifarma.pt/uploads/Decreto_Lei_n_129-05_Altera_o_Decreto_Lei_n_118_92_Re.pdf

997 Decreto-Lei nº 129/2005, de 11 de Agosto, http://www.apifarma.pt/uploads/Decreto_Lei_n_129-05_Altera_o_Decreto_Lei_n_118_92_Re.pdf

21.2.4 Information Transparency and Marketing

The EU provisions on pharmaceutical advertising were by implemented by a decree-law in 1994 and further amended in 1999:[998]

- OTC advertising is allowed in all media.
- The National Council for the Advertising of Medicines, established in mid-1990s, under the auspices of INFARMED acts as consultative body.

In 1994, a decree-law also implemented the EU's patient information provisions.[999] In principle, all packs have to carry patient information leaflets. However, if all the required information is contained on the outer packaging or on the primary packaging, no leaflet is required.

Prices of pharmaceuticals can be accessed on the website of INFARMED.[1000]

21.3 Reimbursement

21.3.1 Pharmaceutical Lists and Reimbursement Categories

In Portugal, there is a **positive list** of pharmaceuticals used in the out-patient sector, which are reimbursed at a certain percentage by the SNS: the so-called "Prontuário". None of the pharmaceuticals on the positive list are fully reimbursed, as the 100% reimbursement rate was reduced to 95% on 10 October 2005. [1001]

Currently, there are the following reimbursement categories in place[1002]:

- Category A: 95% reimbursement
  Category A covers "essential" pharmaceuticals to treat chronic diseases such as cancer and diabetes.
- Category B: 70% reimbursement
  This group includes pharmaceuticals of therapeutic benefit used in treating important conditions, such as anti-asthmatic and cardiovascular pharmaceuticals.

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998 Decreto-Lei n.º 100/1994, de 19 de Abril and Decreto-Lei n.º 48/1999, 16 de Fevereiro de 99

999 Decreto-Lei nº 101/94 de 9 de Abril de 1994, http://www.iapmei.pt/iapmei-leg-03.php?lei=187

1000 www.infarmed.pt

1001 Decreto-Lei nº 129/2005, de 11 de Agosto, http://www.apifarma.pt/uploads/Decreto_Lei_n_129-05_Altera_o_Decreto_Lei_n_118_92_Re.pdf

1002 Decreto-Lei nº 129/2005, de 11 de Agosto, http://www.apifarma.pt/uploads/Decreto_Lei_n_129-05_Altera_o_Decreto_Lei_n_118_92_Re.pdf and
Decreto-Lei nº 118/1992, de 25 de Junho,
http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_IV/105-DL_118_92.pdf

- Category C: 40% reimbursement
  In category C, anti-infectives, vaccines, immunoglobins, anti-parasitics and sera are included.
- Category D: 20% reimbursement
  Category D is intended for new pharmaceuticals whose therapeutic benefit is not yet proven. It is a transitional category for the time till the proof on therapeutic benefit will be given.

There had been additional reimbursement rates for generics, which were 10% higher (i.e. 100% for category A, 80% for category B, 50% for category C, and 30% for category D), in order to promote generics. However, the aim has not been reached as expected. As a consequence, in October 2005, the higher reimbursement rates for generics were abolished.[1003] Furthermore, pensioners under a certain threshold of total annual income (cf. 21.2.3) are granted an additional 15% higher reimbursement, taking reimbursement rates to 100%, 85%, 55% and 35%.

21.3.1.1 Reimbursement Price

In Portugal, the pricing and reimbursement procedure is a two step process: As explained in section 21.2.1.1, the maximum manufacturer price for POM (reimbursable and non-reimbursable pharmaceuticals) is statutory fixed by the DGE in a first step. In a second step, applications for reimbursement are processed by INFARMED, which is the relevant authority in charge of reimbursement.

The reimbursement price may be lower than the manufacturer price, as INFARMED can ask the applying pharmaceutical companies to lower the price in order to obtain reimbursement status.

21.3.1.2 Selection Criteria

In order to be eligible for reimbursement, pharmaceuticals must fulfil one of the following conditions:[1004]

- Innovative pharmaceuticals with no direct equivalent demonstrating a higher level of efficacy or safety than similar pharmaceuticals
- New pharmaceuticals that demonstrate an economic advantage over existing pharmaceuticals of the same composition and pharmaceutical form, i.e. priced 5% less than the cheapest competitive pharmaceutical, generics excluded
- Pharmaceuticals with a new pharmaceutical form, dosage or pack size demonstrating a higher cost-benefit ratio with regard to existing similar pharmaceuticals

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1003 Decreto-Lei nº 129/2005, de 11 de Agosto, http://www.apifarma.pt/uploads/Decreto_Lei_n_129-05_Altera_o_Decreto_Lei_n_118_92_Re.pdf

1004 Artigo 6.º , Decreto-Lei nº 129/2005, de 11 de Agosto, http://www.apifarma.pt/uploads/Decreto_Lei_n_129-05_Altera_o_Decreto_Lei_n_118_92_Re.pdf

- Combination products made up of active ingredients reimbursed as separate products that demonstrate a therapeutic benefit at an equal or lower price compared to the ingredients administered separately
- Combination products made up of active ingredients that do not exist as separate products on the Portuguese market that demonstrate a therapeutic advantage.

However, copy products which have successfully converted to generics are automatically eligible for reimbursement (cf. 21.3.4.2).

The kind of disease for whose treatment the pharmaceutical is used then determines the reimbursement rate (cf. 21.3.1).

In addition, the same decree-law[1005] also lists criteria which exclude pharmaceuticals from reimbursement (cf. 21.3.1.5).

21.3.1.3 Pharmaceuticals on Positive List

Reimbursable pharmaceuticals are put on the positive list ("Prontuário") which is publicly accessible on the website of INFARMED.[1006]

Within a period of 3 years after inclusion into reimbursement, the re-assessment of pharmaceuticals with regard to the reimbursement status shall be undertaken.[1007]

21.3.1.4 Generics

As explained in section 21.2.1.1, the pharmacy retail price of a generic brought on the Portuguese market will have to be at least 35% inferior of the pharmacy retail price of an original product taken as reference pharmaceutical, with the same pharmaceutical form and equal dosage. [1008] The framework agreement[1009] between the government and the industry association Apifarma from February 2006 foresees a new rule that a price difference of 20% (instead of 35%) shall be applied for generics with a pharmacy retail price of less than € 10.-.

As for generics for which a homogeneous group under the reference price system already exists, an enactment of 2003[1010] establishes that the respective pharmacy retail price will be equal or inferior to the reference price of this group (cf. 21.3.2). For promoting the inclusion of generics into the reimbursement list (by facilitating the demonstration of the economic ad-

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1005 Artigo 6.º , Decreto-Lei nº 129/2005, de 11 de Agosto, http://www.apifarma.pt/uploads/Decreto_Lei_n_129-05_Altera_o_Decreto_Lei_n_118_92_Re.pdf

1006 www.infarmed.pt

1007 Artigo 6.º-A , Decreto-Lei nº 129/2005, de 11 de Agosto, http://www.apifarma.pt/uploads/Decreto_Lei_n_129-05_Altera_o_Decreto_Lei_n_118_92_Re.pdf

1008 Portaria n.º 577/2001, de 7 de Junho, http://www.dgcc.pt/anexos/portaria%20577-2001%20(105%20KB).pdf

1009 Protocolo entro o Ministério da Saúde e a Indústria Farmacêutica (2006 - 2009), http://www.apifarma.pt/uploads/PROTOCOLOAPIF-FINAL.pdf

1010 Portaria n.º 914/2003, de 1 de Setembro, http://www.dgcc.pt/anexos/portaria%20914-2003%20(71,1KB).pdf

vantage, cf. 21.3.1.2), the 2006 agreement[1011] between the Ministry of Health and Apifarma provides for the introduction of a local mechanism so that the price will be reduced when a generic enters a homogenous group (cf. 21.3.2).

In September 2000, extra reimbursement rates for generics (10% higher than the normal reimbursement rates) had been introduced,[1012] which were abolished in October 2005.[1013]

21.3.1.5 Non-reimbursable Pharmaceuticals

According to legislation[1014], there are certain criteria, which exclude pharmaceuticals from reimbursement. The 3 major points regard "excessive cost", relatively low therapeutic efficacy and OTC status. In theory, OTC products are not reimbursable, unless in exceptional circumstances which have to be justified on grounds of public health. However, quite a number of OTC products are on the positive list.

21.3.1.6 Delisting and Switches

Due to a legal provision[1015], pharmaceuticals may be delisted if they were considered as too expensive ("excessive cost", cf. 21.3.1.5). In practice, INFARMED will ask pharmaceutical manufacturers to lower their prices in order to avoid delisting, as this happened in 2004/2005 (cf. 21.2.2.5). In July 2004, INFARMED asked manufacturers of 168 pharmaceuticals (52 active ingredients) to cut their prices or else face exclusion from reimbursement. By the deadline of 14 February 2005, most manufacturers had the price cut; there were only 4 delistings.

In addition, delistings (or a lower reimbursement rate) were announced to Portuguese manufacturers of copy products in case that they would not take the possibility to transfer already marketed copy products into the category of generics (cf. 21.3.4.2), as provided by a decree-law[1016] in 2003. Several manufacturers used the option of conversion.

In connection with delistings, the changes from prescription to OTC status (switches) are also of relevance, because, as a general rule, OTC products, which are a small market, are

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[1011] Protocolo entro o Ministério da Saúde e a Indústria Farmacêutica (2006 - 2009), http://www.apifarma.pt/uploads/PROTOCOLOAPIF-FINAL.pdf

[1012] Decreto-Lei n.º 205/2000, de 1 de Setembro, http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_IV/105-DL_118_92.pdf

[1013] Decreto-Lei nº 129/2005, de 11 de Agosto, http://www.apifarma.pt/uploads/Decreto_Lei_n_129-05_Altera_o_Decreto_Lei_n_118_92_Re.pdf

[1014] Artigo 7.º, Decreto-Lei nº 129/2005, de 11 de Agosto, http://www.apifarma.pt/uploads/Decreto_Lei_n_129-05_Altera_o_Decreto_Lei_n_118_92_Re.pdf

[1015] Artigo 7.º, Decreto-Lei nº 129/2005, de 11 de Agosto, http://www.apifarma.pt/uploads/Decreto_Lei_n_129-05_Altera_o_Decreto_Lei_n_118_92_Re.pdf

[1016] Decreto-Lei n.º 249/2003, de 11 de Outubro, http://www.dgcc.pt/anexos/decreto%20lei%20249-2003%20(99%20KB).pdf

non-reimbursable (unless if justified on grounds of public health) in Portugal (cf. 21.1.2.1). Switches are not of great relevance.

21.3.2 Reference Price System

In March 2003, a reference price system was introduced in Portugal.[1017]

Pharmaceuticals are clustered in “homogeneous groups”, which consist of bio-equivalent pharmaceuticals with the same active ingredient, dosage and pharmaceutical form. Each homogeneous group contains an original product and at least one generic.

The reference price, which is reimbursed by the SNS, is the price of the most expensive generic. As generics must be priced at least 35% lower than the cheapest similar original products due to an enactment of 2001[1018] (cf. 21.2.1.1), there is a minimum difference of that 35%. In case of pharmaceuticals with a price superior to the reference price, patients have to pay the difference.

Regarding generics for which a homogeneous group under the reference price system already exists, an enactment from September 2003[1019] provides that the respective pharmacy retail price should be equal or inferior to the reference price of this group (cf. 21.2.1.3).

When a generic enters a homogenous group, the current framework agreement[1020] between the Ministry of Health and the industry association Apifarma establishes that a mechanism for price reductions should take effect (cf. 21.2.1.1).

Copy products cannot be included in the reference price system, as they do not meet the required bio-equivalence criteria. Thus, a decree-law[1021] in 2003 allowed the conversion of that group of pharmaceuticals (copy products account for 25% of the market) into generics (cf. 21.3.4.2).

21.3.3 Pharmaceutical Budgets

In Portugal, there are no prescribing budgets for doctors.

1017 Decreto-Lei n.º 270/2002, de 2 de Dezembro, http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_IV/decreto_lei_270_2002.pdf

1018 Portaria n.º 577/2001, de 7 de Junho, http://www.dgcc.pt/anexos/portaria%20577-2001%20(105%20KB).pdf

1019 Portaria n.º 914/2003, de 1 de Setembro, http://www.dgcc.pt/anexos/portaria%20914-2003%20(71,1KB).pdf

1020 Protocolo entro o Ministério da Saúde e a Indústria Farmacêutica (2006 - 2009), http://www.apifarma.pt/uploads/PROTOCOLOAPIF-FINAL.pdf

1021 Decreto-Lei n.º 249/2003, de 11 de Outubro, http://www.dgcc.pt/anexos/decreto%20lei%20249-2003%20(99%20KB).pdf

The only actor responsible for compensating excess spending of pharmaceutical expenditure is the pharmaceutical industry. As explained in section 21.2.2.7, all four agreements between the government and the industry association established limits of public pharmaceutical expenditure whose overspending would entail industry re-payments. The most recent agreement[1022] between the Ministry of Health and Apifarma, as of February 2006, limits the growth rates of reimbursable pharmaceuticals in the out-patient sector to 0% in 2006 and to the foreseen nominal growth rate in the GDP in 2007. In case of excess, repayments up to € 35 million (2006) and € 45 million (2007) respectively have to be made by the industry.

21.3.4 Other Volume Control Oriented Measures

21.3.4.1 Prescription Monitoring and Other Doctors-related Measures

There are no obligatory prescribing guidelines in place. However, INFARMED has developed a national prescribing formulary in an attempt to rationalise prescribing. The formulary, which describes the benefits and side-effects of more than 4,000 POM, is considered as a tool for doctors to facilitate appropriate prescribing.

21.3.4.2 Generics

Generic promotion has been a key objective of pharmaceutical policy for many years.

In September 2000, generic substitution was introduced: Pharmacists were obliged to dispense the cheapest generic, unless the doctor has explicitly stated the dispensing of the original product on the prescription form.

A further important measure was the introduction of the obligatory prescription by international non-proprietary name (INN) at the beginning of 2003. Together with obligatory INN prescribing, a new prescription form was also introduced giving doctors the choice to opt in or opt out generic substitution:

- If the doctor prescribes by brand name (stating INN plus brand name) and does not tick the box to prohibit generic substitution, pharmacists are allowed to substitute.
- If the doctor prescribes by brand name (stating INN plus brand name) and ticks the box allowing substitution, pharmacists are allowed to substitute.
- If the doctor prescribes by brand name (stating INN plus brand name) and ticks the box prohibiting substitution, then pharmacists are not allowed to substitute.
- If the doctor prescribes generically (by INN only) and does not tick any of the boxes, then pharmacists are allowed to dispense any pharmaceutical with that active ingredient.

[1022] Protocolo entro o Ministério da Saúde e a Indústria Farmacêutica (2006 - 2009), http://www.apifarma.pt/uploads/PROTOCOLOAPIF-FINAL.pdf

In practice, data from the Ministry of Health showed that 43% of all prescriptions in a 3-month-period in 2003 were written by brand name, and not by the INN. In addition, according to figures provided by the pharmacy association ANF for November 2003, generic substitution has not been allowed by doctors in more than half of the prescriptions written.

This explains partly why generic penetration is still at a very modest level (7% by value and less than 5% by volume - data for 2004). Another reason is the prevalence of cheap copy products in Portugal, which account for 25% of the market. Copy products were brought on the market before 1995, when patent protection entered into force. As copy products cannot be included in the reference price system (cf. 21.3.2), the government gave Portuguese pharmaceutical companies until March 2005 to convert their copies to generics (and hence to incorporate them into the reference price system. As an alternative, the manufacturers would have faced delistings (cf. 21.3.1.6) or a reduction of the reimbursement level. The decree-law[1023] regulating the conversion of copy products into generics provided for a relabelling of the product name, consisting of the INN or of the INN plus a fantasy (trade) name or the company name, as the dosage and pharmaceutical form followed by the letters MG (Medicamento Generico).

For the conversion of copy products to generics, a transitional pricing scheme had been developed. It was put in place in addition to the special pricing procedure for generics: a pharmacy retail price at least 35% inferior of the PRP of an identical original product[1024], and in future due to an agreement[1025] of the Ministry of Health and Apifarma, a price difference of 20% for generics with a pharmacy retail price of less than € 10.- (cf. 21.2.1.1).

21.4 Overview of the Reimbursement Market in Portugal

Tasks / Duties	Yes	No	Comment	Legal bases
Public Authorities				
Decide on prescription status	X		INFARMED	Directive 92/26/EC, Decreto-Lei n.º 209/94, de 6 de Agosto, http://www.dgcc.pt/anexos/decreto-lei%20209-94%20(274%20KB).pdf
Decide on manufacturer price	X		DGE, based on strict application of external price referencing	Portaria n.º 29/90, de 13 de Janeiro
Agree on manufacturer price		X	N.app.	

[1023] Decreto-Lei n.º 249/2003, de 11 de Outubro, http://www.dgcc.pt/anexos/decreto%20lei%20249-2003%20(99%20KB).pdf

[1024] Portaria n.º 577/2001, de 7 de Junho, http://www.dgcc.pt/anexos/portaria%20577-2001%20(105%20KB).pdf

[1025] Protocolo entro o Ministério da Saúde e a Indústria Farmacêutica (2006 - 2009), http://www.apifarma.pt/uploads/PROTOCOLOAPIF-FINAL.pdf

Tasks / Duties	Yes	No	Comment	Legal bases
Fix wholesale margin	X		Statutory wholesale mark-up for POM	Portaria n.º 618-A/2005, de 27 de Julho, http://www.dgcc.pt/47.htm#17
Fix pharmacy retail price	X		Statutory wholesale mark-up for POM	Portaria n.º 618-A/2005, de 27 de Julho, http://www.dgcc.pt/47.htm#17
Decide on reimbursement status	X		INFARMED	Decreto-Lei nº 129/2005, de 11 de Agosto, http://www.apifarma.pt/uploads/Decreto_Lei_n_129-05_Altera_o_Decreto_Lei_n_118_92_Re.pdf, and Decreto-Lei nº 118/1992, de 25 de Junho, http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_IV/105-DL_118_92.pdf
Decide on reimbursement price	X		INARMED	Decreto-Lei nº 129/2005, de 11 de Agosto, http://www.apifarma.pt/uploads/Decreto_Lei_n_129-05_Altera_o_Decreto_Lei_n_118_92_Re.pdf, and Decreto-Lei nº 118/1992, de 25 de Junho, http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_IV/105-DL_118_92.pdf
Use Pharmaco-economic guidelines	X		For reimbursement decisions	
Use Internal reference pricing	X		Reference price system since 2003	
Use External reference pricing	X		DGE, methodology for setting the maximum manufacturer price	Portaria n.º 29/90, de 13 de Janeiro, http://www.dgcc.pt/anexos/portaria%2029-90%20(503%20KB).pdf
Price freezes	X		1997-1999	
Margin cuts		X	As of 15 October 2005	Portaria n.º 618-A/2005, de 27 de Julho, http://www.dgcc.pt/47.htm#17
Discounts and Rebates	X		Clawback system for manufacturers; no discounts by wholesalers and pharmacists to SNS	
Company profit control	X		INFARMED commercialisation tax of 0.4% of net pharmacy retail price	

Tasks / Duties	Yes	No	Comment	Legal bases
Country specific				
Pharmaceutical Industry				
Sets manufacturer price freely	X		Free pricing for OTC	
Notifies manufacturer price	X		For OTC products	
Negotiates manufacturer price		X	N.app.	
Is free to set price below fixed manufacturer price		X	N.app.	
Decides on application for re-imbursement	X			
Negotiates reimbursement price		X	Applies for inclusion into re-imbursement and a reim-bursement rate	
Free to keep manu-facturer price above reimbursement price		X	Pharmaceutical companies would face delistings	
Free to grant rebates / discounts to wholesalers	X			
Free to grant rebates / discounts to pharmacies	X			
Can engage in marketing towards doctors	X			
Can engage in public advertising	X		For OTC pharmaceuticals	
Can provide information toward patients	X		For OTC pharmaceuticals	
Applies for switches and de-listing	X			
Country specific:				
Distribution Chain				
Wholesaler				
Margins are fixed by statute	X		For POM	Portaria n.º 618-A/2005, de 27 de Julho, http://www.dgcc.pt/47.htm#17
Margins are subject to statutory dis-counts / rebates		X		

Tasks / Duties	Yes	No	Comment	Legal bases
Free to grant discounts / rebates to pharmacies	X			
Pharmacists				
Margins are fixed by statute	X		For POM	Portaria n.º 618-A/2005, de 27 de Julho, http://www.dgcc.pt/47.htm#17
Free to set retail price	X		For OTC	
Obliged to inform patient on cheaper product	X			
Obliged to substitute by a generic	X		Unless substitution is prohibited by doctor	
Allowed to substitute by a generic	X		Unless substitution is prohibited by doctor	
Obliged to substitute by a parallel import		X	N.app. (parallel imports play no important role)	
Allowed to substitute by a parallel import		X	N.app. (parallel imports play no important role)	
Therapeutic / analogous substitution is allowed		X		
Are subject to statutory discounts / rebates		X		
Claw back system exists		X		
May grant rebates to customers		X	Discussion on revocation of prohibition rule at pharmacy level	
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			
Are obliged to inform on co-payment / deductibles		X		
Prescription habits are monitored		X		
Are subject to prescription guidelines		X		

Tasks / Duties	Yes	No	Comment	Legal bases
Budgets are controlled		X		
Allowed to prescribe INN	X			
Obliged to prescribe INN	X			
Can oppose generic substitution	X			
Can oppose therapeutic substitution		X	N.app.	
Can oppose substitution by parallel import		X	N.app.	
Country specific:				
Patients				
Can shop for cheapest price of the product		X		
Pay a flat rate per prescription / pack		X		
Pay a certain percentage per prescription / pack or a deductible		X		
Annual minimum co-payment		X		
Annual maximum co-payment		X		
May ask for substitution by a generic	X			
May oppose substitution by a generic	X		Patient has to pay the difference between the reference price (reimbursement price) and the actual pharmacy retail price	
May ask for substitution by a parallel import		X	N.app. (parallel import do not play a role)	
Can oppose substitution by a parallel import		X	N.app. (parallel import do not play a role)	
Can oppose substitution only on payment of price difference	X			

Tasks / Duties	Yes	No	Comment	Legal bases
Has to pay the difference between reimbursement price and pharmacy retail price	X			
Has access to full public information on prices and products	X		INFARMED	
Country specifics:				

N. app. = Not applicable, N. a. = Not available

Source: ÖBIG 2006

SLOVAKIA

22 Slovakia

22.1 Pharmaceutical System

22.1.1 Regulatory Framework and Authorities

In 1992, Slovakia, a part of Czechoslovakia, became a new, independent state. In the course of this transition a compulsory health insurance system was introduced in 1994. In 2004 Slovakia became a full member of the European Union. In preparation of Slovakia's accession, many reforms were undertaken among those the implementation of the Act on Medicinal Products and Medical Devices[1026].

In the last few years the Slovakian health care system underwent a decentralisation process, however the most relevant bodies in the pharmaceutical system are still on a central level.

The Slovakian health care system is funded through contributions by employers (10%), employees (4%) and by the State paying the contributions for children, retired and the unemployed, accounting for 60% of the population. One of the central challenges for the Slovakian government is the funding of the health care system. In 2002, Slovakia spent 34% of its health expenditure on pharmaceuticals, which is the highest share among all OECD countries. Of this 34%, public sources covered 28% and private sources 6%. Health insurance funds spent nearly 40% of their expenditures on pharmaceuticals in 2003[1027].

The following overview lists the relevant actors in the pharmaceuticals system in Slovakia:

- the Ministry of Health (Ministerstvo Zdravotnicta Státny ùstav pre kontrolu lieciv, MZ SR) - advised by the Categorisation Committee[1028] - being responsible for the general strategic planning in terms of pharmaceuticals, as well as for the decision on reimbursement of pharmaceuticals. Since 2004 the MZ SR also decides on the pricing of pharmaceuticals[1029],
- the State Institute of Drug Control (Štátny Ústav pre Kontrolu Liečiv, SUKL) under the MZ SR, being responsible for the authorisation and classification of pharmaceuticals, as well

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1026 Act No. 140/1998 on Medicinal Products and Medical Devices http://www.health.gov.sk/redsys/rsi.nsf/0/6F6BAA9762770B3EC1256F5D0041331D?OpenDocument

1027 European Observatory on Health Systems and Policy 2004d

1028 Being composed of 5 members of sickness funds, 3 experts from the MZ SR, 2 members of expert associations, members of the specific ATC working groups

1029 Act of Scope No. 759/2004 http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S

as for the vigilance and the examination of market players in the pharmaceutical system (manufacturer, wholesaler and pharmacies) and for switches[1030],

- the 5 sickness funds; with the General Health Insurance (Vseobecná Zdravotná Poistovña, VsZP) covering around 66% of the population[1031].

SUKL grants market authorisations for pharmaceuticals and is then in charge of the classification of the pharmaceuticals according to their prescription status into[1032]:

- POM prescribed by specialists
- POM
- OTC

Table 22.1 contains an overview of the relevant Slovakian stakeholders introduced in section 22.1.1.

Table 22.1: Slovakia - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Ministerstvo Zdravotnicta (MZ SR) / Ministry of Health	Ministry of Health (regulartory body for pharmaceuticals in charge of pricing and reimbursement)	MZ SR Limbova Street 2 P.O. Box 52 SK-837 52 Bratislava Slovakia Tel.: +421 25 9373 111 Fax: +421 25 4777 983 office@health.gov.sk www.health.gov.sk/	Mr. Juraj Sykora Director Limbova Street 2 P.O. Box 52 SK-837 52 Bratislava Slovakia Tel.: +421 25 9373 572 Fax: +421 25 5565 048 Juraj.sykora@health.gov.sk
Ministerstva Financií (MF SR) / Ministry of Finance	Ministry of Finance (until 2004 set the manufacturer price)	MF SR Štefanovičova 5 P.O. Box 82 SK-817 82 Bratislava Slovakia Tel.: +421 25 9581 111 Fax: +421 25 2498 042 podatelna@mfsr.sk http://www.finance.gov.sk	Mr. Peter Papanek Štefanovičova 5 P.O. Box 82 SK-817 82 Bratislava Slovakia Tel.: +421 25 5958 2203 Fax: +421 25 2498 042 tlacove@mfsr.sk

1030 Act No. 140/1998 on Medicinal Products and Medical Devices http://www.health.gov.sk/redsys/rsi.nsf/0/6F6BAA9762770B3EC1256F5D0041331D?OpenDocument

1031 Act on Health Insurance No. 95/2002 Coll. http://www.slaspo.sk/index_en.php?kategoria=10003

1032 Act No. 140/1998 on Medicinal Products and Medical Devices http://www.health.gov.sk/redsys/rsi.nsf/0/6F6BAA9762770B3EC1256F5D0041331D?OpenDocument

Institution	Task	Contact details/URL	Responsible person
Vseobecná Zdravotná Poistovña (VsZP) / General Health Insurance	Third Party Payer, Reimbursement	VsZP Mamateyova 17 P.O.Box 41 SK-850 05 Bratislava 55 Slovakia Tel.: +421 26 7277 111 Fax: +421 26 2412 631 vszp@vszp.sk www.vszp.sk	Mr. Svätopluk Hlavacka President Mamateyova 17 P.O.Box 41 SK-850 05 Bratislava 55 Slovakia Tel.: +421 26 7277 111 Fax: +421 26 2412 631 vszp@vszp.sk
Štátny ústav pre Kontrolu Liečiv (SUKL) / State Institute for Drug Control	Medicines Agency (Market Authorisation, Classification)	SUKL Kvetná 11 SK-825 08 Bratislava 26 Slovakia Tel.: +421 75 5564 127 or +421 75 5421 860 Fax: +421 73 22618 or +421 75 5423 160 sukl@sukl.sk www.sukl.sk	Mr. Jan Mazag Director Kvetná 11 SK-825 08 Bratislava 26 Slovakia Tel.: +421 255 565 081 Fax: +421 255 564 127 mazag@sukl.sk
Slovenská Lekárnická Komora (SLeK) / Chamber of Pharmacists	Association of Pharmacists	SleK Strecnianska 14 SK-851 05 Bratislava Slovakia Tel.: +421 26 3820 086 Fax: +421 26 3824 881 sekretariat@slek.sk www.slek.sk/	Mr. Stefan Krchnak President Strecnianska 14 SK 851 05 Bratislava Slovakia Tel.: +421 26 3820 086 Fax: +421 26 3824 881 sekretariat@slek.sk
Slovenská Asociácia Farmaceutických Spoloèností (SAFS) / Slovak Association of Research-Based Pharmaceutical Companies	Association of Research-Based Pharmaceutical Companies	SAFS Ružová dolina c.6 SK-821 08 Bratislava Slovakia Tel.: +421 25 0221 414 Fax: +421 25 0221 428 Safs@safs.sk www.safs.sk	Ms. Sona Strachotová Director Ružová dolina c.6 SK-821 08 Bratislava Slovakia Tel.: +421 25 0221 414 Fax: +421 25 0221 428 Safs@safs.sk
Slovak Medical Association	Slovak Medical Association	Slovak Medical Association Legionárska 4, SK-813 22 Bratislava Slovakia Tel.: +421 25 5424 015 Fax: +421 25 5422 363 secretarysma@ba.telecom.sk	Mr. Peter Pružinec Legionárska 4, SK-813 22 Bratislava Slovakia Tel.: +421 25 5424 015 Fax: +421 25 5422 363 secretarysma@ba.telecom.sk

Institution	Task	Contact details/URL	Responsible person
Asociácia na ochranu práv pacientov SR (AOPP) / Association for the protection of patients' rights	Patients' Association	AOPP Prešovská 39, SK-821 08 Bratislava Slovakia Tel.: +421 25 5576 561 Fax: +421 25 5576 561 http://www.aopp.sk/ aopp@zoznam.sk	Ms. Eva Madajová Prešovská 39, SK-821 08 Bratislava Slovakia Tel.: 42 0905 463 515 Fax: +421 25 5576 561 aopp@zoznam.sk
Asociácia Dodávatel ov Liekov A Zdravotníckych Pomôcok (ADL) / Association of Drugs and Healthcare Equipment suppliers	Wholesale Association	ADL Heydukova 1, SK-811 08 Bratislava Slovakia Tel.: +421 25 2962 412 Fax: +421 25 2631 188 / 87 http://www.adl.sk/ adl@adl.sk	Mr. Ján Hajdúch Heydukova 1, SK-811 08 Bratislava Slovakia Tel.: +421 25 2962 412 Fax: +421 25 2631 188 / 87 http://www.adl.sk/

Source: ÖBIG 2006

22.1.2 Market Players

22.1.2.1 Pharmaceutical Industry

After transition, Slovakia had a privatisation process in the public pharmaceutical production and distribution sector. So consequently 15 years ago, local production counted for 80% of the pharmaceutical market, whereas in 2002 it only counted for 18%. The leading Slovakian manufacturer is Zentiva/Slovakofarma[1033], which mainly produces generics especially for cardiovascular diseases and gastro-intestinal diseases.

There are 40 locally producing pharmaceutical companies (mainly generics) and 40 to 50 subsidiaries of international pharmaceutical companies. Most of them are represented in the Association of Research-Based Pharmaceutical Companies (Slovenská Asociácia Farmaceutických Spoloèností, SAFS[1034]).

22.1.2.2 Distribution

On the wholesale level Slovakia is organised in a multi-channel system with 36 mainly private wholesalers operating on the pharmaceutical market, however 11 wholesale companies dominate the market (95% of the pharmaceutical sales). Important wholesalers are Fides, Unipharma and Med-Art.

[1033] www.zentiva.sk

[1034] http://www.safs.sk/En/index_en.html

Pharmaceuticals in Slovakia are mainly sold through pharmacies. There are about 1,164 private pharmacies and 88 state-owned hospital pharmacies. Only pharmacists are allowed to open and own pharmacies. Multiple ownership of pharmacies is not allowed.

Self-dispensing doctors are not allowed.

In 2001 the MZ SR published a "Good pharmacy" guide[1035]. The pharmacists are represented in the Pharmacist's Association (Slovenská Lekárnická Komora, SLeK[1036]).

Table 22.2 gives on overview of the pharmaceutical distribution in Slovakia.

Table 22.2: Slovakia - Pharmaceutical Distribution, 2004

Actors of pharmaceutical distribution	2004
Pharmaceutical Industry	~ 90[1]
Wholesalers	36
Pharmacies	1,164[2]
Inhabitants per pharmacy	4,621[2]

[1] Around 40 - 50 research-based pharmaceutical companies and around 40 locally producing pharmaceutical companies

[2] Year 2002

Source: ÖBIG 2005

22.1.2.3 Patients

The role of patients in the choice of pharmaceuticals is rather minor. Patients are usually informed on pharmaceuticals by their doctors. They have also got the possibility to inform themselves about the prices of pharmaceuticals on the website of VSZP[1037] (cf. 22.2.4). Patients have to pay a fix co-payment of SKK 20 / € 0.48 per prescription (cf. 22.2.3).

Their interests are represented in individual associations, such as associations for asthma, allergy and heart diseases, as well as in the Association for the protection of patients' rights (Asociácia na ochranu práv pacientov, AOPP).

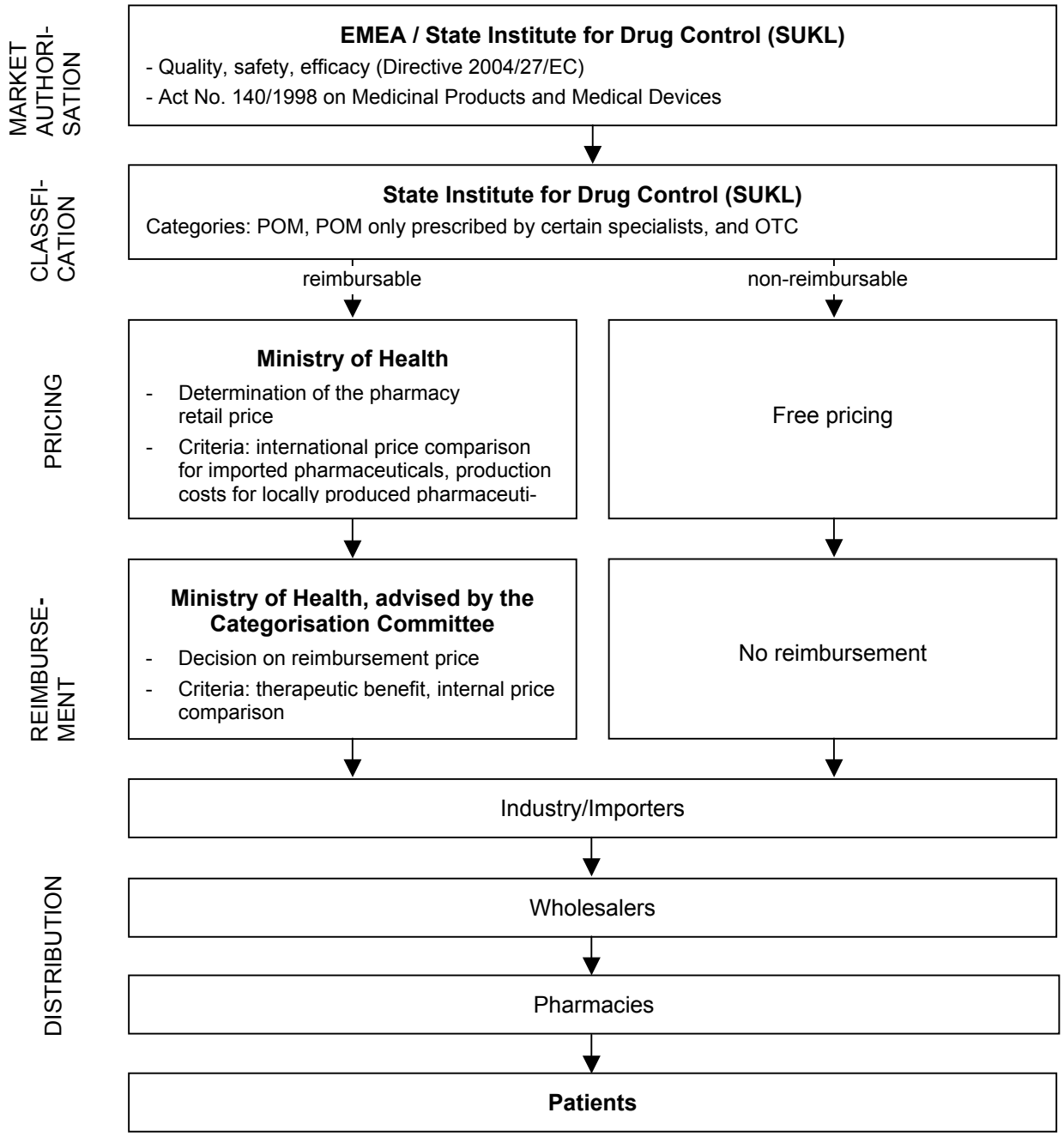
[1035] Public Notice No. 198/2001

[1036] www.slek.sk/

[1037] http://www.vszp.sk/showdoc.do?docid=81

22.1.3 Overview of the Pharmaceutical System

Figure 22.1: Slovakia - Pharmaceutical System, 2006



POM = Prescription-only Medicines, OTC = Over-the-Counter

Source: ÖBIG 2006

22.2 Pricing

22.2.1 Scope of Price Control

Since autumn 2004 the MZ SR has been setting the pharmacy retail prices for reimbursable pharmaceuticals (original products as well as generics). There is free pricing at manufacturer level for non-reimbursable pharmaceuticals. For wholesalers and pharmacies, there are maximum mark-ups for all pharmaceuticals, which were last changed in July 2005 (cf. 22.2.1.2 and 22.2.1.3).

There are no special regulations on pricing for generics. In reality the prices of generics are 20% to 80% lower than the original product.

Table 22.3 provides a concise overview of the Slovakian pricing system.

Table 22.3: Slovakia - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Non-reimbursable pharmaceuticals (mostly OTC)	Not applied	Not applied
Statutory Pricing	Reimbursable pharmaceuticals[1]	All pharmaceuticals regulated via a maximum mark-up scheme	All pharmaceuticals regulated via a maximum mark-up scheme
Price Negotiations	Not applied	Not applied	Not applied
Price/volume agreements, discounts/rebates	No	No	No
Institution in charge of pricing	- MZ SR - Criteria: international price comparison for imported pharmaceuticals, production costs for locally produced pharmaceuticals		
Legal Basis	- Act of Scope No 759/2004		

[1] Inclusive the possibility for the manufacturer to deliver a second (lower) price proposal within 2 weeks (“agreed prices”)

Source: ÖBIG 2006

22.2.1.1 Manufacturer Price

In 2004 major reforms in the pricing and reimbursement system took place (cf. 22.3.1). The reforms of the pricing system in 2004 contained a shift in the decision making power from the MF SR to the MZ SR. The MF SR used to set the prices at the manufacturer level, which were then “deregulated”, meaning that now the MZ SR sets the pharmacy retail price. The manufacturer price is still indirectly regulated through the maximum wholesale and pharmacy mark-ups.

Manufacturers have to submit an application for a maximum pharmacy retail price to the MZ SR. Pricing applications can be submitted four times a year in the months of February, May, August and November. These price proposals are then published on the website of MZ SR[1038]. After two weeks, the pharmaceutical companies again submit a price proposal, which can be the same as the first one or below. Due to strategic thinking (e.g. published price proposals of competitors) pharmaceutical companies very often lower their second price proposal. No further adjustments are allowed after the second round. The Categorisation Committee then sets the maximum retail prices (which corresponds to the reimbursement price, cf. 22.3.1.1) according to the "agreed" prices. In case that the price of a pharmaceutical is too high, the Categorisation Committee decides either not reimburse the pharmaceutical or only partially. After setting of the maximum pharmacy retail price, the manufacturer may apply for reimbursement (cf. 22.3).

In the course of cost-containment measures in 2003, the MZ SR implemented the above described concept of "agreed" price.

The manufacturer has to provide different data for the application depending on whether the pharmaceutical is *imported* or *locally* produced[1039].

- For *locally* produced pharmaceuticals the production costs are the basis for the price calculations.
- For imported pharmaceuticals the pharmaceutical company has to submit price data from nine selected European countries: the country of manufacture, Czech Republic, France, Hungary, Austria, Germany, Spain, Italy and Poland. In reality a special focus is given on Poland, Czech Republic and Hungary. If data for one country are not available, then that country is not considered in the price comparison. The MZ SR asks the pharmaceutical companies for an official proof of the accuracy of the data. The maximum price corresponds to the average of the prices of the three cheapest pharmaceuticals plus a mark-up of 10%.

This pricing system is only applicable for reimbursable pharmaceuticals. Prices of generics are set in the same way; there is no special regulation for generic prices (cf. 22.3.4.2).

Manufacturers can submit applications to increase the price of the pharmaceutical once a year. The application needs to be justifiable taking into account an increase in production costs or changes in exchange rates of more than 5%. Even if a price change seems justified, the MZ SR is under no obligation to grant the requested adjustment.

1038 http://www.health.gov.sk/

1039 Act of Scope No. 759/2004
http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S

22.2.1.2 Wholesale Price

The MZ SR sets maximum wholesale and pharmacy mark-ups for all pharmaceuticals. There are different mark-ups depending if the pharmaceuticals is very expensive, or used for vaccination, or non-reimbursable.

Table 22.4 gives an overview of the maximum wholesale and pharmacy mark-ups.

Table 22.4: Slovakia - Maximum Wholesale and Pharmacy Mark-up Scheme (as of 1.7.2005)[1040]

Categories	Wholesale[1]	Pharmacy[1]
Pharmaceuticals in the outpatient sector		
Authorised, reimbursable pharmaceuticals	11%	21%
Authorised, reimbursable "F" pharmaceuticals (innovative, often expensive[2] pharmaceuticals)	4%	6%
Authorised, reimbursable "V" pharmaceuticals (vaccination)	5%	7%
Authorised, non-reimbursable pharmaceuticals (mainly OTC)	5%	15%
Hospital-only pharmaceuticals	10%	

[1] Maximum price in % of the manufacturer or importer price

Source: Act of Scope No 759/2004; Vestnik 2005

22.2.1.3 Pharmacy Retail Price

As it has already been mentioned in section 22.2.1.1, the MZ SR sets the pharmacy mark-ups. The pharmacy mark-ups are added onto the manufacturer price. Table 22.4 gives an overview of the pharmacy mark-ups.

22.2.1.4 Value Added Tax (VAT)

The VAT rate for pharmaceuticals used to be 14% and the standard VAT rate 20%.

In 2004 the VAT rate for pharmaceuticals increased to 19%, which is also the standard VAT rate.

[1040] Ministry of Health http://www.health.gov.sk/redsys/rsi.nsf/0/3e6b545e2697a78cc1256f970033e1b0/$FILE/Vestnik_MZSR_041_2005.pdf

22.2.2 Price Related Cost-containment Measures

22.2.2.1 Pharmaco-economic Evaluation

In Slovakia pharmaco-economic evaluation does not play an important role. Only a few pharmaco-economic studies have been conducted.

Pharmaceutical companies need to submit cost-effectiveness data, when they apply for the maximum price and for reimbursement. At the moment there are discussions to include pharmaco-economic criteria in the decision process of pricing and reimbursement.

In 2003, the MZ SR started to implement cost-containment measures, such as pharmaceutical budgets for doctors (cf. 22.3.3).

22.2.2.2 Internal Price Referencing

Internal price referencing is the major method to determine the reimbursement price of a pharmaceutical in Slovakia. There is a mix of therapeutic referencing (i.e. comparisons of similar pharmaceuticals on ATC 4 level) and comparison on ATC 5 level (= active ingredient) applied.

The procedure is explained in detail in the section on the reference price system (cf. 22.3.2).

22.2.2.3 External Price Referencing / Cross Country Referencing

As it has been explained in section 22.2.1.1 there is external price referencing for imported pharmaceuticals. External price referencing is also applied in the reimbursement system.

22.2.2.4 Price Freezes / Stops

In Slovakia, there have been no price freezes[1041].

22.2.2.5 Margin Cuts

In July 2005 the mark-up scheme changed[1042] from a linear mark-up to a scheme with different mark-ups according to reimbursement status and scope of pharmaceutical.

22.2.2.6 Discounts and Rebates

In Slovakia, there are no official regulations for rebates or discounts. Additionally, there is the possibility of granting rebates or discounts on a voluntary basis.

[1041] SUKL, personal communication, April 2005

[1042] Ministry of Health
http://www.health.gov.sk/redsys/rsi.nsf/0/3e6b545e2697a78cc1256f970033e1b0/$FILE/Vestnik_MZSR_041_2005.pdf

22.2.2.7 Parallel Trade

Parallel trade currently plays no role, therefore there are no specific regulations in place for parallel imported pharmaceuticals. Slovakia is more an export than an import country.

22.2.3 Co-Payments

Along with the reforms of the reimbursement system in 2004 (cf. 22.3.1), a new legislation has been introduced forcing patients to pay additional fees for various services, among those also prescription fees[1043]. Patients must pay SKK 20.- / € 0.48 per prescription, of which SKK 15.- / € 0.36 is kept by the health insurance and SKK 5.- / € 0.12 by the pharmacist.

Since the patient co-payment was introduced, GP visits have dropped 30%, appointments with specialists 25% and hospital stays 25%. However, there are concerns from consumer associations that these additional fees have created a burden to health care services for people with lower income.

22.2.4 Information Transparency and Marketing

In Slovakia prices of pharmaceuticals are accessible. The positive list used to be published as an annex of the Act of Scope[1044]; nowadays the prices are published in the form of Ministerial Decrees. Additionally, VSZP publishes the prices of the positive list[1045]. There is also a list of authorised pharmaceuticals publicly available by SUKL which is updated on a regularly basis[1046].

According to Slovak legislation[1047], which is in line with the EU provision on advertising[1048], advertising in media to the general public is not allowed for reimbursable pharmaceuticals, for pharmaceuticals not authorised in Slovakia, and for pharmaceuticals containing narcotic, psychotropic and other addictive substances. Furthermore, advertising should not include information on prices of the pharmaceutical and information leading to erroneous self-diagnosis. In general, doctors, pharmacies and pharmaceutical companies are allowed to inform patients about the characteristics of pharmaceuticals.

1043 Act No. 577/2004 http://www.health.gov.sk/redsys/rsi.nsf/0/1A0395EF0A7C88CAC1256F7E0043EEC7?OpenDocument

1044 Act of Scope No. 759/2004 http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S

1045 http://www.vszp.sk/showdoc.do?docid=81

1046 http://monitor.isa/480744200/1499128T060309134913.txt.binXMysM0dapplication/mswordXsysM0dhttp://www.sukl.sk/sukl_eu.doc, http://www.sukl.sk/

1047 Act No. 140/1998 on Medicinal Products and Medical Devices, amended by Law No. 147/2001 and Law No. 308/2000

1048 Title VII of the Community Code, Directive 92/28/EC

On the one hand the MZ SR and SUKL strictly control marketing and advertising actives, and on the other hand the pharmaceutical industry itself has its own voluntary control of sales promotion activities[1049].

22.3 Reimbursement

In Slovakia reimbursement is a combination of different reimbursement categories and a reference price system[1050] (cf. 22.3.2).

The process of reimbursement may only commence once a maximum retail price has been approved (cf. 22.2.1.1), then the manufacturer may submit an application for reimbursement to MZ SR: The MZ SR, advised by the Categorisation Committee, decides on the level of reimbursement and on any prescribing or indication limitations (cf. 22.2.1.1). The application needs to include basic information about the pharmaceutical (such as the name of the pharmaceutical, manufacturer and authorisation holder, the pharmaceutical form, pack size and strength), as well as information on the effectiveness of the pharmaceutical and its DDD.

22.3.1 Pharmaceutical Lists and Reimbursement Categories

Until 1995 all pharmaceuticals were fully reimbursed. This had led to a tremendous increase in pharmaceutical expenditure. Therefore the Act of Scope, which is the legal basis for reimbursement, was reformed in 1995 and then again in 2004. In the course of these reforms a **positive list** for the outpatient sector and a positive list for inpatient sector was implemented. As it is mentioned in section 22.2.4, the positive lists used to be published as an annex of the Act of Scope[1051]; nowadays they are published in the form of ministerial decrees, as well as on the website of VSZP[1052].

Pharmaceuticals in the outpatient sector are subdivided into three categories[1053]:

- I: full reimbursement - including vital pharmaceuticals (such as cytostatics and basic antibiotics) and at least one pharmaceutical in each ATC group listed in the reference price system (cf. 22.3.2)

1049 Act No. 140/1998 on Medicinal Products and Medical Devices

1050 Act of Scope No. 759/2004
http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S

1051 Act of Scope No. 759/2004
http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S

1052 http://www.vszp.sk/showdoc.do?docid=81

1053 Act 98/1995
http://www.health.gov.sk/redsys/rsi.nsf/0/566BB5273057A345C1256D2F00379BA7?OpenDocument

- S: partial reimbursement - including some generics or other equivalent original products
- N: no reimbursement - including OTC products and pharmaceuticals, where no proof of a therapeutic benefit could be found

Additionally, there is a “fast-track” reimbursement process for pharmaceuticals with the same active ingredient as a pharmaceutical already included in the positive list. In that case the pharmaceutical company accepts a 10% lower reimbursement price.

22.3.1.1 Reimbursement Price

The maximum pharmacy retail prices are set by MZ SR and correspond to the reimbursement prices (cf. 22.2.1.1).

Partial reimbursement is not linked to specific reimbursement categories, but the level of reimbursement and thus the reimbursement price is individually set per pharmaceutical. The criteria mentioned in section 22.3.1.2 are relevant for the level of reimbursement.

22.3.1.2 Selection Criteria

The reimbursement level is based on the following criteria[1054]:

Therapeutic benefit of the pharmaceutical

Production cost of the pharmaceutical

Reimbursed reference price for all comparable pharmaceuticals of the respective ATC group (cf. 22.3.1)

An affordable co-payment on the basis of the “agreed” price (cf. 22.2.1.1)

22.3.1.3 Pharmaceuticals on Positive List

In 1995, when the reimbursement categories of the positive list were first implemented, there were around 40% of all pharmaceuticals in category “full reimbursement”, 27% in “partial reimbursement” and 9% in “no reimbursement”. The remaining 24% were hospital-only pharmaceuticals. Nowadays (2005) only every 10% of all pharmaceuticals are fully reimbursed, around half are partially reimbursed and a quarter is not reimbursed.

There are around 5,600 pharmaceuticals on the positive list, this corresponds to around 75% pharmaceutical on the market.

[1054] Act of Scope No. 759/2004
http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S

22.3.1.4 Generics

Estimates suggest that generics, including not-bioequivalent copy products, account by value for around 30% of the market.

Generic substitution is not permitted in Slovakia. Nevertheless, there are discussions that it might be introduced in future.

22.3.1.5 Non-reimbursable Pharmaceuticals

If a product does not qualify for reimbursement, e.g. because a medicinal-therapeutically equal but cheaper treatment alternative is available, which the patient refuses; doctors still may prescribe it and patients may purchase it at their own expense.

22.3.1.6 Delisting and Switches

SUKL is responsible for the switch process (POM to OTC). It receives applications from manufacturers asking to change the prescription status of a pharmaceutical. SUKL then evaluates the application and makes a decision. It follows the criteria of the EU guidelines for switches[1055].

22.3.2 Reference Price System

In 1995, a reference price system was introduced[1056].

In order to set maximum reimbursement prices, all pharmaceuticals on the market are clustered into therapeutic groups based on ATC 5 level (same active ingredient) and ATC 4 level (therapeutically similar products). In the course of the reforms of 2003, the number of ATC groups were radically reduced to 122 groups, thus having more pharmaceuticals in a group. In each ATC group at least one pharmaceutical is fully reimbursed.

For the calculation of the reference price of a group, usually the price per DDD of the cheapest available pharmaceutical is taken. Reimbursement prices for pharmaceuticals can occasionally be set at a different level from the reference price, in order to limit additional payments for pharmaceuticals in the same group with price differences.

In the past, the outcomes of the categorisation process have been reviewed on an annual basis. From 2004 on, the MZ SR intends to increase the frequency of the categorisation process to four times a year. The quarterly reviews will concentrate on the relevant ATC groups (e.g. in the case of a higher reimbursement price and for new pharmaceuticals).

[1055] 2006 EU guideline on changing the classification for the supply of a medicinal product for human use http://pharmacos.eudra.org/F2/eudralex/vol-2/C/switchguide_160106.pdf

[1056] Act 98/1995 http://www.health.gov.sk/redsys/rsi.nsf/0/566BB5273057A345C1256D2F00379BA7?OpenDocument

22.3.3 Pharmaceutical Budgets

In 1995, the first version of the “guidelines on the prescribing and reimbursement expenditure of medicinal products” was issued by the VsZP[1057].

In the course of the reforms of 2003, the MZ SR implemented further prescribing controls, such as pharmaceutical budgets (for pharmaceuticals and medical services) for doctors. The sickness funds negotiate monthly or quarterly maximum prescribing limits (cf. 22.3.4.1) with the contract doctors. With the introduction of pharmaceutical budgets along with co-payments and the reference price system, the MZ SR is trying to reduce pharmaceutical expenditure.

22.3.4 Other Volume Control Oriented Measures

22.3.4.1 Prescription Monitoring and Other Doctors-related Measures

Contract doctors are monitored by prescription habits as well as are subject to prescription guidelines by the VSZP[1058].

22.3.4.2 Generics

As it has already been mentioned in section 22.3.1.4, in Slovakia the generic share by value is 30%.

As stated in section 22.3.1.4 generic substitution is not permitted.

[1057] http://www.vszp.sk/showdoc.do?docid=4

[1058] http://www.vszp.sk

22.4 Overview of the Reimbursement Market in Slovakia

Tasks / Duties	Yes	No	Comment	Legal bases
Public authorities				
Decide on prescription status	X		SUKL under the MZ SR	Act No. 140/1998 on Medicinal Products and Medical Devices http://www.health.gov.sk/redsys/rsi.nsf/0/6F6BAA9762770B3EC1256F5D0041331D?OpenDocument
Decide on manufacturer price	(X)		Indirectly through the maximum wholesale and pharmacy mark-ups	Act No. 140/1998 on Medicinal Products and Medical Devices http://www.health.gov.sk/redsys/rsi.nsf/0/6F6BAA9762770B3EC1256F5D0041331D?OpenDocument
Agree on manufacturer price		X		
Fix wholesale margin	X		MZ SR sets maximum wholesale mark-ups	Act of Scope No. 759/2004 http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S
Fix pharmacy retail price	X		MZ SR sets maximum pharmacy mark-ups	Act of Scope No. 759/2004 http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S
Decide on reimbursement status	X		MZ SR advised by the Categorisation Committee	Act of Scope No. 759/2004 http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S
Agrees on reimbursement price		X		
Decide on reimbursement price	X		MZ SR advised by the Categorisation Committee	Act of Scope No. 759/2004 http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S
Use Pharmaco-economic guidelines		X	No clear guidelines	
Use Internal reference pricing	X		Reimbursement decision	Act 98/1995 http://www.health.gov.sk/redsys/rsi.nsf/0/566BB5273057A345C1256D2F00379BA7?OpenDocument

Tasks / Duties	Yes	No	Comment	Legal bases
Use External reference pricing	X		Pricing decision for imported pharmaceuticals on the manufacturer level, as well as for the reimbursement process	Act of Scope No. 759/2004 http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S
Price freezes			N.app.	
Margin cuts	X		In 2005	Ministry of Health http://www.health.gov.sk/redsys/rsi.nsf/0/3e6b545e2697a78cc1256f970033e1b0/$FILE/Vestnik_MZSR_041_2005.pdf
Discounts and Rebates		X		
Company profit control	X		Locally manufactured pharmaceuticals	
Country specific:				
Pharmaceutical Industry				
Sets manufacturer price freely	X		Only for non-reimbursable OTC	Act of Scope No. 759/2004 http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S
Notifies manufacturer price		X		
Negotiates manufacturer price		X		
Is free to set price below fixed manufacturer price	X			
Decides on application for reimbursement	X			Act of Scope No. 759/2004 http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S
Negotiates reimbursement price		X		
Free to keep manufacturer price above reimbursement price		X		
Free to grant rebates / discounts to wholesalers	X		On a voluntary basis	

Tasks / Duties	Yes	No	Comment	Legal bases
Free to grant rebates / discounts to pharmacies	X		On a voluntary basis	
Can engage in marketing towards doctors	X		In line with the code of conduct	
Can engage in public advertising	X		Only for OTC	
Can provide information toward patients	X			
Applies for switches and de-listing	X		At SUKL	Act No. 140/1998 on Medicinal Products and Medical Devices http://www.health.gov.sk/redsys/rsi.nsf/0/6F6BAA9762770B3EC1256F5D0041331D?OpenDocument
Promotional control		X		
Country specific:				
Distribution chain				
Wholesaler				
Margins are fixed by statute	X		MZ SR sets maximum wholesale mark-ups	Act of Scope No. 759/2004 http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S
Margins are subject to statutory discounts / rebates		X		
Free to grant discounts / rebates to pharmacies	X		On a voluntary basis	
Pharmacists				
Margins are fixed by statute	X		MZ SR sets maximum pharmacy mark-ups	Act of Scope No. 759/2004 http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S
Free to set retail price		X		
Obliged to inform patient on cheaper product	X			
Obliged to substitute by a generic		X		
Allowed to substitute by a generic		X		

Tasks / Duties	Yes	No	Comment	Legal bases
Obliged to substitute by a parallel import			N.app.	
Allowed to substitute by a parallel import			N.app.	
Therapeutic / analogous substitution is allowed		X		
Are subject to statutory discounts / rebates		X		
Claw back system exists			N.app.	
May grant rebates to customers		X	Only informal rebates are possible	
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			
Are obliged to inform on co-payment / deductibles	X			
Prescription habits are monitored	X		By the VSZP, only for contract doctors	http://www.vszp.sk
Are subject to prescription guidelines	X		By the VSZP, only for contract doctors	http://www.vszp.sk
Budgets are controlled	X		Implemented in 2003 by MZ SR	
Allowed to prescribe INN	X			
Obliged to prescribe INN		X		
Can oppose generic substitution			N.app.	
Can oppose therapeutic substitution			N.app.	
Can oppose substitution by parallel import			N.app.	
Country specific:				
Patients				

Tasks / Duties	Yes	No	Comment	Legal bases
Can shop for cheapest price of the product	X		OTC	
Pay a flat rate per prescription / pack	X		Patients must pay SKK 20 / € 0.48 per prescription	Act No. 577/2004 http://www.health.gov.sk/redsys/rsi.nsf/0/1A0395EF0A7C88CAC1256F7E0043EEC7?OpenDocument
Pay a certain percentage per prescription / pack or a deductible		X		
Annual minimum co-payment		X		
Annual maximum co-payment		X		
May ask for substitution by a generic		X		
May oppose substitution by a generic		X		
May ask for substitution by a parallel import			N.app.	
Can oppose substitution by a parallel import			N.app.	
Can oppose substitution only on payment of price difference	X			
Has to pay the difference between reimbursement price and retail price	X		Difference between reference and pharmacy retail price	
Has access to full public information on prices and products	X		In Ministerial Decrees as well as on the website of VSZP	http://www.vszp.sk/showdoc.do?docid=81
Country specifics:				

N. app. = Not applicable, N. a. = Not available

Source. ÖBIG 2006

SLOVENIA

23 Slovenia

23.1 Pharmaceutical System

23.1.1 Regulatory Framework and Authorities

In Slovenia the health care system is based on a health insurance system. The National Health Insurance Fund (Zavod za zdravstveno zavarovanje Slovenjie, ZZZS) provides universal coverage for the entire population at primary, secondary and tertiary level. Health care is financed through payroll-based contributions from employers and employees and contributions of self-employed, farmers and for pensioners. In addition there are voluntary private insurance companies mainly covering co-payments. The Law on Health Care and Health Insurance states the basis for the present system of compulsory and voluntary health insurance.[1059]

Primary care is mainly provided in municipality health centres or small health care stations where doctors with contracts with the health insurance work. General practitioners act as gatekeepers to the specialist services. They are remunerated on a capitation fee basis and a fee-for service basis. Specialists mainly work in public hospitals and polyclinics.

The most relevant players in the Slovenian pharmaceutical system are:

- The Ministry of Health (Ministrstvo za zdravstvo, MZ) who is responsible for preparing legislation for health care and health protection and for ensuring regulation and supervision of the implementation of legislation. The MZ furthermore is in charge of supervising the production, trade and supply of pharmaceuticals. The MZ is consulted by the National Chemicals Bureau, Office for medicinal products and Health Inspectorate concerning pharmaceuticals decisions.
- The Agency of Medicinal Products and Medical Devices (Agencija Republike Slovenije za zdravila in medicinske pripomočke, ARSZMP) is responsible for marketing authorisation, registration, classification and pricing of pharmaceuticals.[1060]
- The Health Council is the highest coordination expert body of health care, advising the Minister and formulating health programs with regard to their feasibility and access to health care services.
- The National Health Insurance Fund (ZZZS) provides compulsory health insurance but also a voluntary private insurance for the population. The ZZZS is responsible for reim-

[1059] Law on Health Care And Health Insurance. Official Gazette of the Republic of Slovenia, 9: 590-601 (1992), http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

[1060] Law on Pharmaceutical and Medical Supplies, Official Gazette of the Republic Slovenia (RS), No. 101/99, No. 7/02, No. 13/02-Zkrimi, No. 67/02 and No. 47/04, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

bursement of pharmaceuticals. More precisely the Drug Committee at ZZZS takes decision on reimbursement and reimbursement category as well as the status of pharmaceuticals as innovative and orphan.

- Voluntary health insurance which covers mainly co-payments due to the provision of pharmaceuticals by the ZZZS is offered by three institutions. The ZZZS is by far the largest insurance company. The two other insurance companies are Adriatic and Triglav zdravstvena zavarovalnica. Approximately 90% of the population are covered by voluntary health insurance. The billing with the voluntary insurance takes place directly via the pharmacies. The insurance company pays the fee-for-service directly to the pharmacy (cf. 23.3.1.3)

In February 2004 the ARSZMP was founded as a constitutive body of the MZ on the basis of the Medicinal Products and Medical Devices Act[1061] and the General Administrative Procedure Act[1062]. This agency is successor of the former Office for Medicinal Products which was established in the year 1996.

ARSZMP is responsible for the market authorisation and registration in accordance with the Medicinal Products and Medical Devices Act[1063] mentioned before. The basic provision for market authorisation for all pharmaceuticals are defined in The Regulation Defining the Provision of Marketing Authorisation for Medicinal Products, Gazette No. 67/00 and Gazette No. 60/04.[1064] The national list of authorised pharmaceuticals, semi-annual lists of mutually interchangeable pharmaceuticals[1065], as well as the register of nationally registered medical devices are published by the ARSZMP. ARSZMP is also responsible for pricing (cf. 23.3.1).The basic law is the Medicinal Products and Medical Devices Act[1066], which is fully compliant with EU provisions. The Pharmaceutical Pricing Act has been updated in 2005 and is published in Official Gazette of the RS, No. 96/2005 and No. 106/05.

1061 Medicinal Products and Medical Devices Act (1999), Official Gazette of the RS, No. 71/03, No. 51/04 and No. 47/02, No. 75/03 and No. 51/04, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

1062 Organization and Systemization Act 2004, Zakon o splošnem upravnem postopku (uradno prečiščeno besedilo) / ZUP-UPB1 / Official Gazette of the RS, No. 22/2005), http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

1063 Medicinal Products and Medical Devices Act (1999), Official Gazette of the RS, No. 71/03, No. 51/04 and No. 47/02, No. 75/03 and No. 51/04, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

1064 The Regulation Defining the Provision of Marketing Authorisation for Medicinal Products, Official Gazette of the RS, No. 67/00 and updated version Official Gazette of the RS, No. 60/04, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

1065 List of mutually interchangeable pharmaceuticals, http://www2.gov.si/mz/mz-splet.nsf/V/KD4F204EDA9237E19C1256FD600367D9C/$file/seznam_MZZ.pdf

1066 The Medicinal Products and Medical Devices Act, http://www2.gov.si/mz/mz-splet.nsf/V/K2E80F4C58367137DC1256FB1004AEC00/$file/Medicinal Products and Medical Devices Act.pdf

The ZZZS was founded in March 1992, according to the Law on Health Care and Health Insurance.[1067] The institute was created as a public not-for-profit organisation strictly supervised by the state and bound by statute to provide compulsory health insurance to the population. ZZZS has 55 branch offices altogether, including 10 at the regional and 46 at the local level.

Table 23.1 contains an overview of relevant Slovenian stakeholders.

Table 23.1: Slovenia - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Ministrstvo za zdravstvo (MZ) / Ministry of Health	Ministry of Health (Regulatory Body for Pharmaceuticals)	Ministry of Health Štefanova ulica 5 SI-1000 Ljubljana Slovenia Tel.: +386 61 1786 001 Fax: +386 61 1786 058 gp.mz@gov.si www2.gov.si/mz/mz-splet.nsf	Mr. Janez Janša Štefanova ulica 5 SI-1000 Ljubljana Slovenia Tel.: +386 61 1786 001 Fax: +386 61 1786 058
The National Health Insurance Fund (ZZZS)	Third Party Payer, Pricing and Reimbursement	ZZZS Miklošiceva 24 SI-1507 Ljubljana Slovenia Fax: + 386 13 0772 21 kzz@zzzs.si www.zzzs.si/	Mr. Juri Fürst Head of Department of Pharmaceutical Products Miklošiceva 24 SI-1507 Ljubljana Slovenia Tel.: +386 1 30 77 230 Fax: +386 13 0772 21 Doroteja.novak-gosaric@zzzs.si
Agencija Republike Slovenije za zdravila in medicinske pripomočke (ARSZMP) / Agency for Medicinal Products and Medical Devices of the Republic	Medicines Agency (Authorisation, Vigilance, Pricing, etc.)	ARSZMP Maly trg 6 SI-1000 Ljubljana Slovenia Tel.: +386 1 47862 40 Fax: +386 1 47862 60 gp-arszmp.mz@gov.si http://www2.gov.si/mz/mz-splet.nsf/f1?OpenFrameSet&Frame=main&Src=/mz/mz-splet.nsf/0/6A4C3562F6E310A4C1256B1E004D1B8F?OpenDocument	Mr. Stanislav Primožič Director Maly trg 6 SI-1000 Ljubljana Slovenia Tel.: +386 1 47862 40 Fax: +386 1 47862 60 Stanislav.primozic@gov.si

[1067] Law on Health Care And Health Insurance. Official gazette of the RS, 9: 590-601 (1992)

Institution	Task	Contact details/URL	Responsible person
Lekova Domaca Lekarna / The Slovenian Pharmaceutical Manufacturers Association (SPMA)	Association of Manufacturers	SPMA Verovskova 57, P.O. Box 81 SI-1526 Ljubljana Slovenia Tel.: +386 61 3483 93 Fax: +386 61 1683 517 info@zpzs-giz.si	SPMA Verovskova 57, P.O. Box 81 SI-1526 Ljubljana Slovenia Tel.: +386 61 3483 93 Fax: +386 61 1683 517 info@zpzs-giz.si
GZS Zdruzenje za trgavino / Chamber of Commerce and Industry of Slove-nia, Trade Asso-ciation - Section of Wholesalers of Pharmaceutical and Medical devices	Association of Full-line Pharmaceutical Wholesalers	GZS Dimiceva 13 SI-1000 Ljubljana Slovenia Tel.: + 386 15 8982 16 Fax: + 386 15 8981 9 infolink@gzs.si www.gzs.si/eng/	Barbara Krivic Dimiceva 13 SI-1000 Ljubljana Slovenia Tel.: + 386 15 8982 16 Fax: + 386 15 8981 9 Barbara.krivic@gzs.si
Lekarniska Sborni-ca Slovenije / Slovenian Cham-ber of Pharmacy	Association of Pharmacists	Slovenian Chamber of Pharmacy Ulica stare pravde 11 SI-1000 Ljubljana Slovenia Tel.: +386 61 1324 321 Fax: +386 61 1318 168 lek-zbor@lek-zbor.si www.lek-zbor.si	Mr. Remskar Ulica stare pravde 11 SI-1000 Ljubljana Slovenia Tel.: +386 61 1324 321 Fax: +386 61 1318 168
Zdravniska Sbor-nica Slovenije / Slovenian Medical Association	Medical Doctors´ Association	Slovenian Medical Association Komenskega 4 SI-61001 Ljubljana Slovenia Tel.: + 386 61 3234 69 Fax: + 386 61 3019 55	Ms. Marija Cevc General Secretary Komenskega 4 SI-61001 Ljubljana Slovenia Tel.: + 386 61 3234 69 Fax: + 386 61 3019 55
Zavod za farmacijo in za preizkušanje zdravil (ZAF) / Institute of Phar-macy and Drug research	Institute of Pharmacy and Drug Research	ZAF Ptujska ulica 21 SI-1000 Ljubljana Slovenia Tel.: +386 13 0037 00 Fax: +386 13 0037 01 www.zaf.si	Mrs. Cvelbar Ptujska ulica 21 SI-1000 Ljubljana Slovenia Tel.: +386 13 0037 00 Fax: +386 13 0037 01 martina.cvelbar@zaf.si

Institution	Task	Contact details/URL	Responsible person
Mednarodni forum znanstveno raziskovalnih farmacevtskih družb, (GIZ) / Slovenian Forum of International Research and Development Pharmaceutical Industries	Pharmaceutical industry Association	GIZ Smartinska cesta 140 SI-1000 Ljubljana Slovenia Tel.: +386 15 2042 07 Fax: +386 15 2043 49 www.firdpc.com	Ms. Burnik Smartinska cesta 140 SI-1000 Ljubljana Slovenia Tel.: +386 15 2042 07 Fax: +386 15 2043 49 Tjasa_burnik@merck.com

Source: ÖBIG 2006

23.1.2 Market Players

23.1.2.1 Pharmaceutical Industry

There are five pharmaceutical companies mainly producing generics in Slovenia, thereof three are regional companies and the other two of them are the two largest generics companies in Europe, Krka and Lek/Sandoz. Krka and Lek together served about one third of the Slovenian pharmaceutical market in the year 2005. Lek and Krka are members of the Slovenian Pharmaceutical Manufacturers Association (SPMA).

23.1.2.2 Distribution

On the wholesale level Slovenia is organised in a multi-channel system. Eleven private companies are involved in pharmaceutical wholesale, dominated by two wholesale companies Kemofarmacija and Salus (the two market leaders cover 75% of the pharmaceutical wholesale market).

In Slovenia pharmaceuticals are mainly sold through community pharmacies, additionally self-dispensing doctors are allowed. In 2005 there were 271[1068] pharmacies and 27[1069] hospital pharmacies which, however, only serve inpatients. The opening of pharmacies is based on geographic and demographic criteria. For the opening of a new pharmacy, the following conditions are applied:

- Minimum distance between pharmacies: 400 metres
- Minimum population served by one pharmacy: 5,000 inhabitants

Distance selling and teleshopping of non-prescription pharmaceuticals are not allowed in Slovenia.

[1068] AESGP 2005. Economic and Legal Framework for non-Prescription Medicines in Europe. Brussels 2005

[1069] AESGP 2005. Economic and Legal Framework for non-Prescription Medicines in Europe. Brussels 2005

Only pharmacists are allowed to open and own pharmacies. Multiple ownership of pharmacies are only allowed under state ownership. Pharmacy ownership is regulated by law. [1070]

The Government plans to deregulate the pharmacy sector in terms of ownership and establishment. This means that in future also non-pharmacists might own a pharmacy and open new pharmacies anywhere. Furthermore also distance selling of pharmaceuticals might be allowed in the near future[1071].

There are two pharmaceutical classes: prescription only (POM) and non-prescription pharmaceuticals (OTC). POM may only be sold in pharmacies, while OTC products can also be sold in specialised stores[1072]. In Slovenia OTC are subdivided into "pharmacy only" and "available in pharmacy and specialised stores". The classification of homeopathic pharmaceuticals, which may only be dispensed in pharmacies, is regulated. [1073] Additionally, the classification of medical devices is also determined in a law. [1074]

Common and specialised stores are allowed to sell some of the non-prescription pharmaceuticals like herbals, vitamins and minerals.[1075] The Directive on Conditions for Specialised Stores (Official Gazette No. 73/00)[1076] regulate these stores:

- Proper labelling
- Supply being limited to Over-the-Counter (OTC)
- Employment of a pharmacist
- Separate place for storing, handling and selling of pharmaceuticals
- Self-service for non-prescription pharmaceuticals is not allowed.

1070 The Pharmacy Act and Regulations and The Law of Pharmacy Activities

1071 PGEU Annual Assembly March 2006, Personal communication

1072 The Directive on Conditions for Specialised Stores, Official Gazette of the RS, No. 73/00, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

1073 Classification of Homeopathic Medicinal Products, Official Gazette of the RS, No. 90/04, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

1074 Classification of Medical Devices, Official Gazette of the RS, No. 71/03, No. 51./04, 75/03 and 51/04, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

1075 Classification of Vitamins and Minerals, Official Gazette of the RS, No. 83/03, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

1076 The Directive on Conditions for Specialised Stores, Official Gazette of the RS, No. 73/00, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

Table 23.2: Slovenia - Actor of Pharmaceutical Distribution, 2005

Actors of the pharmaceutical distribution	2005
Pharmaceutical industry	51
Wholesalers	11
Pharmacies	271
Common and specialised stores2	80
Inhabitant per dispensaries	5.672
Inhabitants per pharmacy	7.340

[1] Local pharmaceutical companies

[2] Distribution of restricted range of pharmaceuticals - year 2003

Source: AESGP 2005, ARSZMP; data gathering by ÖBIG

23.1.2.3 Patients

The role of the patients in the choice of a pharmaceutical prescribed is rather minor. Patients are usually not informed about products and their prices when they get them prescribed.

A directive on the labelling of pharmaceuticals was issued in the year 2000[1077]. It determined the list of particulars that should appear on the outer packaging of each pharmaceutical or, where there is no outer packaging, on the inner packaging. All packs should contain the patient information leaflet which should include a Summary of Pharmaceutical Characteristics.

Under The Freedom of the Information Act 2005[1078] and Personal Data Protection Act 2006[1079], every person has the right to access the records held by Government departments and certain public bodies.

In Slovenia, prices of pharmaceuticals are accessible for patients (cf. 23.3.4).

23.2 Overview of the Pharmaceutical System

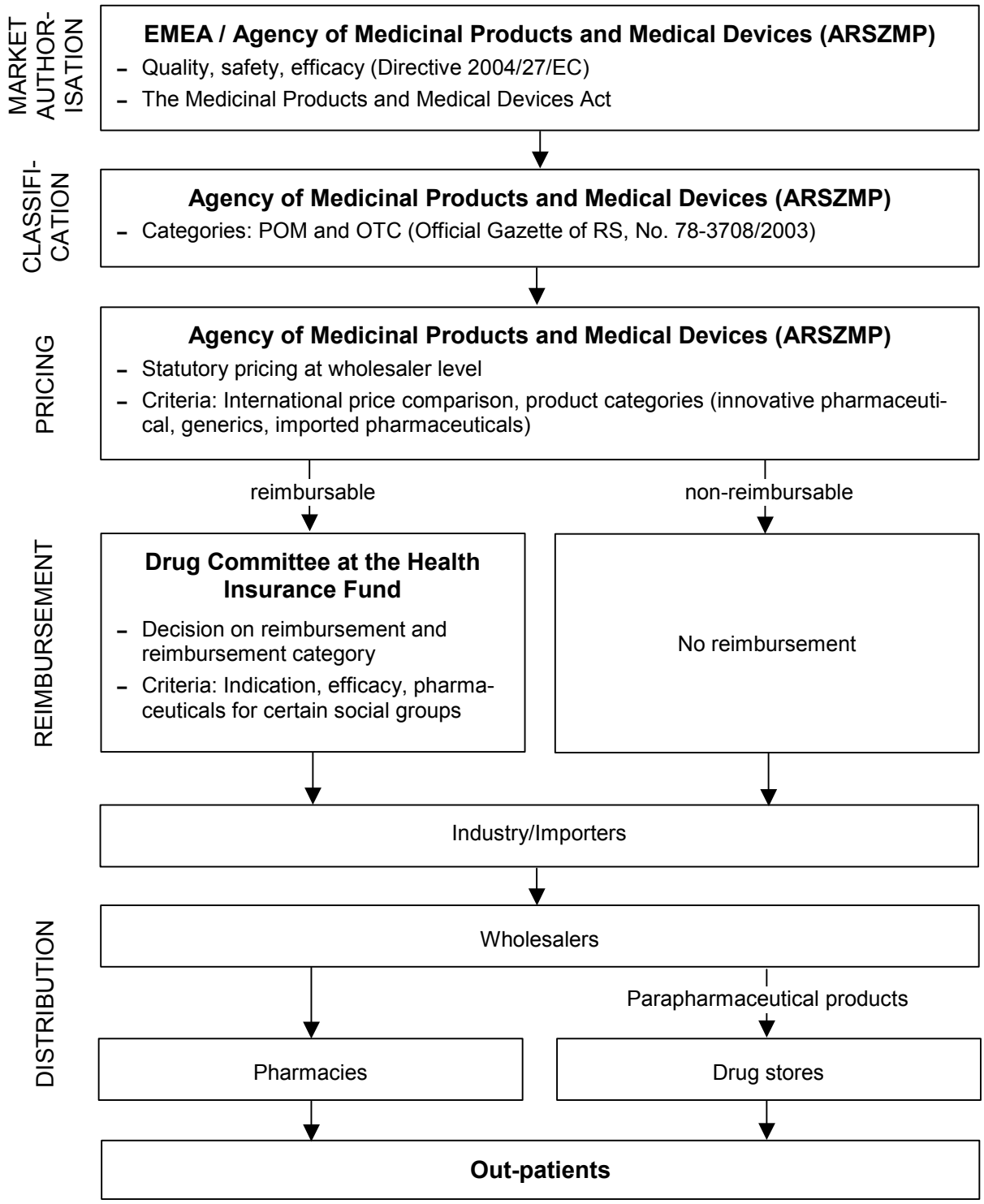
Figure 23.1 shows an overview of the pharmaceutical system in Slovenia.

[1077] Rules on labelling medicinal products, Official Gazette of RS, No. 82/00, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

[1078] The Freedom of Information Act, Official Gazette of the RS, No. 76/05, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

[1079] The Personal Data Protection Act, http://www.who.int/idhl-rils/frame.cfm?language=english

Figure 23.1: Slovenia - Pharmaceutical System, 2006



Source: ÖBIG

23.3 Pricing

23.3.1 Scope of Price Control

In Slovenia, there is statutory pricing for all public funded (reimbursable) pharmaceuticals including POM, pharmaceuticals for hospitals, generics and OTC products, at the wholesale level. The responsible agency is the ARSZMP, the wholesale prices are determined on the basis of international price comparisons (Italy, France and Germany). The wholesale price of a pharmaceutical may in general not exceed 85% of the average price determined by the price comparison. For imported products an extra 0.5% is added. For generics the price may not exceed 95% of the average wholesale price in three reference countries (cf. 23.3.1.2).

There are no fixed regulated mark-ups for wholesalers or for pharmacies. Wholesalers negotiate the manufacturer price with the pharmaceutical industry. In 2002 the average wholesale mark-up was 9% for POM and 12% for OTC products.

Pharmacies are remunerated for pharmaceutical products and services on the basis of a fee-for-service system (which corresponds to an average pharmacy mark-up of 8.5%). The pharmacy retail price arises from the wholesale price and the performance-oriented remuneration of pharmacies as well as the VAT.

The basic law is the Medicinal Products and Medical Devices Act[1080], which is fully compliant with pharmaceutical law of the European Union. The pharmaceutical pricing act was amended and published in 2005 in Official Gazette of the RS No. 96/2005[1081] and No. 106/05[1082].

Table 23.3 provides a concise overview of the Slovenian pharmaceutical pricing system.

[1080] The Medicinal Products and Medical Devices Act, http://www2.gov.si/mz/mz-splet.nsf/V/K2E80F4C58367137DC1256FB1004AEC00/$file/Medicinal Products and Medical Devices Act.pdf

[1081] Official Gazette of the RS, No. 96/05, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

[1082] Official Gazette of the RS, No. 106/05, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

Table 23.3: Slovenia - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Not applicable	Non-reimbursable OTC products	Not applied
Statutory Pricing	Not applied	All pharmaceuticals except non-reimbursable OTC products	Not applied
Price Negotiations	Wholesalers with manufacturers	ZZZS with manufacturers	Not applied
Price/volume agreements, discounts/rebates	No	No	No
Institution in charge of pricing	- ARSZMP - Criteria: international price comparison for imported pharmaceuticals, production costs for locally produced pharmaceuticals		
Legal Basis	- The Medicinal Products and Medical Devices Act		

ARSZMP = Agencija Republike Slovenije za zdravila in medicinske pripomočke, ZZZS = The National Health Insurance Fund

Source: ÖBIG 2006

23.3.1.1 Manufacturer Price

Wholesalers negotiate the manufacturer price with the pharmaceutical industry.

23.3.1.2 Wholesale Price

The MZ defines the wholesale price together with the ARSZMP on the basis of the Medicinal Products and Medical Devices Act[1083] and several bylaws. This law applies to reimbursable pharmaceuticals and non-reimbursable pharmaceuticals. A price regulation for pharmaceuticals was published on 10 August 2001 in the Official Gazette of the Republic of Slovenia No. 67/01[1084] and Official Gazette No. 75/03[1085]. This regulation defined prices for prescription pharmaceuticals, for which the wholesale price of the pharmaceutical may not exceed 85 % of the average wholesale price of identical or similar pharmaceuticals within a reference basket of three countries (Germany, France and Italy).

[1083] The Medicinal Products and Medical Devices Act, http://www2.gov.si/mz/mz-splet.nsf/V/K2E80F4C58367137DC1256FB1004AEC00/$file/Medicinal Products and Medical Devices Act.pdf

[1084] Rules on the provisions for wholesale pricing of pharmaceutical products, Official Gazette of the RS, No. 67/01 and Official Gazette of RS, No. 75/03. http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

[1085] Rules on detailed conditions of wholesale of pharmaceutical products, Official Gazette of the RS, No. 75/03. http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

An exemption to this law exists for innovative pharmaceuticals[1086] and some orphan pharmaceuticals. These pharmaceuticals can be priced up to 96% of the average wholesale price in the three reference countries. The Drug Committee at the ZZZS is responsible for defining the status of innovative and orphan pharmaceuticals.

Another exemption regards imported pharmaceuticals which are permitted a 0.5% premium over the comparative price to cover import costs, and pharmaceuticals for which it is not possible to calculate a comparative wholesale price using the three reference countries.[1087]

The ARSZMP communicates directly with wholesalers or their representatives in Slovenia. All decisions made by ARSZMP for pharmaceuticals products are sent to the ZZZS. If the price of a pharmaceutical exceeds the limit set by this agency, reimbursement is denied.

Although the MZ sets wholesale prices, wholesale margins are not controlled. It is up to wholesalers and distributors to negotiate their own profit margins with pharmaceutical companies, based on price, volume, service and other factors. Although it is difficult to estimate, wholesale margins are, in general, falling and average around 8-9%, which is relative low by European standards.

23.3.1.3 Pharmacy Retail Price

Pharmacies are remunerated by the ZZZS on a fee-for-service basis, rather than by margins. The government assigns a value in points to each prescription (this fee-for-service system regulates also OTC products), and the pharmacist is paid on the basis of total points. In practice, the remuneration received corresponds to an average pharmacy profit margin of around 11-12%, which is low compared to other EU Member States.

For non-reimbursable pharmaceuticals except OTC products, the patient has to pay the full price in the pharmacy.

1086 Rules on the classification, prescribing and dispensing of medicinal products for humane use, Official Gazette of the RS, No. 59/03 and 114/03. http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

1087 Rules on the conditions and the procedure for obtaining a special authorisation for the import of medicinal products and medical devices, Official Gazette of the RS, No. 72/00, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

Table 23.4: Slovenia - Price Build Up for Prescription-only Medicines, 2005

	Mark-up in %	
	POM	
Manufacturer Price	100.0	74.1
Wholesale Price (estimated margin = 9%)	109.9	81.4
Pharmacy Retail Price (margin = 11.7%)	124.5	92.2
Pharmacy Retail Price incl. VAT (8.5%) = Consumer Price	135.0	100.0

POM = Prescription only medicines, VAT = Value Added Tax

Source: AESGP 2005

Table 23.5: Slovenia - Price Build up for OTC Products, 2005

	Mark-up in %	
	OTC products	
Manufacturer Price	100.0	56.8
Wholesale Price (estimated margin = 12%)	113.6	64.5
Pharmacy Retail Price (margin = 30%)	162.3	92.2
Pharmacy Retail Price incl. VAT (8.5%) = Consumer Price	176.1	100.0

OTC = Over-the-Counter, VAT = Value Added Tax

Source: AESGP 2005

23.3.1.4 Value Added Tax (VAT)

The value added tax, which replaced a former retail sales tax in July 1999, was initially set at 8% for pharmaceuticals and 19% for standard goods and services. In 2002 these rates were increased in 2002 to 8.5% for pharmaceuticals and 20% standard rate.

23.3.2 Price Related Cost-containment Measures

23.3.2.1 Pharmaco-economic Evaluation

In Slovenia pharmaco-economic evaluations do not play an important role. Only a few pharmaco-economic studies have been conducted. The ZZZS is limited on analysing the pharmaceutical consumption at national and international level.

Pharmaceutical companies need to submit cost-effectiveness data, when they apply for the wholesale price and for reimbursement (only for innovative pharmaceuticals). At the moment there are discussions to include pharmaco-economic criteria in the general decision process of pricing and reimbursement.

23.3.2.2 Internal Price Referencing

Internal price referencing plays no role in Slovenia.

23.3.2.3 External Price Referencing / Cross Country Referencing

Slovenia links its pharmaceutical wholesale price by formula to those of three other EU Member States. The wholesale price of a pharmaceutical may not exceed 85 % of the average wholesale price[1088,1089] of an identical or similar pharmaceutical within a reference basket of three countries Germany, France and Italy. For more details cf. 23.3.1.2 and 23.3.2).

23.3.2.4 Discounts and Rebates

There are no official discounts and rebates which manufacturers, wholesalers or pharmacies have to grant the ZZZS.

23.3.2.5 Parallel Trade

In Slovenia there are almost no parallel imported pharmaceuticals[1090]. In any occasion the Republic of Slovenia is more concentrated on export than on import.

23.3.3 Co-Payments

There are two reimbursement lists: a positive list and a so-called intermediate list.

In general, pharmaceuticals on the positive list are reimbursed at a rate of 75%, this means patients have to make a co-payment of 25%. Beside the positive list there exists an additional list (intermediate list) which contains all other pharmaceuticals which are reimbursable on the basis of the Law on Health Insurance. Pharmaceuticals from the intermediate list are reimbursed at a rate of 25%, this means a co-payment of 75% is scheduled.

For pharmaceuticals stated on the positive list[1091], which are reimbursed at a rate of 100% by the ZZZS - that is, as mentioned in 23.3 and 23.4.1.3, for certain social groups (among others, children up the age of 18 years and pregnant woman) or with certain diseases (e.g. dia-

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1088 Rules on detailed conditions of wholesale of pharmaceutical products, Official Gazette of the RS, No. 75/03, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

1089 Rules on the classification, prescribing and dispensing of medicinal products for humane use, Official Gazette of the RS, No. 59/03 and 114/03, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

1090 Rules on the conditions and the procedure for obtaining a special authorisation for the import of medicinal products and medical devices. Official Gazette of the RS, No. 72/99, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

1091 Decision specifying the list of inter-exchangeable medicinal products. Official Gazette of the Republic of Slovenia No. 6/05 in 17/05. http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

betes) defined in Article 23 of the Law on Health Care and Health Insurance[1092, 1093], there is no co-payment.

There are no exemptions from co-payments due to income criteria.

Over 90% of all people who are subject to co-payments have concluded a voluntary health insurance, which covers expenses from co-payments. The billing with the voluntary insurance is directly done via the pharmacies.

In 2003, a reference price system was introduced (cf. 23.3.2). Mutually interchangeable pharmaceuticals are clustered by the ARSZMP. The ZZZS is responsible for attributing a maximum reference price to each group, usually at the level of the cheapest pharmaceutical of that group. The introduction of the reference price system had considerable influence on the amount of the co-payments. The difference between reference price of a group of comparable pharmaceuticals and the actual price of the selected pharmaceuticals must be paid by the insured person (the voluntary health insurance does not pay). So patients have the choice between purchasing branded pharmaceutical at a higher out-of-pocket co-payment or opting for lower priced generics.

There are no co-payments for pharmaceuticals used for treatment in hospitals. Prescriptions written on a patient's discharge from hospital are dispensed in the same way as all other prescriptions in the out-patient sector.

23.3.4 Information Transparency and Marketing

In Slovenia prices of pharmaceuticals are publicly accessible. The data[1094, 1095] are published at the websites http://www.zzzs.si/egradiva (only for reimbursed pharmaceuticals) and http://www.zdravila.net/ (the register for authorised pharmaceuticals and prices). This register needs a user name and password.

According to Slovenian legislation[1096, 1097], which is in line with the EU provisions on advertising[1098], advertising in media to the general public is not allowed for reimbursable pharmaceu-

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1092 Law on Health Care and Health Insurance. Official gazette of the RS, 9: 590-601 (1992), http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

1093 Regulations on Compulsory Health Insurance, Official gazette of the RS, No. 79-2855/1994, last amendment Official Gazette No. 44-1769/2005, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

1094 Decision amending list of medicinal products on the basis of Decision on criteria for the classification of medicinal products in lists, Official Gazette of the RS, No. 100/2003

1095 Decision on determining the list of mutually interchangeable medicinal products, Official Gazette of the RS, No. 97/2003

1096 Health Care and Health Insurance Act, Official Gazette of the RS, No. 9/1992, 13/93, 99/2000 and 60/2002

1097 Medicinal Products and Medicinal Devices Act, Official Gazette of the RS, No.101/99, 70/2000, 7/2002, 67/2002

1098 Rules regulating advertising of medicinal products and medical devices, Official Gazette of the RS, No. 76/01

ticals, for pharmaceuticals not authorised in Slovenia, and for pharmaceuticals containing narcotic, psychotropic and other addictive substances. Furthermore, advertising should not include information on prices of the pharmaceuticals and information leading to erroneous self-diagnosis. In general, doctors, pharmacies and pharmaceutical companies are allowed to inform patients about the characteristics of pharmaceuticals[1099]. The advertising and promotion of OTC products is allowed in all media in Slovenia. Pharmaceuticals for children are however excluded[1100].

Implementation of all advertising aspects, including the advertising regulations, is supervised by health inspectors. Breaches of the advertising provisions of the Medicinal Product and Medicinal Devices Acts[1101] are punishable by a fine of not less than SIT 2.0 million / € 8,342 at the 2005 exchange rate.

23.4 Reimbursement

The National Health Insurance Fund (ZZZS) and the Drug Committee are responsible for the decision on reimbursement of pharmaceuticals. In the reimbursement system the private insurance funds play an important role in covering the co-payments of the patients. In 2003 a reference price system including 40 substances was introduced.

The criteria which allow for inclusion of pharmaceuticals on the positive list and intermediate list are legally defined[1102]. The positive list includes pharmaceuticals for prevention measures, therapy of certain social groups (such as people under 18 years) or for the treatment of certain diseases defined in the law (such as HIV/AIDS, diabetes). These pharmaceuticals are reimbursed at a rate of 100% with no patients co-payment or 75% with patients co-payment of 25% depending on their indication and social group. Furthermore, special effective pharmaceuticals as well as pharmaceutical ampullaes are included in the positive list. Besides the positive list, there is an additional intermediate list including all other reimbursable pharmaceuticals. They are reimbursed at 25% with patients co-payment of 75%. Over 70% of the prescription pharmaceuticals are covered at 75% or at least partly by social insurance.

Most of the non-reimbursable pharmaceuticals are OTC products.

1099 Regulation on Compulsory Health Insurance, Official Gazette of the RS, No. 208/2005

1100 AESGP 2005

1101 Medicinal Products and Medicinal Devices Act, Official Gazette of the RS, No. 101/99, 70/2000, 7/2002, 67/2002

1102 Decision on the Criteria for Classification of Medicines to Lists, Official Gazette of the RS, No. 78-3708/2003, page 11647

23.4.1 Pharmaceutical Lists and Reimbursement Categories

The ZZZS is responsible for the drafting of the positive and intermediate pharmaceutical list. The ZZZS Drug Committee, who contains 15 members of different medical and public institutions (representing doctors, pharmacists, Ministry of Health, Institute of Public Health as well as the ZZZS) decides on the reimbursement of pharmaceuticals. Only pharmaceuticals priced in line with the wholesale price, as explained in section 23.3.1.2, are considered for reimbursement.

The committee may consult with the Health Council at the Ministry of Health, a national body that advises the Minister of Health on important health issues.

Pharmaceuticals in the outpatient sector are subdivided into three categories[1103]:

- full reimbursement (positive list) - these pharmaceuticals are reimbursed at a rate of 100% (no co-payment)
- partial reimbursement (positive list) - these pharmaceuticals are reimbursed at a rate of 75%
- intermediate list - these pharmaceuticals are reimbursed at a rate of 25%
- no reimbursement - including OTC products and pharmaceuticals where no proof of a therapeutic benefit could be found

The positive list and intermediate list are revised half-annually and published. Pharmaceuticals of the positive list and intermediate list are reimbursed, if a contract doctor prescribes it on a “green prescription form”. Pharmaceuticals which are not mentioned in the lists or which are not prescribed by a contract doctor are not reimbursed.

23.4.1.1 Reimbursement Price

The maximum reimbursement price is specified by the ZZZS and depends if a pharmaceutical is included in the positive list or to the intermediate list (cf. 23.3.3, 23.3 and 23.3.1).

23.4.1.2 Selection Criteria

The criteria for the inclusion in pharmaceutical lists are defined in an official document, the “Decision on the Classification of Medicines to Lists”[1104]. The following pharmaceuticals are eligible for to the positive list:

- Pharmaceuticals applied in prevention and in therapy for certain groups of insured persons (people under 18 years, students, in pregnancy and motherhood) and pharmaceuticals for the diseases and health states defined in paragraph 1 of Article 23 of the Law on

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[1103] Decision on the Criteria for Classification of Medicines to Lists, Official Gazette of the RS, No. 78-3708/2003

[1104] Decision on the Criteria for Classification of Medicines to Lists, Official Gazette of RS, No. 78-3708/ 2003 page 11647

Health Care and Health Insurance[1105] (pharmaceuticals for the treatment of most important contagious diseases including AIDS, diabetes, mellitus, major psychiatric diseases, epilepsy, muscular dystrophy, multiple sclerosis and psoriasis)

Pharmaceuticals that have the best record of effectiveness within a particular therapeutic area and that are not covered under Article 23 of the Law on Health Care and Health Insurance

- Single ingredient products (combination products are rarely included in the positive list)
- Out-patient pharmaceuticals designed for self-administration by patients trained in the self-management of chronic diseases including diabetes, multiple sclerosis and deep vein thrombosis

Positive listed products are reimbursable at one of the two rates. Products for the treatment of conditions included in Article 23 of the Law on Health Care and Health Insurance are reimbursed at 100%. In addition, certain patient groups are eligible for 100% reimbursement (under 18 years, students,…). All other positive listed pharmaceuticals are reimbursed by the compulsory health insurance scheme at a 75% rate[1106].

The intermediate pharmaceutical list contains pharmaceuticals that do not meet the criteria for inclusion on the positive list, but which are nevertheless provided as benefits under the compulsory health insurance scheme. These are reimbursed at the rate of 25% by compulsory health insurance.

23.4.1.3 Pharmaceuticals on Positive List

The pharmaceuticals on the positive list are published in the Official Gazette of the RS, No. 67/05. At the end of 2004, there were about 1,120 pharmaceuticals on the positive list and 286 pharmaceuticals at the intermediate list.

Table 23.6: Slovenia - Number of Pharmaceuticals, 2005

Pharmaceuticals1	2005
Authorised[2]	~3,000
Prescription-only[3]	1,940
Reimbursable[4]	1,406

1 Counted including different pharmaceutical forms, excluding different dosages and pack sizes

2 Excluding centrally authorised pharmaceuticals

3 In the out-patient sector, year 2004

4 Year 2004

Source: AESGP 2005, ARSZMP, ZZZS 2005; gathered by ÖBIG

1105 Law on Health Care And Health Insurance. Official Gazette of RS, No. 9: 590-601 (1992)

1106 PPR 2004. Pharmaceutical Pricing & Reimbursement in European Union Accession Countries 2004. A Concise Guide. Cambridge 2004

23.4.1.4 Generics

The generic market share by value accounts for around 37% and by value around 52-56%[1107]. They are produced by Slovenian pharmaceutical companies and promoted heavily. There are generic substitution rights for pharmacists which were launched with the reference price system in the year 2003. Pharmacists are permitted to replace the proprietary pharmaceutical prescribed by a physician with an essentially similar and cheaper pharmaceutical if both pharmaceuticals are classified on the list of interchangeable medicinal products[1108]. The prices of generics are controlled by the paragraphs 15 and 16 of the Regulations on Criteria for Setting Wholesale Price of Medicinal Products[1109]. For generics the same methodology for the calculation of comparative prices as for original products is used. The main differences are that the price of the cheapest generic in each of the referenced countries is taken into account instead of the same or identical product and that the wholesale price of a generic must not exceed 95% of the comparative price, rather than 85% in the case of original products.

23.4.1.5 Non-reimbursable Pharmaceuticals

Most of the non-reimbursable pharmaceuticals are OTC products. Patients may purchase them at their own expense. There is no exception, e.g. for old-age pensioners or children, from this rule.

23.4.1.6 Delisting and Switches

Switching pharmaceuticals from prescription to OTC status is possible. There are no national rules concerning the regulation of switching pharmaceuticals. Each manufacturer has to apply separately for non-prescription status of a pharmaceutical.

Switches of a pharmaceutical leads to the de-reimbursement of the pharmaceutical. All switched pharmaceuticals can directly be advertised to the general public.

23.4.2 Reference Price System

A reference price system was introduced on 1 November 2003[1110] for POM. There are 40 molecules and approximately 239 pharmaceuticals on the list of interchangeable pharmaceuticals which includes originals, copy products and generics. ARSZMP is in charge of the generation and modification of reference price groups. The revision of the list of reference

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1107 Personal communication with ZZZS, July 2006

1108 Decision specifying the list of inter-exchangeable medicinal products, Official Gazette of the RS, No. 6/05 and 17/05, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

1109 Rules on the provisions for wholesale pricing of pharmaceutical products, Official Gazette of the RS, No. 67/01 and Official Gazette of RS, No. 75/03, http://www.uradni-list.si/1/main.cp2?view=1&urlid=2000114

1110 The Medicinal Products and Medical Devices Act, http://www2.gov.si/mz/mz-splet.nsf/V/K2E80F4C58367137DC1256FB1004AEC00/$file/Medicinal Products and Medical Devices Act.pdf

prices is published half-yearly. The ZZZS determines the maximum reimbursable amount which corresponds to the price of the cheapest available generic at wholesaler level. The patient has to pay, in addition the percentage co-payment, the difference between the reference price and the actual price in the pharmacy (cf. 23.3.3 and 23.3).

23.4.3 Pharmaceutical Budgets

In Slovenia there are no pharmaceutical budgets being applied for doctors or other health care providers, meaning there are no fixed prescribing budgets in terms of money for health care professionals. There are no plans to introduce pharmaceutical budgets. Nonetheless, doctors are encouraged to follow prescribing guidelines prepared by the ZZZS (cf. 23.4.4.1).

23.4.4 Other Volume Control Oriented Measures

23.4.4.1 Prescription Monitoring and Other Doctors-related Measures

In 2002, the government introduced new prescribing guidelines which include a one-month restriction on all prescriptions where previously a three-month supply could be prescribed. An exemption was made for chronically ill patients, whose prescriptions may continue to run for up to three months. Doctors may prescribe only one pharmaceutical on each prescription.

The ZZZS collects prescribing information on a national and individual level. Pharmacies send their prescribing data to the ZZZS where they are processed and analysed. Information on pharmaceutical consumption is compared with international data in defined daily doses per 1,000 inhabitants per day and then published in the Drug Bulletin which is distributed for free to all doctors.

Smart cards are also in use but only to check if a patient is covered by health insurance. In future, smart cards will also contain records of prescribed pharmaceuticals. More cost-cutting initiatives can be expected in the future, e.g. the creation of a health economics institute responsible for analysing the expenditure of new medical services and pharmaceuticals[1111].

23.4.4.2 Generics and Parallel Trade

As it has already been mentioned in section 23.4.1.4, in Slovenia the generic market by value is 22%.

Doctors have to inform patients of the reimbursement status of all prescribed pharmaceuticals which leads to cost awareness among patients.

As stated in section 23.3.2.5, parallel trade does not play an important role in Slovenia.

[1111] Tilson, L, Barry, M. 2005, European Pharmaceutical Pricing & Reimbursement Strategies. National Centre for Pharmacoeconomics, Dublin 2005

23.5 Overview of the reimbursement market in Slovenia

Tasks / Duties	Yes	No	Comments	Legal bases
Public Authorities				
Decide on prescription status	X		ARSZMP	Official Gazette of RS, No. 59/03 and 114/03
Decide on manufacturer price		X	Indirectly influenced via regulated wholesale price for reimbursable pharmaceuticals	Official Gazette of RS, No. 51/04
Agree on manufacturer price		X	N.app.	
Fix wholesale margin		X	Reference pricing with 3 countries (Germany, France and Italy)	Official Gazette of RS, No. 67/01 and 75/03
Fix pharmacy retail price			N.app.	
Decide on reimbursement status	X		Drug Committee at the Health Insurance (ZZZS)	Decision on the Criteria for Classification of Medicines to Lists, Official Gaztette of the RS, No. 78-3708/2003 page 11647
Agrees on reimbursement price	X		ARSZMP and pharmaceutical companies	
Decide on reimbursement price	X		Drug Committee at the Health Insurance (ZZZS)	The Medicinal Products and Medical Devices Act
Use Pharmaco-economic guidelines	X			
Use Internal reference pricing	X		Maximum reimbursable amount, which is usually the price of the cheapest available generic at wholesaler level	The Medicinal Products and Medical Devices Act Pricing Act
Use External reference pricing	X		Germany, France Italy	The Medicinal Products and Medical Devices Act Pricing Act, Official Gazette of the RS, No. 96/05 and No. 106/05
Price freezes		X		
Margin cuts		X		
Discounts and Rebates		X	There are no regulations	
Company profit control		X		
Country specific:				
Pharmaceutical Industry				

Tasks / Duties	Yes	No	Comments	Legal bases
Sets manufacturer price freely	X		For non-reimbursable OTC products For reimbursable pharmaceuticals the manufacturer price is indirectly influenced via regulated wholesale price	The Medicinal Products and Medical Devices Act Pricing Act
Notifies manufacturer price		X		
Negotiates manufacturer price		X	The wholesale price is negotiated	
Is free to set price below fixed manufacturer price	X		Changes need to be reported to ZZZS	The Medicinal Products and Medical Devices Act Pricing Act, Official Gazette of the RS, No. 96/05 and No. 106/05
Decides on application for reimbursement	X			The Medicinal Products and Medical Devices Act
Negotiates reimbursement price	X			
Free to keep manufacturer price above reimbursement level	X			The Medicinal Products and Medical Devices Act
Free to grant rebates / discounts to wholesalers	X			The Medicinal Products and Medical Devices Act
Free to grant rebates / discounts to pharmacies	X			The Medicinal Products and Medical Devices Act
Can engage in marketing towards doctors	X			The Medicinal Products and Medical Devices Act
Can engage in public advertising	X		Only with non reimbursable pharmaceuticals (OTC)	Rules regulation advertising of medicinal products and medical devices, Official Gazette of the RS, No. 76/01
Can provide information toward patients	X		ARSZMP	The Freedom of Information Act, Official Gazette of the RS, No. 76/05
Applies for switches and delisting	X			The Medicinal Products and Medical Devices Act
Promotional control				
Country specific:				
Distribution chain				
Wholesaler				

Tasks / Duties	Yes	No	Comments	Legal bases
Margins are fixed by statute		X		
Margins are subject to statutory discounts / rebates		X		
Free to grant discounts / rebates to pharmacies	X		On a voluntary basis	
Pharmacists				
Margins are fixed by statute		X	Fee-for-service	
Free to set retail price	X		For OTC products	The Medicinal Products and Medical Devices Act Price Act
Obliged to inform patient on cheaper product	X			
Obliged to substitute by a generic		X		
Allowed to substitute by a generic	X			
Obliged to substitute by a parallel import			N. app.	
Allowed to substitute by a parallel import			N. app.	
Therapeutic / analogous substitution is allowed		X		
Are subject to statutory discounts / rebates		X		
Claw back system exists		X		
May grant rebates to customers		X		
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			The Freedom of Information Act, Official Gazette of the RS, No. 76/05
Are obliged to inform on co-payment / deductibles	X			The Medicinal Products and Medical Devices Act

Tasks / Duties	Yes	No	Comments	Legal bases
Prescription habits are monitored	X		The ZZZS collects prescribing information	
Are subject to prescription guidelines	X			
Budgets are controlled		X		
Allowed to prescribe INN	X			
Obliged to prescribe INN		X		
Can oppose generic substitution	X		There must be a mark on the prescription that generic substitution is allowed	
Can oppose therapeutic substitution			N. app.	
Can oppose substitution by parallel import			N. app.	
Country specific:				
Patients				
Can shop for cheapest price of the product		X	N. app.	
Pay a flat rate per prescription / pack		X		
Pay a certain percentage per prescription / pack or a deductible		X		
Annual minimum co-payment		X		
Annual maximum co-payment		X		
May ask for substitution by a generic	X			
May oppose substitution by a generic	X			
May ask for substitution by a parallel import			N. app.	
Can oppose substitution by a parallel import			N. app.	
Can oppose substitution only on payment of price difference	X			

Tasks / Duties	Yes	No	Comments	Legal bases
Has to pay the difference between reimbursement price and manufacturer price	X			Law on the Health Care and Health Insurance. Official Gazette of the RS, 9:590.601 Price Act
Has access to full public information on prices and products	X			Decision on determining the list of mutually interchangeable medicinal products, Official Gazette of the RS, No. 97/2003 Official Gazette of the RS, No. 67/05
Country specifics:				

N. app. = Not applicable, N. a. = Not available; ZZZS = The National Health Insurance Fund

Source: ÖBIG 2006

SPAIN

24 Spain

24.1 Pharmaceutical System

In 1986, the General Health Law established a National Health System (NHS) in Spain. It is a highly decentralised system, with universal coverage and finance from general taxation. This has replaced a more centrally organised system. There are 17 Autonomous Communities which have complete power regarding public health and healthcare services planning. Financing of the health system remains centralised and is distributed to the Autonomous Communities according to a capitation formula. Health care is provided free of charge except for pharmaceuticals. Only 15% of the Spanish population is covered by private health insurance.

Pharmaceuticals are classified in Spain into the following groups:

- Prescription-only pharmaceuticals, which are all reimbursed
- Non-prescription pharmaceuticals, including:
  - Non-prescription reimbursable pharmaceuticals, which can be prescribed by a medical doctor (in which case they are reimbursed) or not prescribed (and not reimbursed).
  - Especialidades Farmaceuticas Publicitarias (EFP) (or OTC), which are not reimbursed
  - Non-prescription, non-reimbursable pharmaceuticals, which are not EFP

In November 2004, the Spanish Minister of Health presented a Strategic Pharmaceutical Policy Plan (Plan Estratégico de Política Farmacéutica para el Sistema Nacional de Salud Español) which should guide the Spanish Health Administration for the following four years. The key notes of this plan were laid down in a package of 67 policy measures in order to achieve a more rational use of drugs and specially in order to contain public spending on pharmaceuticals.

Currently, a law is being drafted on “Guarantees and the Rational Use of Medicines and Health Products” (Ley de Garantias y Uso Racional de los Medicamentos y productos Sanitarios). The new law will replace the Spanish Medicines Act of 1990[1112] and, among others, will introduce a new reference price system. The law will probably become effective in 2006.

24.1.1 Regulatory Framework and Authorities

By law, all authorisation, pricing and reimbursement issues are centrally decided. The Law on Cohesion and Quality of the National Healthcare System[1113] foresees the participation of

[1112] Ley 25/1990, de 20 de diciembre, del Medicamento

[1113] Ley 16/2003, de 28 de mayo, de cohesión y calidad del Sistema Nacional de Salud

the regions in pricing and reimbursement issues, although there is no indication yet as to how and when this will take place.

The most relevant actors in the pharmaceutical system are:

- the Directorate General of Pharmacy and Health Products of the Ministry of Health.
- the General Subdirectorate of Quality of Medicines and Health Products (Subdireccion General de Calidad de Medicamentos y Productos Sanitarios) within the Directorate General of Pharmacy and Health Products (Direccion General de Farmacia y Productos Sanitarios, DGFPS) of the Ministry of Health
- the Interministerial Commission on Pharmaceutical Prices (Comision Interministerial de Precios de los Medicamentos)
- the Spanish Medicines Agency (Agencia Espanola del Medicamento y Productos Sanitarios, AEMPS)

Following Parliamentary approval in 1997, the Spanish Medicines Agency (Agencia Espanola del Medicamento y Productos Sanitarios, AEMPS) was set up in 1998. The AEMPS is responsible for the evaluation, authorisation, inspection, vigilance and control of pharmaceuticals. The Committee for the Evaluation of Medicinal Products for Human Use (Comité de Evaluación de Medicamentos de Uso Humano, CODEM) is the associate body of the Spanish Medicinal Products Agency responsible for advising on the technical and scientific issues involved in the authorisation of new medicines. The membership of this Committee was renewed by Ministerial Order[1114], issued on 14 March 2005. Requirements for market authorisation for pharmaceuticals are laid down in a Decree[1115].

The pricing and reimbursement process is controlled by the General Subdirectorate of Quality of Medicines and Health Products within the Directorate General of Pharmacy and Health Products of the Ministry of Health.

The final pricing decision is taken by the Interministerial Commission on Pharmaceutical Prices (Comision Interministerial de Precios de los Medicamentos).

Manufacturers receive a preliminary resolution regarding the Interministerial Commission's proposed price. Manufacturers can appeal in case of disagreement, but they can also choose to launch the product unreimbursed.

The decision on inclusion into reimbursement lays in the competence of the Ministry of Health (Directorate General of Pharmacy and Health Products).

[1114] Orden SCO/932/2005, de 14 de marzo, por la que se nombran los miembros del Comité de Evaluación de Medicamentos de Uso Humano de la Agencia Española de Medicamentos y Productos Sanitarios

[1115] Real Decreto 767/1993, de 21 de mayo, por el que se regula la evaluación, autorización, registro y condiciones de dispensación de especialidades farmacéuticas y otros medicamentos de uso humano fabricados industrialmente

Since December 2002, the procedures have been combined in order to speed up the process. At the end of the procedure, a single pricing and reimbursement decision is communicated to the manufacturer.

Table 24.1 contains an overview of relevant Spanish stakeholders.

Table 24.1: Spain - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Ministerio de Sanidad y Consumo / Ministry of Health	Ministry of Health	Ministerio de Sanidad y Consumo Paseo del Prado, 18-20 E-28014 Madrid Spain Tel.: +34 91 5961 000 Fax. +34 91 4201 042 www.msc.es/	Ms. Maria Teresa Pagés Jiménez Paseo del Prado, 18-20 E-28014 Madrid Spain Tel.: +34 91 5961 000 Fax. +34 91 4201 042 Jmartinez@msc.es
Instituto Nacional de Gestion Sanitaria / National Health Service	National Health Service	Instituto Nacional de Gestion Sanitaria c/ Alcalá E-28014 Madrid Spain Tel.: +34 91 3380 006/07; Fax: +34 91 3307 51; mamez@insalud.es www.ingesa.msc.es/	Instituto Nacional de Gestion Sanitaria c/ Alcalá E-28014 Madrid Spain Tel.: +34 91 3380 006/07; Fax: +34 91 3307 51; mamez@insalud.es www.ingesa.msc.es/
Agencia Española de Medicamentos y Productos Sanitarios / Spanish Agency of Pharmaceuticals and Medical Devices	Medicines Agency	Agencia Española de Medicamentos y Productos Sanitarios Calle Alcalá 56 E-28071 Madrid Spain Tel.: +34 91 8225 129 Fax: +34 91 8225 144 www.agemed.es/	Mr. D. Fernando Puig President de la Bellacasa Aguirre Calle Alcalá 56 E-28071 Madrid Spain Tel.: +34 91 8225 129 Fax: +34 91 8225 144 sdaem@agemed.es
Farmaindustria / Association of Pharmaceutical Industry	Association of Pharmaceutical Industry	Farmaindustria Calle Fray Juan Gil 5 E-28002 Madrid Spain Tel.: +34 91 5631 324 Fax: +34 91 5637 380 www.farmaindustria.es/	Farmaindustria Calle Fray Juan Gil 5 E-28002 Madrid Spain Tel.: +34 91 5631 324 Fax: +34 91 5637 380 www.farmaindustria.es/

Institution	Task	Contact details/URL	Responsible person
Asociacion Espanola de Fabricantes de Sustancias y Especialidades Farmaceuticas Genericas (AESEG) / Spanish Association of Manufacturers of Generics	Association of Generic Industry	AESEG Velazquez 102 7a planta E-28006 Madrid Spain Tel.: +34 91 7811 015 Fax: +34 91 7811 104 www.aeseg.es/	Mr. Guillermo Tena Suriani President Velazquez 102 7a planta E-28006 Madrid Spain Tel.: +34 91 7811 015 Fax: +34 91 7811 104 aeseg@aeseg.es
Federacion Nacional de Asociaciones de Mayoristas Distribuidores de Especialidades Farmacéuticas y Productos Para-farmacéuticos / National Federation of Wholesalers Association of Pharmaceutical and Parapharmaceuti-cal Products	Association of Wholesalers	Federacion Nacional de Asociaciones de Mayoristas Distribuidores de Especialidades Farmacéuticas y Productos Parafarmacéuticos General Oàa, 70 E-28006 Madrid Spain Tel.: +34 91 5624 025 Fax: +34 91 4114 326	Mr. Miguel Valdés General Oàa, 70 E-28006 Madrid Spain Tel.: +34 91 5624 025 Fax: +34 91 4114 326 fedifar@ctv.es
Asociacion de Exportadores de Productos Farmaceuticos / Association of Exporters of Pharmaceuticals	Association of Pharmaceutical Exporters	Asociacion de Exportadores de Productos Farmaceuticos P. San Francisco de Sales 41 esc. 2a 5 AY E-28003 Madrid Spain Tel.: +34 91 3752 210 Fax: +34 91 3752 233	Mr. Raffael Conde Cerrato P. San Francisco de Sales 41 esc. 2a 5 AY E-28003 Madrid Spain Tel.: +34 91 3752 210 Fax: +34 91 3752 233 rconde@cfn.es
Consejo General de Colegios Farmaceuticos / Association of Pharmacies	Association of Pharmacies	Consejo General de Colegios Farmaceuticos Farmaceuticos Villanueva 11-6 E-28001 Madrid Spain Te.l: +34 91 4312 560 Fax: +34 91 5763 905 www.portalfarma.com/home.nsf	Mr. Pedro Capilla Martínez President Villanueva 11-6 E-28001 Madrid Spain Tel.: +34 91 4312 560 Fax: +34 91 5763 905 congral@recol.es

Institution	Task	Contact details/URL	Responsible person
Associacíon de Farmacéuticos de Madrid (ADEFARMA) / Association of Pharmacists in Madrid	Association of Pharmacists	ADEFARMA Santa Engracia, 17 E-28010 Madrid Spain Tel.: +34 91 4466 210 Fax: +34 91 4466 987 www.adefarma.es/	Mr. Don Enrique García Trevijano Nestares Santa Engracia, 17 E-28010 Madrid Spain Tel.: +34 91 4466 210 Fax: +34 91 4466 987 adefarma@adefarma.es
Consejo General de Colegios Medicos de Espana / Spanish Association of Doctors	Association of Doctors	Consejo General de Colegios Medicos de Espana Villanueva, 11, 4 E-28001 Madrid Spain Tel.: +34 91 4317 780 Fax: +34 91 5759 548 www.medicos-naturistas.org/	Mr. Fransisco Perteguer Villanueva, 11, 4 E-28001 Madrid Spain Tel.: +34 91 4317 780 Fax: +34 91 5759 548
Organización de Consumidoies y usarios (OCU) / Organisation of Users and Consumers	Consumers Association	OCU C/Albarracín, 21 E-28037 Madrid Spain Tel.: +34 91 3000 045 Fax: +34 91 7543 870 www.ocu.org/	OCU C/Albarracín, 21 E-28037 Madrid Spain Tel.: +34 91 3000 045 Fax: +34 91 7543 870 informacion@ocu.org

Source: ÖBIG

24.1.2 Market Players

24.1.2.1 Pharmaceutical Industry

As well as a buoyant pharmaceutical market, Spain is a growing centre for pharmaceutical research and development (R&D). The pharmaceutical sector is widely considered to be the most innovative industry in Spain. Figures of pharmaceutical industries and associations, including Farmaindustria, the National Association of the Pharmaceutical Industry in Spain, show that there has been a rapid rise in R&D investment in the country since the early 1990s.

There are currently around 250 pharmaceutical companies with production activity in Spain. Almost 90% of pharmaceutical companies are located in the Madrid and Catalonia autonomous communities. Most of the companies are considered as small- to medium-sized enterprises, with about 35% of them employing from 100 to 250 people and only 2% having more than 1,000 employees. Since 1985, Spain has seen increasing investment from the large multinational pharmaceutical companies. It is estimated that foreign companies now represent 75% of pharmaceutical producers in Spain. In 2002, eight multinational companies fea-

tured among the top ten leading companies in Spain and accounted for over 50% of the national market. (Kermani, F. 2004)

In order to promote the use of generics in Spain, the Association of Generic Industry (Asociacion Espanola de Fabricantes de Sustancias y Especialidades Farmaceuticas Genericas, AESEG) was established in 1998. Currently, 25 companies take part in this association.

24.1.2.2 Distribution

The pharmaceutical wholesale system in Spain is multi-channel. Over 100 wholesalers operate in the market. Traditionally, wholesalers focus on their own region and, as a result, the market is highly fragmented. The five largest wholesalers - of which the Cooperativa Farmaceutica Espanola (Cofares) is the largest with an 18.2% market share - account for 50.4% of the market in 2003.

According to the Royal Decree of 2003[1116], wholesalers have the responsibility of supplying information on their customers and the prices of their pharmaceuticals to both the Ministry of Health and the regions. In addition, the decree establishes that wholesalers are obliged to retain invoices and documentation relating to all pharmaceuticals entering and leaving warehouses.

Pharmaceuticals (prescription-only and non-prescription) can only be sold in pharmacies[1117]. In 2005, there were 20,461 community pharmacies, each serving an average of 2,047 patients. 78% of the community pharmacies in Spain (15,973 pharmacies as of 1 January 2004 and 15,896 per 1 January 2005) are situated in areas defined as urban (settlements with more than 5,000 inhabitants)[1118].

In Spain, there are establishment rules concerning the opening of new pharmacies, taking into account geographic and demographic criteria. These rules are based on a federal law[1119]. In addition, each Autonomous Community has adjusted the criteria for establishment to their geographic and demographic peculiarities. Pharmacies must be owned by a qualified pharmacist. Thus, market strategies as vertical integration by wholesalers are unknown in Spain. The law prohibits pharmacy chains and mail order pharmacy.

There is a national law stating that pharmacies are obliged to provide a compulsory stock of pharmaceuticals; in addition, some Autonomous Communities have their own regulation. The compulsory stock is considered as minimum.

1116 Real Decreto 725/2003, de 13 de junio, por al que se desarrollan determniados aspectos del articulo 100 de la ley 25/1990, de 20 de diciembre, del medicamento

1117 Ley 25/1990, de 20 de diciembre, del Medicamento (Title 1, Article 5)

1118 ÖBIG 2006

1119 Ley 16/1997, de 25 de abril, de Regulación de Servicios de las Oficinas de Farmacia

24.1.2.3 Patients

In Spain, patients do not have a formal role in pricing and reimbursement. Their interests are represented in the national users and consumers association[1120].

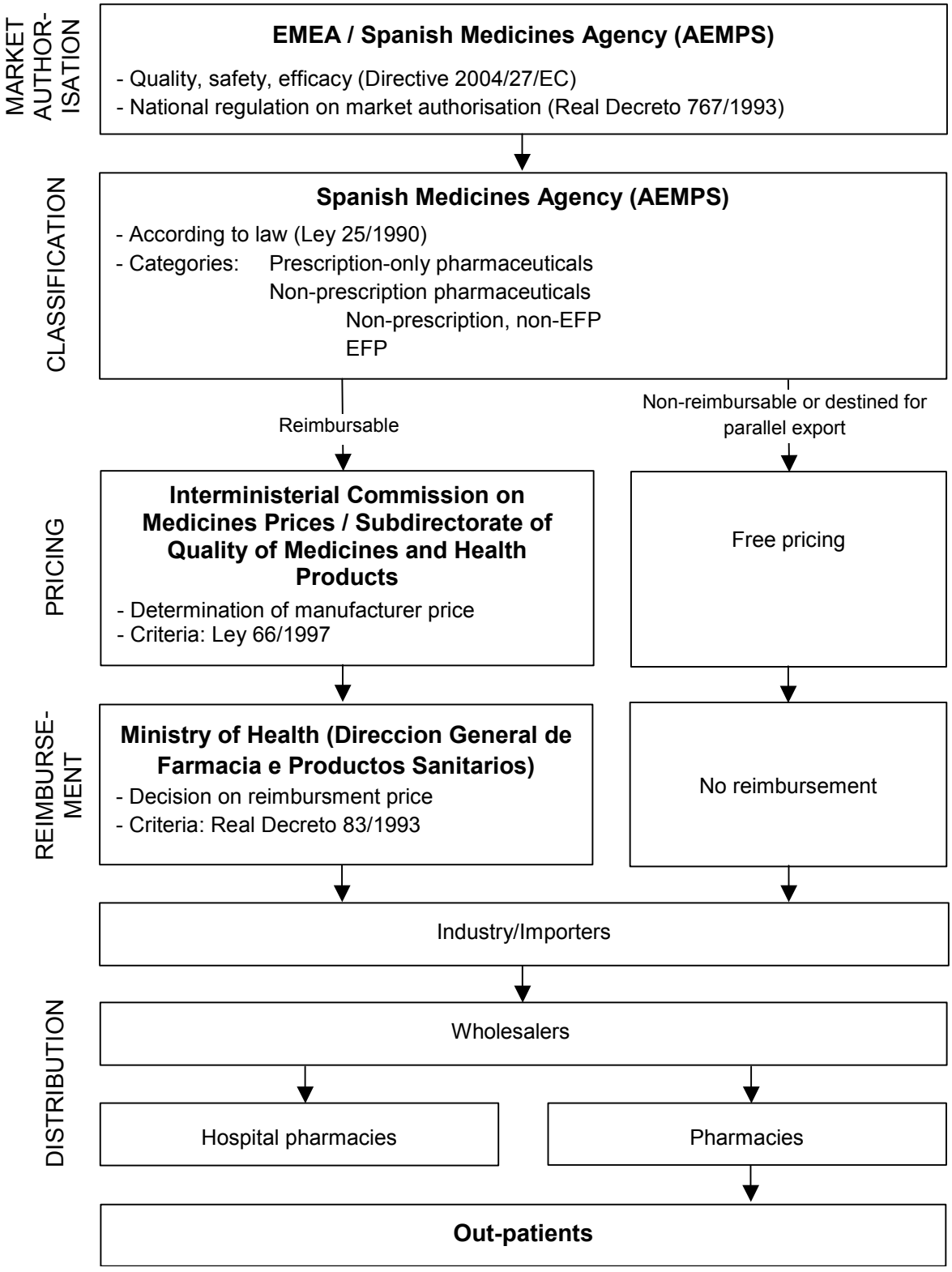
Primary care is provided through general practitioners (médico de cabecera), who usually have their practice in so-called primary health care centres (Centros de Salud). Every neighbourhood has its health centre. Since 1986, patients have had the right to choose their physician within the health area.

24.1.3 Overview of the Pharmaceutical System

Figure 24.1 gives an overview on the Spanish pharmaceutical system.

[1120] http://www.ocu.org

Figure 24.1: Spain - Pharmaceutical System, 2006



EFP = Especialidades Farmaceuticas Publicitarias

Source: ÖBIG 2006

24.2 Pricing

24.2.1 Scope of Price Control

Until the end of 1997, the prices of all pharmaceuticals were statutorily regulated. The pricing of non-reimbursable pharmaceuticals is now unregulated.

The pricing of reimbursable prescription-only pharmaceuticals is carried out by the Interministerial Commission on Pharmaceutical Prices operating under the Ministry of Health, which is made up of representatives of the Ministry of Health, the Ministry of Finance and the Ministry of Industry, although it is the former of these that has the most say.

The Ministry of Health may set a time period for which the price acceptable for reimbursement is valid, and prices may be revised due to technical, budgetary or health-related issues. However, there are no formal post-launch price reviews and, with the exception of a very small number of pharmaceuticals, once the price of a pharmaceutical has been agreed, the government will generally not seek to revise it.

Non-reimbursable prescription-only pharmaceuticals are freely priced, but final prices still need to be approved, though it is simply an administrative procedure.

There are two types of non-prescription medicine in Spain, with pricing regulations varying accordingly:

- Non-advertisable OTC: have to follow the same pricing process as other pharmaceuticals and can be reimbursed if prescribed.
- Advertisable OTC (Especialidades Farmaceuticas Publicitarias, EFPs): prices are not regulated at the manufacturer level but the retail price has to be the same in all pharmacies - except for an optional discount of up to 10% (including VAT) that pharmacists are permitted to offer.

Generics (Especialidades Farmacéuticas Genéricas, EFGs) follow the same pricing procedure as other reimbursed prescription medicines. Although there are no official guidelines, generics included in the reference price system must be priced at, or below, the reference price level. In fact, most are now priced below the reference price level.

Table 24.2: Spain - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Non-reimbursable pharmaceuticals, parallel exported pharmaceuticals	Non-reimbursable pharmaceuticals, parallel exported pharmaceuticals	Non-reimbursable products, parallel exported pharmaceuticals
Statutory Pricing	Reimbursable pharmaceuticals	Reimbursable pharmaceuticals, regulated via fixed margins	Reimbursable pharmaceuticals, regulated via fixed margins
Price/volume agreements, discounts/rebates	Clawback system	Not applied	On OTC 10% discount for patients allowed
Institution in charge of pricing	Interministerial Commission on Pharmaceutical Prices (Comision Interministerial de Precios de los Medicamentos)		
Basis	- Ley 25/1990, de 20 de diciembre, del Medicamento - Real Decreto 2402/2004, de 30 de diciembre por el que se desarrollo el articulo 104 de la ley 25/1990, de 20 de diciembre del Medicamento, par alas revisions coyunturales de precios de especialidades farmacéuticas y se adoptan medidas adicionales para la contencion del gasto farmacéutico		

Source: ÖBIG 2006

24.2.1.1 Dual Pricing System

In Spain, Article 38 of the Spanish Constitution[1121] represents the basic constitutional rule concerning the exercise of a business activity in Spain. Article 38 recognises the freedom of enterprise as one of the pillars of the current economic model of the Spanish State. One of the basic consequences of this general principle is that market operators are free to set the prices of their products.

Within the pharmaceutical sector, under the EU Transparency Directive[1122], EU Member States retain the power to set the prices of pharmaceuticals and some EU Member States - including Spain – have chosen to do so. As a limitation to the constitutional freedom to set the prices in Spain, governmental intervention in pricing must be exceptional, construed narrowly and strictly limited to its justified object and scope. In this context, Spanish State intervention in the price of pharmaceuticals is only justified on certain limited grounds, which are, in turn, also protected under the Spanish Constitution. These grounds are (i) the need to protect public health, by ensuring that patients in Spain have adequate access to pharmaceuticals, and (ii) the need to control public healthcare expenditure. [1123]

Article 100 of the Spanish Medicines Act is the key legal provision dealing with Spanish State intervention in the pricing of pharmaceuticals. The current wording of Article 100 is the result

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1121 Constitución Española (http://www.constitucion.es/constitucion/lenguas/ingles.html)

1122 Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance system, http://pharmacos.eudra.org/F2/eudralex/vol-1/new_v1/890105en.pdf#search='89/105/EECeudra'

1123 Paz-Ares Rodríguez, T; Montero, A. 2006

of an amendment of the Spanish Medicines Law in December 1999. Article 100 confirms that pharmaceutical manufacturers are free to determine the prices of their pharmaceuticals. However, where the conditions for government intervention are met, they are obliged (by operation of law) to replace the freely-determined price by the intervened price, established by the Spanish health authorities. According to article 100 the prices of pharmaceuticals that (i) are reimbursed with public funds; and (ii) are dispensed in Spain, are subject to government intervention.[1123]

In order to apply pricing schemes contemplated under Article 100, pharmaceutical manufacturers must know whether the pharmaceuticals sold by them fulfil the two above-mentioned criteria for government intervention. They know before hand whether a pharmaceutical is listed for financing. However, it is not known whether pharmaceuticals sold at wholesaler level will be dispensed in Spain. Thus, it is in the essence of Article 100 that wholesalers provide pharmaceutical manufacturers information on dispensing in Spain. Nevertheless the identification of which medicines were routed to foreign markets appeared to be rather problematic. In a move designed to overcome this problem, the government approved a royal decree on 13 June 2003[1124], introducing a system to track pharmaceuticals. Through the distribution chain.

The legality of the Royal Decree of 2003 was challenged by the Federation of Spanish Pharmacists, the Association of Spanish Exporters of Pharmaceuticals, and the Spanish Company for the Development and Pharmaceutical Incentive. Two rulings in June 2005 by the Spanish Supreme Court confirmed that the royal decree was not contrary to any Law.

At the end of 2005, the National Association of Consumers and Users of Healthcare Services (ASUSALUD) has reportedly questioned the demand for proprietary patient data. ASUSALUD has alerted the Ministry of Health.

On 8 May 2001, the European Commission prohibited the dual pricing system in Spain[1125]. The Commission took the view that it infringed Article 81(1) of the EC Treaty[1126] and could not be exempted under Article 81(3). In the view of the European Commission, the Spanish dual pricing system interferes with the Community's objective of integrating domestic markets and restricts price competition. The Commission also concluded that the system cannot be justified on economic grounds. (European Commission 2001)

1124 Real Decreto 725/2003, de 13 de junio, por al que se desarrollan determniados aspectos del articulo 100 de la ley 25/1990, de 20 de diciembre, del medicamento

1125 European Commission – DG Competition. Commission Decision of 8 May 2001 (O.J.L 302, 17.11.2001), http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_302/l_30220011117en00010043.pdf

1126 European Commission - Consolidated version of the treaty establishing the European Community. Official Journal of the European Communities, 24 December 2002, C 325/33, http://europa.eu.int/eur-lex/lex/en/treaties/dat/12002E/pdf/12002E_EN.pdf

24.2.1.2 Manufacturer Price

The manufacturer price of all prescription-only medicines is set by the Interministerial Commission on Pharmaceutical Prices. In the pricing process, the following criteria are assessed:

- The therapeutic value of a pharmaceutical
- Sales forecast (if the company exceeds this forecast, it is penalised)
- Prices of similar pharmaceuticals in Spain and other European countries (cf. 24.2.2.2 and 24.2.2.3)
- The overall cost of R&D, production costs and the price of raw materials

The pricing decision is based mainly on the calculation of the "total cost" of the pharmaceutical, which includes R&D costs, production costs and a certain level of profit. The profit level per company is set within an industry range, which is calculated on a yearly basis by the Governmental Delegate Committee for Economic Issues (Comision Delegada del Gobierno para Asuntos Economicos) within the Treasury. The final pricing decision is taken by the Interministerial Commision on Pharmaceutical Prices. Manufacturers receive a preliminary resolution regarding the Interministerial Commission's proposed price. Manufacturers can appeal in case of disagreement, but they can also choose to launch the product unreimbursed.

Manufacturers may apply for individual price revisions. The process is similar to that for obtaining an initial price, although companies also have to submit an application for modification of the price and a document justifying why the price should be increased.

The aim is to set a price that would generate a return of approximately 12-18% on the company's investment, i.e. profit must not exceed12-18% of capital employed.

Generics manufacturers are legally obliged to price their products at or below the reference price level. Most have opted to cut their prices below the reference price for competitive reasons.

24.2.1.3 Wholesale Price

The wholesale margin is a statutorily fixed rate of 7.6% of the wholesale price if the manufacturer price for a pharmaceutical is below € 89.62 (cf. Table 24.3). If the manufacturer price is € 89.62 or higher, the wholesale margin is a fixed sum of € 7.37, as of March 2006.[1127]

These margins apply to all pharmaceuticals - reimbursable and non-reimbursable pharmaceuticals, branded pharmaceuticals and generics, and OTC.

[1127] Real Decreto 2402/2004, de 30 de diciembre por el que se desarrollo el articulo 104 d la ley 25/1990, de 20 de diciembre del Medicamento, par alas revisions coyunturales de precios de especialidades farmacéuticas y se adoptan medidas adicionales para la contencion del gasto farmacéutico.

24.2.1.4 Pharmacy Retail Price

The pharmacist's margin for pharmaceuticals with a manufacturer price below € 89.62 is statutorily fixed at 27.9% of the pharmacy retail price as of March 2006[1127]. If the manufacturer price is € 89.62 or higher, the pharmacy margin is a fixed sum of € 37.53. (cf. Table 24.3)

Table 24.3: Spain - Wholesale and Pharmacy Margins, 2006

Manufacturer price in € (excl. VAT)	Wholesale margin	Pharmacy margin
0.00 - 89.62	7.6% of the wholesale price	27.9% of pharmacy retail price
> 89.62	€ 7.37	€ 37.53

Source: Real Decreto 2402/2004

24.2.1.5 Value Added Tax (VAT)

The standard VAT rate is 16% and the VAT rate for pharmaceuticals is 4%.

24.2.2 Price Related Cost-containment Measures

24.2.2.1 Pharmaco-economic Evaluation

Pharmaco-economic studies are beginning to be used in several decision making contexts, although their submission is not mandatory, nor is it clear to what extent they actually influence the outcome of price and reimbursement decisions. A Spanish proposal for methodological standardisation of economic analysis of health technologies and programs was compiled in 1995.

Providing pharmaco-economic evidence is not mandatory but companies normally submit a pharmaco-economic report showing the pharmaceutical's budgetary benefits along with the pricing dossier. Although these data are used to some extent in deciding access to reimbursement for pharmaceuticals likely to have a large budgetary impact, European average prices, volumes / unit price trade-offs and company turnover are more important factors in the pricing and reimbursement process than economic evaluations.

24.2.2.2 Internal Price Referencing

In the pricing of pharmaceuticals, the prices of similar pharmaceuticals in Spain are taken into consideration. However, the way that these prices determine pricing is not formally defined.

24.2.2.3 External Price Referencing / Cross Country Referencing

In price setting the prices of similar pharmaceuticals in other countries are taken into consideration. However, the way that price referencing determines price setting is not formally defined.

24.2.2.4 Price Freezes / Stops

In 1994, prices were reduced by 3% and frozen until 1998.

24.2.2.5 Price Cuts

In 1999 prices of all reimbursable pharmaceuticals were reduced by an average of 6% (4-10% depending on the price of the pharmaceutical). A few years later, in May 2002, a price reduction of 15% was applied to pharmaceuticals with a higher price than the average of the three cheaper, corresponding pharmaceuticals.

In 2005, manufacturer prices of nearly 4,500 non-reference priced pharmaceuticals, marketed for over one year, were cut by 4.2%. In 2006 these prices were again cut by 2%. Pharmaceuticals covered by the reference price system (cf. 24.3.2) and those with manufacturer prices at or below € 2.- were excluded from these price cuts. In addition, the prices of the affected pharmaceuticals were not allowed to fall below € 2.- once the discounts had been applied. [1128]

24.2.2.6 Margin Cuts

The wholesaler margin was cut in 1997 and again in 1999. In May 1999 the margin was reduced from 11% to 9.6%. A new decree lowering the distribution margins was approved on 30 December 2004[1128]. According to this decree, margins were lowered by 1% as of February 2005 and by another 1% as of February 2006. The decree also states that statutory margins will be updated on an annual basis according to the evolution of the consumer price index, gross domestic product and sales increases in pharmacies.

24.2.2.7 Discounts and rebates

A pharmacy clawback system has been in place since August 2000, with pharmacies making payments based on a percentage of their annual sales of reimbursable pharmaceuticals at manufacturer prices (cf. Table 24.4). Changes to the operation of the system came into effect in 2004. To determine the required clawback percentage, pharmacies' monthly prescription values continued to be based on public prices but, for pharmaceuticals with a manufacturer price over € 78.34, the amount exceeding the manufacturer price is now excluded. The latest adaptation of the pharmacy clawback levels were implemented in February 2005[1128].

[1128] Real Decreto 2402/2004, de 30 de diciembre por el que se desarrollo el articulo 104 d la ley 25/1990, de 20 de diciembre del Medicamento, par alas revisions coyunturales de precios de especialidades farmacéuticas y se adoptan medidas adicionales para la contencion del gasto farmacéutico

Table 24.4: Spain - Pharmacy Clawback Levels, 2006

Monthly prescription value (euro)	Pharmacy clawback (%)
< 31,627.66	0%
31,627.66 - 42,628.59	8.0%
> 42,628.59 - 57,067.30	9.4%
> 57,067.30 - 117,572.39	10.9%
> 117,572.39 - 203,517.12	13.5%
> 203,517.12 - 288,774.29	14.5%
>288,774.29	15%

Source: PPR 2/2005

An additional disposition of the Spanish Medicines Act replaced the Stability Pact between the government and the pharmaceutical industry, which expired at the end of 2004. These new arrangements include a system of payments by pharmaceutical companies and manufacturers of healthcare products based on a percentage of their annual sales of reimbursed products. Companies are eligible for discounts of up to 25% on their payments, depending on their R&D projects in Spain (companies investing more will pay less) [1129].

Half of the contributions will be allocated to R&D projects carried out by the Spanish scientific research institute (Instituto de Salud Carlos III), with the remainder administered by the regions to finance policies to encourage the rational use of medicines or training programmes for healthcare professionals.

The scale of payments, based on turnover at manufacturer selling prices is given in Table 24.5. Pharmacies may give customers discounts of up to 10% for Over-the-Counter medicines.

Table 24.5: Spain - Industry Payback Levels, 2006

Company turnover on reimbursed pharmaceuticals	% payback
< € 3 million	1.5%
< € 6 million	2.0%
< € 15 million	2.5%
< € 30 million	3.0%
< € 60 million	3.5%
< € 120 million	4.0%
< € 300 million	4.5%
> € 300 million	5.0%

Source: PPR 2005

[1129] Real Decreto 2402/2004, de 30 de diciembre por el que se desarrollo el articulo 104 d la ley 25/1990, de 20 de diciembre del Medicamento, par alas revisions coyunturales de precios de especialidades farmacéuticas y se adoptan medidas adicionales para la contencion del gasto farmacéutico

24.2.2.8 Company profit controls

In 1995 a three year profit control agreement was made with the pharmaceutical industry which aimed to keep growth to a level of 7%. If annual reimbursable pharmaceutical expenditure increased by more than 7%, the manufacturers would pay back 57% of the excess to the State. Manufacturers would also repay 1% of the sales value of reimbursed pharmaceuticals to the State.

24.2.2.9 Parallel Trade

Due to its low price levels, Spain is one of the most important parallel export countries. Parallel import is virtually non-existent.

In order to control the parallel export of pharmaceuticals from Spain, it is allowed for pharmaceuticals to be priced differently depending on whether they are distributed and dispensed within Spain, or destined for other European markets. This policy of dual pricing has been initiated in 1999 by a pharmaceutical company from the United States, Pfizer, by taking advantage of article 100 of the Spanish pharmaceutical law.

A 2003 Royal Decree[1130] introduced requirements for pharmaceutical producers and pharmaceutical wholesalers to trace the movement of every single pharmaceutical through the country's pharmaceutical market, in order to determine which pharmaceuticals exactly can qualify as reimbursable. A system was introduced to track pharmaceuticals through the distribution chain. The main points included in this system are as follows[1130]:

- Manufacturers have to provide the Ministry of Health with information on the number of units sold to wholesalers.
- Wholesalers have to report to both the Ministry of Health and the regional health authority the number of units supplied to either Spanish pharmacists or other wholesalers.
- When requested by manufacturers, the Ministry of Health will then compare the number of units bought by wholesalers with the number of units supplied to pharmacists and other wholesalers within Spain.
- Wholesalers are obliged to retain invoices and documentation relating to all pharmaceuticals entering and leaving the warehouses.

If there is no proof that pharmaceuticals have been sold under the country's national health insurance system, manufacturers can charge a different price either higher or lower than the Spanish maximum price. Practice shows that certain manufacturers request higher prices for certain pharmaceuticals. This way, the manufacturers hope to discourage parallel exports of their pharmaceuticals from Spain.

[1130] Real Decreto 725/2003, de 13 de junio, por al que se desarrollan determniados aspectos del articulo 100 de la ley 25/1990, de 20 de diciembre, del medicamento

24.2.3 Co-Payments

There is evidence that the level of co-payment is low in comparison with other EU Member States. These are two main patient co-payments in Spain

1. 10% up to a maximum limit of € 2.64 for pharmaceuticals for chronic illnesses.
2. 40% for all other pharmaceuticals.

Pensioners and certain categories of patients, for example handicapped patients and those suffering work related illnesses, are exempt from any co-payment. For historical reasons, civil servants, the military and people with legal responsibilities pay a special rate for pharmaceutical services (30% of the price of medicines and 10%, up to a maximum limit of € 2.64, for pharmaceuticals indicated for the treatment of chronic illnesses). Approximately 20% of the Spanish population obtain their pharmaceuticals free of charge, and these pharmaceuticals account for approximately 70% of all pharmaceutical expenditure. In the past decade, co-payment contributions fell from 18% to just 8% of total expenditure.

24.2.4 Information Transparency and Marketing

In July 2002, the Code of Practice for the Promotion of Medicines[1131] (Codigo de buenas Practicas para la Promocion de Medicamentos) was implemented by manufacturers. The main points of this code include:

- Sales representatives are allowed to visit a doctor six times per year
- Better training will be offered in order to improve information provided
- Pharmaceuticals without market authorisation in Spain cannot be promoted
- Free pharmaceuticals to doctors and discounts to distributors or pharmacists will be viewed as infringing the code

Promotional expenditure on pharmaceuticals is limited to 12-16% of the manufacturer sales. The Ministry of Health sets a concrete percentage for each product within this range, according to the following criteria[1132].

- manufacturer price of the pharmaceutical
- promotional expenses as a percentage of the manufacturer's total sales
- potential market share in terms of volume and value
- the pharmaceutical's market sector (retail pharmacies, hospitals)
- the health care professionals likely to receive information on the particular pharmaceutical.

[1131] http://www.farmaindustria.es/Index_secundaria_codigo

[1132] Tilson, L.; Barry, M. 2005

In addition, imposing controls over sales representatives' visits to physicians, with the purpose of reducing the influence of commercial promotional activities on prescribing habits, has been a focus of attention for several of the Autonomous Regions. For example, regulations governing representatives' visits have already been approved in Madrid, Castilla-La Mancha and Valencia, with other regions set to follow suit. According to the pharmaceutical industry association, Farmaindustria, this has resulted in a highly fragmented set of rules that, in some cases, are so unrealistic that compliance by health administrators, physicians and the industry is virtually impossible.

Spanish law[1133] stipulates that only pharmaceuticals containing active ingredients included in a positive list established by the Ministry of Health (EFP pharmaceuticals) can be advertised to the general public. EFP advertising is allowed in all media. The obligation to include "Special warnings" in TV advertising was removed in 1994. However, the existing system of OTC advertising pre-control by the health authorities was maintained.

The Royal Decree from 1994 on pharmaceutical advertising also contains special rules for advertising to health professionals. The sanctions for companies breaching the advertising law are laid down in the General Law on Medicines[1134].

24.3 Reimbursement

24.3.1 Pharmaceutical Lists and Reimbursement Categories

Once the "price acceptable for reimbursement" has been set and agreed, the dossier is sent back to the General Subdirectorate of Quality of Medicines and Health Products and the reimbursement stage of the process begins.

The decision on inclusion into reimbursement lays in the competence of the Ministry of Health (Directorate General of Pharmacy and Health Products).

The Spanish regions will be included in the pharmaceutical reimbursement process under new draft statutes for the Spanish Medicines Agency (AEMPS). The regions will participate through the creation of an Evaluation Committee for the Therapeutic Utility of Human Pharmaceuticals. This new body will be responsible for carrying out therapeutic evaluations and will be made up of a group of experts named by the regions. The evaluations will become an integral part of the pricing and reimbursement process as stated in the draft law on Guarantees and the Rational use of Health Products.

1133 Real Decreto 1416/1994, de 25 de junio, por el que se regula la publicidad de los medicamentos de uso humano

1134 Ley 25/1990, de 20 de diciembre, del Medicamento

Pharmaceuticals having reimbursement approval receive a “cupón precinto”, which is a label with a six digit reimbursement code for identification of the reimbursement conditions, such as the reimbursement category to which the pharmaceutical belongs.

There are four reimbursement categories:

1. 100% reimbursement for hospital pharmaceuticals
2. 90% reimbursement for pharmaceuticals for the management of chronic illnesses such as epilepsy, asthma and diabetes
3. 60% reimbursement for the majority of prescription-only pharmaceuticals
4. 0% reimbursement for pharmaceuticals on the negative lists

24.3.1.1 Reimbursement Price

The Interministerial Commission on Pharmaceutical Prices determines the price acceptable for reimbursement at the manufacturer level.

24.3.1.2 Selection Criteria

The following criteria are considered when making reimbursement decisions[1135]:

- The nature of the illness
- The therapeutic value of the pharmaceutical
- The efficacy of the pharmaceutical
- The price of the pharmaceutical
- The total expenditure as compared to corresponding products, as well as expenditures incurred by the pharmaceutical to the National Health Service

24.3.1.3 Pharmaceuticals on Positive List

In Spain, there are two negative lists (cf. 24.3.1.5) in operation, in order to identify pharmaceuticals which are not reimbursed. The main share of reimbursable pharmaceuticals are prescription-only. A number of non-prescription pharmaceuticals are reimbursed under the condition that they have been prescribed by a doctor.

In Spain, nearly 12,000 pharmaceuticals (counted including different pharmaceutical forms, dosages, and pack sizes) have market authorisation. 85% of these pharmaceuticals are prescription-only medicines, so they account for the core business in a pharmacy. 80% of all pharmaceuticals are reimbursable. The share of prescription-only medicines and reimbursable medicines has risen in the last five years.

[1135] Real Decreto 83/1993, de 22 de enero, por el que se regula la selección de los medicamentos a efectos de su financiación por el Sistema Nacional de Salud

Table 24.6: Spain - Pharmaceuticals on the Market, 2000 - 2005

Pharmaceuticals[1]	2000	2001	2002	2003	2004	2005
ph. with market authorisation	11,806	11,094	12,775	11,137	11,157	11,783
POM	9,226	9,403	10,181	9,056	9,119	10,074
EFP	1,241	1,238	1,253	1,152	1,163	1,127
Reimbursable ph.	8,922	8,756	9,580	8,348	8,474	9,569
Generics	580	857	1,211	1,669	1,675	2,202

EFP = Especialidades Farmaceuticas Publicitarias, ph. = pharmaceuticals, POM = Prescription-only medicines

[1] Data per 1 January. Pharmaceuticals for human use, excluding magistral or officina formula, counted including different pharmaceutical forms, dosages, pack sizes

Source: ÖBIG 2006

24.3.1.4 Generics

Generics manufacturers are legally obliged to price their products at or below the reference price level. Most have opted to cut their prices below the reference price for competitive reasons.

24.3.1.5 Non-reimbursable Pharmaceuticals

Two negative lists have excluded some pharmaceuticals from public financing, being equivalent to setting a 100% co-payment rate. If a pharmaceutical falls into a therapeutic group which is on a negative list, it is automatically excluded from reimbursement. The Spanish government used this policy for the first time in 1993 and then again in 1998 to control public pharmaceutical expenditure, resulting in two negative lists. These two negative lists led to the exclusion from public funding of 29% of the total pharmaceutical brands on the market.

The Spanish 1993 Royal Decree[1136] was based on two main objectives: (1) to prioritise public financing for those drugs whose need or the severity of the illnesses for which they were used was greater, and (2) to exclude from public financing those pharmaceuticals with low therapeutic value. This led to the development of the first negative list. The government introduced a second list of excluded medicines in 1998[1137] (834 products corresponding to 39 therapeutic groups). This delisting policy was agreed between the Ministry and the industry. The second list was not accepted by some Autonomous Communities, which decided to finance the consumption of excluded medicines with funds from its own budget.

[1136] Real Decreto 83/1993, de 22 de enero, por el que se regula la selección de los medicamentos a efectos de su financiación por el Sistema Nacional de Salud

[1137] Real Decreto 1663/1998, de 24 de julio, por el que se amplía la relación de medicamentos a efectos de su financiación con cargo a fondos de la Seguridad Social o a fondos estatales afectos a la sanidad

24.3.1.6 Delisting and Switches

Reimbursement status revisions by the government are also permitted, at the earliest after one year of having reimbursement approval. Revisions are based on the existence of other effective pharmaceuticals at a lower price or budgetary constraints relating to pharmaceutical expenditure. So far, only two reviews have taken place: introducing a negative list in 1993 and additional delistings made in 1998 (although the regions of Andalucia and Navarra decided to continue to reimburse a number of delisted pharmaceuticals).

Prescription-only to OTC switches are uncommon in Spain. The procedure for switching a pharmaceutical to EFP status is clearly defined in the Spanish Medicines Law. A list of active ingredients suitable for switching is published in the Spanish Official Bulletin. All pharmaceuticals containing these active ingredients may have their status changed if the manufacturer applies for the switch to the Spanish Agency for Medicines and Health Products, although not many companies choose to do so. Only around three to four products are switched from prescription-only to OTC each year.

In all cases, switching to EFP status leads to the loss of reimbursement.

24.3.2 Reference Price System

24.3.2.1 National Reference Price System

The reference price system, first introduced in December 2000, was radically modified with effect from 1 January 2004. Paving the way for this overhaul of the reference price groups and the way reference prices are calculated was the Law of Cohesion and Quality of the National Healthcare System[1138].

Reference price groups include all pharmaceuticals with the same active substance, form and route of administration. Although each group must contain at least one generic version, there is no bio-equivalence requirement. This means that pharmaceuticals with the same active ingredient but different doses, as well as corresponding copy products, are included in the same group. Original branded products, with no generic equivalent available, are not included in the reference price system.

The reference price level for each group is calculated as the simple arithmetic mean of the three cheapest pharmaceuticals in terms of cost per treatment per day (calculated in DDD). The three products selected must be produced by three different companies. Products with a manufacturer price below € 2.- are excluded. Revisions to reference price levels can be made on an annual basis.

[1138] Ley 16/2003, de 28 de mayo, de cohesión y calidad del Sistema Nacional de Salud

Under the new system, the price of generics must be reduced to the same level or below the reference price to which they belong within two months after the legislation has come into force. Manufacturers of branded pharmaceuticals are not required to reduce their prices.

The pharmaceutical company, rather than the patient, pays the difference when the pharmaceutical dispensed has a higher price than the reference price. In case the price of a dispensed pharmaceutical is above the reference price, the patient will only pay the applicable co-payment for the reference price.

In May 2004[1139], 200 pharmaceuticals were added to the reference price system. After these changes were made, the reference price system covered 2,270 presentations, 72 active ingredients and 94 groups.[1140]

Future plans to extend the reference price system are being considered by the government. The new law which is expected to come into effect in 2006 will introduce a new reference price scheme.

24.3.2.2 Regional Reference Price Systems

Meanwhile, maximum price reimbursement systems, establishing maximum reimbursement prices by active substance, have been introduced in a number of the Autonomous Communities over recent years. But, as a result of the new national level reference price arrangements in place from January 2004, only 4 of the 17 regions (Andalucia, Extremadura, Aragon and Castilla-La Mancha) still use such systems. With the exception of Andalucia, they are now only applied to pharmaceuticals not affected by national reference price levels. The schemes only apply when physicians prescribe by active ingredient, and patients are obliged to pay co-payments up to the maximum price level, leaving pharmacists responsible for paying any excess.

24.3.3 Pharmaceutical Budgets

As of January 2003, all 17 Spanish regions have full responsibility for formulating their own health budgets. The Law of Cohesion and Quality of the National Healthcare System sets a common legal framework and guarantees a minimum level of health services to be provided by all regions.

As a tool to target physicians' prescribing habits, some regions use incentives for doctors to stay within a specified budget. For example, in Baleares, if prescription values do not rise above the forecasted regional pharmaceutical expenditure increase, doctors will be rewarded with a bonus (cf. 24.3.4.1).

1139 Orden SCO/1344/2004, de 5 de mayo, por la que se determinan los nuevos conjuntos de presentaciones de especialidades farmacéuticas y se aprueban los correspondientes precios de referencia.

1140 PPR 2005

24.3.4 Other Volume Control Oriented Measures

24.3.4.1 Prescription Monitoring and Other Doctors-related Measures

Prescribing controls have been implemented at a regional level in line with the regions' autonomy in health matters. The regions are currently experimenting with budgets and incentives for GPs to reduce pharmaceutical expenditure and increase awareness of prescribing costs. For instance, in Baleares, if prescription values do not rise above the 2004 forecasted regional pharmaceutical expenditure increase of +8.5%, each doctor will be rewarded with a bonus of between € 900 and € 6,000. On the other hand, Navarra, Extremadura and Cataluna offer doctors financial incentives to prescribe drugs with high therapeutic effectiveness and generics, by subjecting GPs to set targets over both the efficiency and quality of their prescribing practices.

Most of the Autonomous Communities have launched electronic prescription monitoring systems to verify physicians' prescribing habits and to help combat fraud.

Both the national and regional authorities have implemented further prescribing controls in an attempt to control pharmaceutical expenditure. A number of pharmaceuticals fall under a national prior inspection visa system (visados previos de inspeccion), which aims to ensure that products are used for the right indications. Under the scheme, a prescription can only be dispensed after being verified by the regional inspection services to confirm that the product is being used correctly. More than 500 pharmaceuticals require a visa.

Regional evaluation committees have also been established to increase the quantity and quality of information available to doctors, as well as making them aware of the price differences between similar pharmaceuticals. Electronic prescription systems have been tested in several regions as another way to promote the rational use of medicines.

24.3.4.2 Generics and Parallel Trade

The 1990 Medicines Act was modified in 1996[1141] and in 1997[1142] in order to open the way for the introduction of generic pharmaceuticals within the Spanish health care market. The first generic brands were authorised for commercial distribution in July 1997.

The Spanish authorities consider the promotion of generics as a key strategy to curb pharmaceutical expenditure. However, eight years after generics were given legal status (Especialidad Farmacéutica Genérica, EFG) in Spain, their penetration remains low compared with other EU Member States. Pharmacists in Spain may practice generic substitution for pharmaceuticals under the reference price system unless it is specifically forbidden by the prescriber. If a doctor prescribes by the international non-proprietary name (INN), the cheapest generic must be dispensed. If the doctor prescribes the original brand at a price which is equal to or below the reference price, the pharmacist must dispense it and the standard re-

[1141] Ley 13/1996, de 30 de diciembre, de Medidas Fiscales, Administrativas y del Orden Social

[1142] Ley 66/1997, de 30 de diciembre, de Medidas Fiscales, Administrativas y del Orden Social

imbursement system applies. If a branded prescribed pharmaceutical is priced above the reference price and there is a generic equivalent available, then the pharmacist is required to dispense the cheapest generic. If there is no generic available, then the pharmacist will dispense the prescribed pharmaceutical at the reference price and the patient will only pay the applicable co-payment for the reference price.

Patients may reject generic substitution. Under the reference price system, all patients (including those exempted from co-payment) who reject substitution and insist on receiving a medication priced above the reference price are obliged to pay the full price of the pharmaceutical - no reimbursement is granted. In reality, this is largely theoretical, as manufacturers have cut their prices.

In 2004 generics represented 4.96% of total prescription medicines sales by value and 9.13% by volume. (PPR 2005)

Spain is one of the lowest priced markets in the European Union and, as a consequence, one of the leading parallel exporters of pharmaceuticals. Parallel import, on the other hand, plays a very minor role in Spain.

24.4 Overview of the Reimbursement Market in Spain

Tasks / Duties	Yes	No	Comment	Legal bases
Public Authorities				
Decide on prescription status	X		Spanish Medicines Agency	Real Decreto 767/1993
Decide on manufacturer price	X		Interministerial Commission on Pharmaceutical Prices	Ley 25/1990, RealDecreto 2402/2004
Fix wholesale margin	X		Percentage margin and fixed margin	
Fix pharmacy retail price	X		Via statutory margins	
Decide on reimbursement status	X		Ministry of Health (Directorate General of Pharmacy and Health Products).	Ley 25/1990, Real Decreto 83/1993
Decide on reimbursement price	X		Ministry of Health (Directorate General of Pharmacy and Health Products).	Ley 25/1990, Real Decreto 83/1993
Use Pharmaco-economic guidelines	X		Not mandatory	
Use Internal reference pricing	X		Not formally defined	
Use External reference pricing	X		Not formally defined	
Price freezes		X	Last prize freeze in 1998	
Margin cuts	X		Last margin cut in February 2006	Real Decreto 2402/2004
Discounts and Rebates	X		Towards Industry and Pharmacies	
Company profit control		X		
Country specific:				
Pharmaceutical Industry				
Sets manufacturer price freely	X		Sets prices of non-reimbursable pharmaceuticals and of reimbursable pharmaceuticals destined for parallel export.	
Notifies manufacturer price	X		Prices of non-reimbursed pharmaceuticals need to be approved.	
Negotiates manufacturer price	X		Companies enter into negotiations with subdirectorate officials.	

Tasks / Duties	Yes	No	Comment	Legal bases
Is free to set price below fixed manufacturer price	X			
Decides on application for reimbursement		X		
Negotiates reimbursement price		X		
Free to keep manufacturer price above reimbursement price	X	X	“Yes” for trade names, “no” for generics	
Free to set price below reimbursement level	X			
Free to grant rebates / discounts to wholesalers	X			
Free to grant rebates / discounts to pharmacies	X			
Can engage in marketing towards doctors	X		Must be in line with code of Practice for the Promotion of Medicines	
Can engage in public advertising	X		Only for EFP	Real Decreto 1416/1994
Can provide information towards patients		X		
Applies for switches and de-listing	X			
Promotional control	X		Must be in line with code of Practice for the Promotion of Medicines. In addition, promotional expenditure on pharmaceuticals is limited to 12-16% of the manufacturer sales.	
Country specific:				
Distribution Chain				
Wholesaler				
Margins are fixed by statute	X		Based on manufacturer price	Real Decreto 2402/2004
Margins are subject to statutory discounts / rebates		X		

Tasks / Duties	Yes	No	Comment	Legal bases
Free to grant discounts / rebates to pharmacies	X			
Pharmacists				
Margins are fixed by statute	X		Based on manufacturer price	Real Decreto 2402/2004
Free to set retail price		X		
Obliged to inform patient on cheaper product		X		
Obliged to substitute by a generic		X	Only if a doctor prescribes by the international non-proprietary name (INN), or if a branded prescribed pharmaceutical is priced above the reference price and there is a generic equivalent available	
Allowed to substitute by a generic	X		Unless it is specifically forbidden by the prescriber	
Obliged to substitute by a parallel import		X		
Allowed to substitute by a parallel import		X		
Therapeutic / analogous substitution is allowed		X		
Are subject to statutory discounts / rebates	X		Pharmacy clawback system	
Claw back system exists	X			
May grant rebates to customers	X		Maximum of 10%, only on EFP	
Country specific:				
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			
Are obliged to inform on co-payment / deductibles		X		
Prescription habits are monitored	X		Regional initiatives	
Are subject to pre-	X		Regional initiatives	

Tasks / Duties	Yes	No	Comment	Legal bases
scription guidelines				
Budgets are controlled	X		Regional initiatives	
Allowed to prescribe INN	X			
Obliged to prescribe INN		X		
Can oppose generic substitution		X		
Can oppose therapeutic substitution			N.appl.	
Can oppose substitution by parallel import			N.appl.	
Country specific:				
Patients				
Can shop for cheapest price of the product	X			
Pay a flat rate per prescription/pack		X		
Pay a certain percentage per prescription / pack or a deductible	X		40% (in some cases 10%)	
Annual minimum co-payment		X		
Annual maximum co-payment		X		
May ask for substitution by a generic	X			
May oppose substitution by a generic		X		
May ask for substitution by a parallel import			N.appl.	
Can oppose substitution by a parallel import			N.appl.	
Can oppose substitution only on payment of price difference	X			
Has to pay the difference between reimbursement price and retail price	X			

Tasks / Duties	Yes	No	Comment	Legal bases
Has access to full public information on prices and products	X			
Country specifics:				

Source: ÖBIG 2006

SWEDEN

25 Sweden

25.1 Pharmaceutical System

25.1.1 Regulatory Framework and Authorities

The main responsibility for the provision of health care services for Swedish residents lies in the hand of the 290 Swedish municipalities and 18 county councils and the two regions Skåne and Götaland (Sveriges Kommuner och Landsting, SKL).[1143] The county councils took over the reimbursement of pharmaceuticals from the state in 1998. Both, the municipalities and county councils, have the right to levy income taxes on their population. In addition they receive subsidies from the government to finance health care in their region.[1144]

A core characteristic of the Swedish health care market is, that it is very much dominated by public institutions like the state-owned National Corporation of Swedish Pharmacies (Apoteket). Thus, it is not surprising that also doctors, dentists and other health care persons are mainly salaried employees.

The Ministry of Health and Social Affairs (Socialdepartementet) has only a governing role in the pharmaceutical system as the most relevant stakeholder on federal level is the Pharmaceuticals Benefits Board (Läkemedelsförmånsnämnden, LFN)[1145] that was established in October 2002 by statute.[1146] The main body of the board is its independent Pharmaceutical Benefit Committee, that consists of a chairman and ten committee members from different institutions, like SLK, or patient groups, who are all appointed by the government.[1147]

The main purpose of LFN is to make the utilisation of pharmaceuticals more effective, whereby it is in charge of pricing and reimbursement decisions. The guidance issued by LFN is mandatory for all county councils.[1148]

The Swedish Medical Products Agency (Läkemedelsverket, MPA) is in charge of granting market authorisation, post-licensing and market surveillance and monitoring of clinical trials. The legal basis is the Swedish Medicinal Products Act (Läkemedelslagen), that was revised for the last time by 1 May 2006 to implement the three latest EU Directives 2004/24/EC, 2004/27/EC and 2004/28/EC on, for instance the improvement of free movement of human,

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1143 Hälso- och sjukvårdslag (Health and Medical Service Act) 1982 :763 as amended with Swedish Code of statutes (2002:163), Section 3, http://www.sweden.gov.se/content/1/c6/02/31/25/a7ea8ee1.pdf ; http://www.notisum.se/rnp/SLS/lag/19820763.htm#P16

1144 Anell 2005

1145 http://www.lfn.se

1146 Act on Pharmaceutical Benefits etc. (2002:160) from 1 October 2002

1147 LFN 2006

1148 Anell 2005

veterinary and herbal pharmaceuticals and expanding the powers of the European Medicines Agency (EMEA).[1149]

A further central body in the pharmaceutical sector is the Swedish Council on Technology Assessment in Health Care (Statens beredning för medicinsk utvärdering, SBU). SBU was together with the British NICE one of the first institutions preparing pharmaco-economic evaluation reports, starting some 15 years ago.[1150]

Table 25.1: Sweden - Relevant Authorities and Market Players in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Socialdepartement / Ministry of Health and Social Affairs	Ministry of Health (legal framework)	Ministry for Health and Elderly Care, Health Care Division Fredsgatan 8 S-103 33 Stockholm Sweden Tel: +46 8 405 10 00 Fax: +46 8 723 11 91 www.regeringen.se/sb/d/1474	Mr. Ylva Johansson Minister S-103 33 Stockholm Sweden Tel: +46 8 405 10 00 Fax: +46 8 723 11 91 registrator@social.ministry.se (or use direct link on website)
Läkemedelsverket / Medical Products Agency	Medicines Agency (Registration, Post market Surveillance)	Medical Products Agency P.O. Box 26, Dag Hammarskjölds väg 42 S-75103 Uppsala Sweden Tel.: +46 18 17 46 00 Fax: +46 18 54 85 66 registrator@mpa.se	Mr. Gunnar Alvan Director General Dag Hammarskjölds väg 42 S-75103 Uppsala Tel.: +46 18 17 46 93 Fax: +46 18 54 85 66 gunnar.alvan@mpa.se www.mpa.se/index.shtml
Läkemedels-förmånsnämnden (LFN) / Pharmaceutical Benefits Board	Decides on Pricing and Reimbursement	LFN P.O. Box 55 Sundbybergsvägen 1 S-171 11 Solna Sweden Tel.: +46 8 5684 2050 Fax: +46 8 5684 2099 thord.redman@lfn.se	Ms. Ann-Christine Taubermann General Director P.O. Box 55 S-171 11 Solna Sweden Tel: +46 8 5684 2051 ann-christin.tauberman@lfn.se www.LFN.se

[1149] Swedish Medicinal Products Act (Läkemedelslagen, 1992:859) amended by Läkemedelsförordning 2006:272), http://rixlex.riksdagen.se/htbin/thw?${HTML}=SFST_LST&${OOHTML}=SFST_DOK&${SNHTML}=SFST_ERR&${MAXPAGE}=26&${TRIPSHOW}=format=THW&${BASE}=SFST&${FREETEXT}=&BET=2006%3A272&RUB=&ORG=

[1150] http://www.sbu.se

Institution	Task	Contact details/URL	Responsible person
Institutet för Hälso- och Sjukvårds-ekonomi / Institute for Health Economics (IHE)	State pharma-ceuticals re-search institution	Institut for Health Economics P.O. Box 2127, Råbygatan 2 S-220 02 Lund Sweden Tel.: +46 32 910 Fax: +46 12 1604 http://www.ihe.se/english/index.htm	Mr. Anders Annell Director P.O. Box 2127, Råbygatan 2 S-220 02 Lund Sweden Tel.: +46 32 9105 Fax: +46 12 1604 aa@ihe.se
Statens beredning för medicinsk utvärdering (SBU) / Swedish Council on Technology Assessment in Health Care	National evalua-tion institute in charge of phar-maco-economical appraisals	SBU P. O. Box 5650, Tyrgatan 7 S-114 86 Stockholm Sweden Tel.: +46 8 412 32 00 Fax +46 8 411 32 60 http://www.sbu.se/www/index.asp	Ms. Nina Rehnqvist Executive Director S-114 86 Stockholm Sweden Tel: +46 8 412 32 24 Fax +46 8 411 32 60 rehnqvist@sbu.se
Läkemedelsindustri-föreningen (LIF) / Swedish Association of the Pharma-ceutical Industry	Trade Associa-tion of Pharmaceutical Industry	LIF P.O. Box 17608, Ringvägen 100, hus A, S-118 92 Stockholm Sweden Tel.: +46 8 462 37 00 Fax: +46 8 462 02 92 info@lif.se	Mr. Richard Bergström Managing Director Ringvägen 100, hus A, S-118 92 Stockholm Sweden Tel.: +46 8 462 37 00 richard.bergstrom@lif.se http://www.lif.se
Apoteket AB / National Corporation of Swedish Pharmacies	Association of Pharmacies	Affärsomrade vard Statistikenhe-ten / Statistics Department S-131 88 Stockholm Sweden Tel.: +46 8 4661 076 Fax: +46 8 4661 510 http://www.apoteket.se	Ms. Ulla Hultgren Södermalmsallén 36 S-131 88 Stockholm Sweden Tel.: +46 8 4661 417 Ulla.Hultgren@apoteket.se
Sveriges läkarförbund / Swedish Medical Association (SMA)	Medical Doctors' Association	SMA P. O. Box 5610, Villagatan 5 S-114 86 Stockholm Sweden Tel.: +46 8 790 33 00 Fax: +46 8 20 57 18 www.slf.se	Mr. Gunnar Lönnquist International Secretary S-114 86 Stockholm Sweden Tel.: +46 8 790 33 00 gunnar.lonnquist@slf.se
Föreningen för parallellimportörer av läkemedel (FPL)/ Association of Pharmaceuticals Parallel Importers	Trade Association of Parallel Traders	FPL c/o Paranova Läkemedel AB Vallgatan 11 S-17067 Solna Sweden	Mr. Göran Heintz Tel.: +46 844 63030 goran.heintz@paranova.se or fpe@orifarm.se

Source: ÖBIG

25.1.2 Market Players

25.1.2.1 Pharmaceutical Industry

The pharmaceutical industry is an important economic sector, employing about 22,000 persons.[1151] In 2005 about 70 manufacturers and several parallel importers were operating in Sweden. The market is dominated by five companies (Pfizer, AstraZeneca, GlaxoSmithKline, Novartis and Orifarm), of which two - AstraZeneca and the parallel importer Orifarm - are based in Sweden.[1152]

In 2003 pharmaceutical production amounted to approximately SEK 53 billion / € 5,758 million at manufacturer prices, of which the majority went to export.[1153]

25.1.2.2 Distribution

The Swedish wholesale market is organised as single-channel distribution system, meaning that wholesalers have exclusive distribution contracts with the individual pharmaceutical companies, thus only being partly assorted.[1154]

The market is dominated by Kronans Droghandel (Oriola KD) and Tamro (Phoenix group) which together have a market share of 100%.[1155] Wholesalers are only allowed to deliver to pharmacies, health centres and hospitals but not directly to patients.[1156]

All Swedish pharmacies are fully owned by the state and are organised as pharmacy chain called the National Corporation of Pharmacies (Apoteket). Although this monopoly is challenged from time to time, on 31 May 2005 the European Court of Justice has ruled[1157] that it may be held up-right provided that certain conditions, especially non-discriminatory of product selection for stocks by Apoteket are met. Socialdepartementet has already declared that this conditions will be met and has additionally announced that a very selected range of non-prescription nicotine replacement pharmaceuticals will be approved for sale out-side pharmacies.[1158]

Dispensing of pharmaceuticals to patients happens solely through the 800 pharmacies, 80 hospital pharmacies also serving out-patient customers (so-called "expedit apotek") and for a limited selection of Over-the-Counter (OTC), i.e. non-prescription pharmaceuticals, through

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1151 EFPIA 2005

1152 LIF 2005

1153 EFPIA 2005

1154 This system is approved by the Swedish Competition Authority and is based on an exception originally made in 1995. The current exception has been prolonged by 1 January 2006.

1155 http://www.girp.org

1156 Current Act relating to wholesale trading in pharmaceuticals

1157 Case C-438/02 Apoteket vs. Hanner

1158 PPR 7/2005 and PPR 8/2005

so-called medicine chests, that operate under the supervision of a pharmacy. On average a Swedish pharmacy serves about 1,018 inhabitants.[1159]

Neither dispensing doctors nor drugstores are allowed in Sweden.[1160] However distance selling of pharmaceuticals (POM and OTC) including e-pharmacies are allowed but only if operated by Apoteket.

25.1.2.3 Patients

According to the Health and Medical Service Act[1161] patients have to be fully informed on their medication by the prescribing doctor in the first place and by the dispensing pharmacists in second place. The latter has to inform the patient on additional co-payments, in case the patient or the prescribing doctor denies the obligatory substitution of a pharmaceutical within the generic substitution system by its generic or parallel import (cf. 25.3.1.4).

There is no necessity for patients to shop around in search for cheap pharmaceuticals as retail prices of reimbursed pharmaceuticals are the same throughout the country as the "approved" wholesale price is binding for wholesalers and pharmacy mark-ups are statutorily fixed (cf. 25.2.1.3). Doctors prescribed 61.3 million pharmaceuticals (counted by number of items) for their patients in 2005.[1162]

Nevertheless, in case of non-prescription medicines (OTC) considerable price differences may occur due to free pricing (cf. 25.2.1).

25.1.3 Overview of the Pharmaceutical System

In 2005 total expenditure on pharmaceuticals amounted to SEK 30.7 billion / € 3.3 million (including VAT)[1163]. This sum includes all reimbursement expenses, pharmaceutical used in in-patient/hospital care, patient co-payments and private expenses for OTC.[1164] The share of pharmaceutical expenditure on total health care expenditure is some 15%.

In general around 75% of total pharmaceuticals expenditure is publicly financed while the remaining 25% are paid for by patients via co-payment charges and for self-medication.[1165]

The following figure shows the pharmaceutical system in Sweden.

1159 PGEU 2005

1160 http://www.apoteket.se

1161 Health and Medical Service Act 1982:763 as amended with Swedish Code of statutes 2002:163, Section 2b

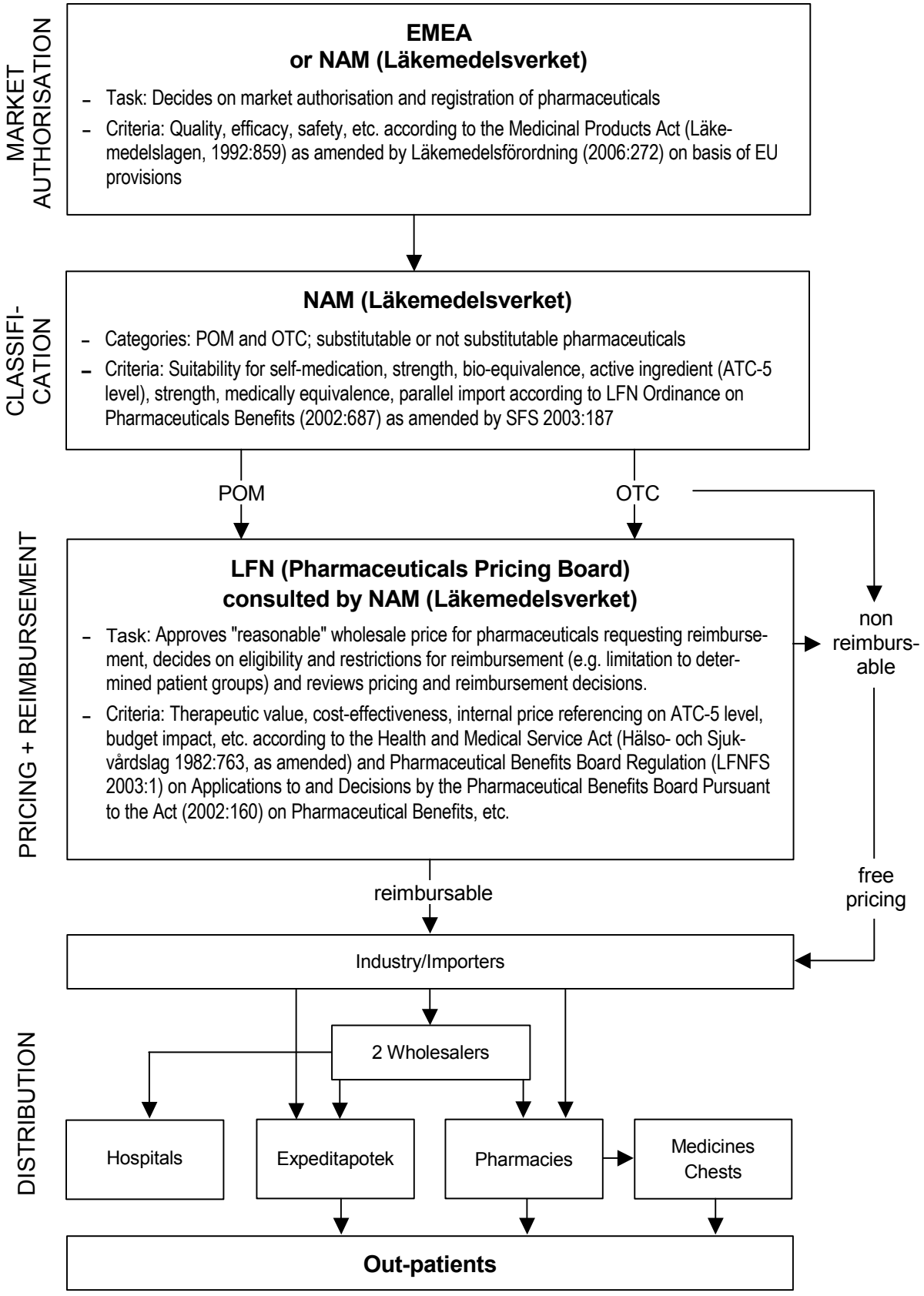
1162 LIF 2006

1163 Please note that exchange rate used for all further calculations was: € 1 = SEK 9,2822 (Annual rate 2005 as published by the Austrian National Bank on basis of European Central Bank, cf. http://www.oenb.at/de/stat_melders/datenangebot/zinssaetze/wechselkurse/wechselkurse.jsp

1164 LIF 2006

1165 http://www.sweden.gov.se/sb/d/4087

Figure 25.1: Sweden - Pharmaceutical System, 2006



Source: ÖBIG

25.2 Pricing

25.2.1 Scope of Price Control

In Sweden there is free pricing for all pharmaceuticals on manufacturer and wholesale price level, but in reality prices are indirectly controlled through the reimbursement system. Pharmaceuticals companies wishing to include their products in the reimbursement system have to apply for approval of the so-called "reasonable" wholesale price[1166] at LFN (cf. 25.3.1.1 for details).

Therefore in most cases only OTC are really priced freely, whereas all other pharmaceuticals are subject to indirect price control.

The pharmacy retail price is regulated by a statutory mark-up scheme, that is enacted by LFN (cf. 25.2.1.3).

Table 25.2: Sweden - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Non-reimbursable products, mostly OTC	Non-reimbursable products, mostly OTC	Not applied
Statutory Pricing	To be eligible for reimbursement a so-called "reasonable" price has to be notified by the manufacturers to LFN, that has formally to approve this price.		All pharmaceuticals are regulated via a regressive mark-up scheme
Price Negotiations	In general no, but price negotiations may take place for pharmaceuticals used in hospitals.		No
Price/volume agreements, discounts/rebates	No	No	No
Institution in charge of pricing	- LFN negotiates reimbursement price with manufacturers		
Legal Basis	- Act on Pharmaceutical Benefits etc. (2002:160) from 1 October 2002 - LFN Enactment on Pharmacy Mark-ups from 1 November 2005		

HOM = Hospital-only Medicines, LFN = Läkemedelsförmånsnämnden, OTC = Over-the-Counter

Source: ÖBIG 2006

[1166] The term “reasonable price” is a little misleading as is the cost of using the pharmaceutical that shall appear reasonable from medical humanitarian and economic aspects.

25.2.1.1 Manufacturer Price

As already mentioned pharmaceutical companies may freely set the price for pharmaceuticals when placing them on the market. They are only obliged to inform Apoteket of their applicable wholesale price (and the respective pharmacy retail price, cf. 25.2.1.3) as to include it in the official pharmacy sales list.

However, pharmaceutical companies seeking for reimbursement need LFN to approve a so-called "reasonable" wholesale price for their product. When deciding on the reasonable price - and on reimbursement - as pricing and reimbursement are a parallel process (cf. Figure 25.1) LFN takes several aspects into account.[1167]

The most important criteria are:

- The medical value of the pharmaceutical
- The human value principle
- The needs/solidarity principle
- The cost-effectiveness principle[1168]

However, LIF has criticised the process as in-transparent as the concrete application of the criteria, e.g. which price bands / envelops are considered for cost-effectiveness comparison with competitors and official documents are not freely available to the public.[1169] LFN in contrary states that the new system is still developing and claims to interpret and clarify the principles enshrined in the Act on Pharmaceutical Benefits in the course of the on-going reimbursement review (cf. 25.3.1.7).[1170]

Generics and parallel imports subject to substitution (cf. 25.3.1.4 on generic substitution) may be also priced freely by manufacturers respectively importers, as long as the price remains below the most expensive pharmaceutical in their group.[1171]

LFN is not in charge of pricing of non-reimbursable pharmaceuticals (like many OTC) and of products for hospital use (Hospital-only-Medicines, HOM). HOM prices use are usually negotiated between manufacturers and the county councils respectively their purchasing organisations. Public procurement of HOM is also very common and usually performed by several counties together.[1172]

1167 Act on Pharmaceutical Benefits etc. "Lag om läkemedelsförmåner m.m." (2002:160) from 1 October 2002

1168 LFN 2006

1169 http://www.lif.se/Media/Media.asp

1170 LFN 2006

1171 Tilson / Barry 2006

1172 PPR 2005

25.2.1.2 Wholesale Price

The wholesale margin is not regulated by the government but based on free agreements between manufacturers and wholesalers, that are not public. On average it is estimated to be 2.7% of the pharmacy purchasing price (as per 2004).[1173]

But as already explained in section 25.2.1.1 the wholesale price of reimbursable pharmaceuticals is indirectly controlled through the reimbursement system. To be eligible for reimbursement pharmaceuticals need an approved "reasonable" wholesale price.

25.2.1.3 Pharmacy Retail Price

Since 1 January 2006 two different pharmacy mark-up schemes are in place in Sweden.[1174] Before that time a unique scheme was valid for all pharmaceuticals (POM and OTC, reimbursable and non-reimbursable, (branded) originals and generics).

The current mark-up system differs between POM (cf. Table 25.3) and OTC pharmaceuticals (cf. Table 25.4), being a slight reduction of the pharmacy mark-ups compared to the previous one. Furthermore for dental pharmaceuticals and medical devices modified mark-ups are applied.

The average gross pharmacy margin was 19.6% in 2004.[1175]

Table 25.3: Sweden - Pharmacy Mark-up Scheme for Prescription-only Medicines, 2006

PPP from ... till ... in SEK / €	Gross PRP in SEK / €
until SEK 75.00 / € 8.08	PPP x 1.20 + SEK 31.25 / € 3.37
SEK 75.01 - 300.00 / € 8.08 - 32.32	PPP x 1.03 + SEK 44.00 / € 4.74
SEK 300.01 - 6,000.00 / € 32.32 - 646.40	PPP x 1.02 + SEK 47.00 / € 5.06
> SEK 6,000.01 / € 646.40	PPP + SEK 167.00 / € 17.99

PPP = Pharmacy purchase price, SEK = Swedish Crowns, PRP = Pharmacy Retail Price

Source: LFN Enactment on Pharmacy Mark-ups from 1 November 2005

[1173] AESGP 2005

[1174] LFN Enactment on Pharmacy Mark-ups from 1 November 2005

[1175] Apoteket 2005

Table 25.4: Sweden - Pharmacy Mark-up Scheme for Over-the-counter Pharmaceuticals, 2006

PPP from ... till ... in SEK / €	Gross PRP in SEK / €
until SEK 20.00 / € 2.15	(PPP x 1.42 + SEK 4.10 / € 0.44) x 1.25
SEK 20.01 - 50.00 / € 2.15 - 5.39	(PPP x 1.40 + SEK 4.50 / € 0.48) x 1.25
SEK 50.01 - 100.00 / € 5.39 - 10.77	(PPP x 1.12 + SEK 18.50 / € 1.99) x 1.25
100.01 - 1,000.00 / € 10.77 - 107.73	(PPP x 1.11+ SEK 19.50 / € 2.10) x 1.25
> SEK 1,000.01 / € 107.73	(PPP x 1.10 + SEK 29.50 / € 3.18) x 1.25

PPP = Pharmacy purchase price, SEK = Svenska Kroner, PRP = Pharmacy Retail Price
Note: Multiplication with 1.25 attributes to VAT rate.

Source: LFN Enactment on Pharmacy Mark-ups from 1 November 2005

25.2.1.4 Value Added Tax (VAT)

Standard VAT rate is 25% for all products in Sweden. However, with the exception of OTC products, pharmaceuticals are exempt from VAT.[1176]

25.2.2 Price Related Cost-containment Measures

25.2.2.1 Pharmaco-economic Evaluation

In case of new or innovative pharmaceuticals manufacturers are encouraged to present an economic evaluation of their product to LFN when applying for price approval and / or claiming reimbursement status. Basing on Article 15 of the law on pharmaceutical beenfits (2002:160) LFN already has published a guideline on the conduct of such studies in April 2003, stating that:

Pharmaco-economic evaluations, for instance,

- have to demonstrate the therapeutic value and cost-effectiveness of the pharmaceutical in question compared to the most common treatment alternative,
- should give a clear scope of the potential patient groups and
- preferable the cost per QALY (Quality Adjusted Life Year Gained).[1177]

The guideline is very detailed and gives also information on the preferred perspective (social economic perspective), on discount rates to be used and the necessity of a sensitivity analysis.

[1176] European Commission/DG Taxation and Trade Union 2006

[1177] General guidelines for economic evaluations from the Pharmaceutical Benefits Board (LFNAR 2003:2), http://www.lfn.se/upload/English/ENG_lfnar2003-eng.pdf

On behalf of the LFN then its independent Pharmaceuticals Benefit Committee assesses each pharmaceutical's therapeutic value and cost-effectiveness in relation to other pharmaceuticals regarded as the most common treatment alternative or to other types of treatment. This means, that pharmaceuticals not necessarily have to be clinically superior. If it is cheaper it can be granted reimbursement status even it is not better than the existing treatment.[1178]

25.2.2.2 Internal Price Referencing

When approving a reasonable price, which is the basis for reimbursement eligibility, LFN takes the price of comparable bioequivalent products (on ATC 5 level) and other pharmaceuticals used for the treatment of the same disease into account for off-patent pharmaceuticals and their parallel imports included in the list of substitutable products.[1179, 1180, 1181]

LIF claims that the price range (so-called "price band" or "price envelop")[1182] considered for determining the price in the reimbursement review is in-transparent. However the ongoing reimbursement review (cf. 25.3.1.7) made the decision procedure of LFN clearer, as the price-bconcep.

In addition, the price of the cheapest available pharmaceutical (generic or parallel import) containing the same amount of the same active ingredient (identified by the International Non-Proprietary Name, INN) is the basis for reimbursement if generic competition has been established, cf. section 25.3.1.4 for details on generic substitution.

25.2.2.3 External Price Referencing / Cross Country Referencing

Although the prices of pharmaceuticals in other countries might be considered in very selected occasions by LFN when determining a "reasonable" price, formal external price referencing - like it was the case before the 2002 reform as long as RFV was in charge - is no longer applied.[1183]

25.2.2.4 Price freezes / cuts

Together with the abolishment of the 1993 reference price system obligatory generic substitution (cf. 25.3.1.4) was established in 2002, thus leading to price adaptations to the generic price level of about 5,000 products during 2003.[1184, 1185] The price reductions were triggered

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1178 LFN 2006

1179 Läkemedelsverket 2006; according to LFN Ordinance on Pharmaceuticals Benefits (2002:687) as amended by SFS 2003:187, Section 12

1180 Act on Pharmaceutical Benefits etc. "Lag om läkemedelsförmåner m.m." (2002:160) from 1 October 2002

1181 List of substitutable pharmaceuticals by 7 July 2006

1182 LNF has informed that the price-band concept was only used in one reimbursement review but not for any other decision.

1183 Wessling 2005

1184 AESGP 2005

1185 PPR 11/2004

by generic competition and were performed by the companies themselves after their initial application.[1186]

The ongoing reimbursement review (cf. 25.3.1.7) claimed the price cut of several pharmaceuticals which otherwise would be de-listed. However, many of these intended cuts were challenged by the concerned pharmaceutical companies and have therefore not yet happened.[1187]

25.2.2.5 Margin Cuts

LFN has changed the pharmacy mark-up scheme for the last time by 1 January 2006, but this change rather meant an increase than a reduction.[1188] The latest cut of the pharmacy margins took place in 1 January 2005, when the compensation (service fee) for unit-dose packaging was removed from the mark-up regulations and become subject of negotiations with the county councils.[1189]

25.2.2.6 Discounts and Rebates

Because of the exclusive distribution contracts between manufacturers and wholesalers - that are the main characteristic of a single-channel distribution system like in Sweden - it is very likely that they grant discounts to each other. Yet, there are nor legal provisions in place and agreements between wholesalers and manufacturers are not public, therefore no details are available.[1190]

There is no claw-back system in place as Apoteket is fully owned by the state (cf. 25.1.2.2.[1191]

Especially before the introduction of obligatory substitution county councils were likely to "shop around", seeking for discounts from manufacturers and wholesalers as well as for pharmaceuticals for hospital use as for out-patient pharmaceuticals. In the meantime the financial pressure has eased somehow, leaving only a minority of counties seeking for discounts.[1192]

25.2.2.7 Company Profit Controls

There are neither direct nor indirect company profit control mechanisms like claw-back systems or controls over companies' promotional expenditure in place in Sweden. However the

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1186 LFN 2006

1187 PPR 3/2006

1188 PPR 2/2006

1189 Apoteket 2005

1190 ÖBIG 2003

1191 Redman 2006

1192 PPR 2005

price of reimbursable pharmaceuticals are indirectly controlled via the necessary approval of a "reasonable" wholesale price by LFN (cf. 25.2.1).

The ongoing reimbursement review also defined so-called price bands (also known a price envelops) for some pharmaceuticals, meaning that they are only considered cost-effective if their price is in a range pre-defined by LFN (cf. 25.3.1.7).

25.2.2.8 Parallel Trade

Due to the rather high prices of pharmaceuticals in Sweden, parallel trade plays an important role since the granting of licenses had begun in 1994.[1193] One reason might be, that MPA accepts foreign labels on parallel imports. There are no parallel exports known of.

There are no specific pricing rules in place for parallel imported products as there is in general free pricing in Sweden. However, parallel imports underlie the same conditions of reimbursement like their originals (cf. 25.3.2).

The market share of parallel imports in 2005 on total pharmaceuticals sales was 12.2%, equalling SEK 3,016 million / € 324.9 million.[1194] Table 25.5 displays the market development since 1997, which shows a more than 10-fold rise.

Table 25.5: Sweden - Development of Parallel Imports, 1997 and 2000 - 2005

Year	Import value in SEK / €	Share of total pharmaceutical sales
2000	1,749 Mio. / 188.4 Mio.	8.8%
2001	2,011 Mio. / 216.7 Mio.	9.5%
2002	2,085 Mio. / 224.6 Mio.	9.1%
2003	2,099 Mio. / 226.1 Mio.	9.0%
2004	2,525 Mio. / 272.0 Mio.	10.6%
2005	3,016 Mio. / 324.9 Mio.	12.2%

Source: LIF 2006b

The products mostly re-imported to Sweden, are those already manufactured in Sweden, e.g. from AstraZeneca.[1195]

[1193] http://www.lakemedelsverket.se/Tpl/NormalPage 2180.aspx

[1194] Redman 2006

[1195] IIR Workshop on Parallel Trade, Barcelona 27 January 2006

25.2.3 Co-Payments

Pharmaceutical benefits are regulated by law[1196] and are the same for everyone in the country. There are no social clauses, e. g. for old age pensioners or unemployed persons in place but there is an upper co-payment. When a patient has paid up to a ceiling of SEK 1,800.- / € 194.- for prescribed pharmaceuticals, a free pass is issued which exempts him/her from further co-payments over a 12-month period. Co-payments of dependent children under the age of 18 are calculated in the 12-month ceiling. Furthermore patients in nursery care (in an elderly home, in an institution for mentally handicapped persons or at their private home) are exempt from co-payments.

Before the patient receives the above mentioned free pass, he or she has to pay the full cost of his/her medication up to a threshold of SEK 900.- / € 97.-. After this, the reimbursement rate rises gradually and the patient pays[1197]:

- 50% of the costs between SEK 901.- and 1,700.- / € 97.- and 183.15
- 25% of the costs between SEK 1,701.- and 3,300.- / € 183.16 and 355.5
- 10% of the costs between SEK 3,301.- and 4,300.- / € 355.6 and 463.25
- 0% of the costs above SEK 4,301 / € 463.26

The reimbursement rate is calculated on basis of the reimbursement price, that is

- the price of the cheapest available product in case of pharmaceuticals falling under obligatory generic substitution, i.e. off-patent pharmaceuticals and generics as well as parallel imports of such products and
- the gross pharmacy retail price for all reimbursable pharmaceuticals not included in the list of substitutable pharmaceuticals (cf. 25.3.1.4), i.e. new, innovative products.

In addition to above mentioned co-payments, patients have to pay the difference between the reimbursement price and the gross pharmacy retail price if they refused substitution of the pharmaceutical by a cheaper, often generic, one (cf. 25.3.1.4 for generic substitution). These co-payments as well as out-of-pocket payments for OTC are not regarded for the calculation of the 12-month co-payment ceiling of SEK 1,800.- / € 194.-.

The only pharmaceutical being totally excluded from any kind of co-payment is Insulin.[1198]

1196 Lag om högkostnadsskydd vid köp av läkemedel (The Cost Limitation (Purchases of medicinal products etc.) Act) 1996:1150) Art. 4 http://www.notisum.se/rnp/sls/lag/19961150.HTM as amended by Lag om läkemedelsförmåner (Pharmaceutical Benefits Act) 2002:160

1197 Pharmaceutical Benefits Act 2002:16, Art. 5 http://62.95.69.3/SFSDOC/02/020160.PDF

1198 ÖBIG2001

25.2.4 Information Transparency and Marketing

Patients have - compared to other countries - extensive information rights, which could be explained by the liberal tradition of the country. The Health and Medical Service Act obliges all health care persons to give patients all necessary information on his/her health status, available treatment options and also guarantees patients the right of a "second opinion".[1199]

The good cooperation and exchange of experience between pharmaceutical companies and patient groups and consumer associations have a long tradition.[1200] Furthermore information transparency is an important asset in the Swedish pharmaceutical system. Since 2001 the Internet portal "Fass" offers - free of charge - wide-spread information on pharmaceuticals (e.g. package leaflets, contents, etc.) not only for doctors, but also for patients in electronic form.[1201] In contrary to almost all other EU Member States the prices of all reimbursable pharmaceuticals including generics and parallel imports are published in the internet - in the "Fass" database and also by LFN, however only in Swedish language.[1202]

Besides the long liberal Swedish tradition on data-transparency the background for the provision of price information is to allow patients to calculate their co-payment rate before getting the product filled.

Advertising of pharmaceuticals to the general public is allowed in line with Directive 2001\83\EC, meaning that OTC pharmaceuticals may be advertised in all media but point-of-sale advertising has to be approved by Apoteket. The coherence to all advertising rules are controlled through a self-regulatory code of the Association of Pharmaceutical Industry LIF and the National Board of Consumer Policies (Konsumentverket).[1203]

25.3 Reimbursement

In 1998 the government transferred the responsibility for the reimbursement of pharmaceutical expenses from the state to the county councils (represented by the SKL, the Swedish Association of Local Authorities and Regions). [1204]

At the same time a state subsidy was introduced to cover these costs and county councils expanded the powers of the already existing health care councils, who now also acted as an advisory board to the county governments for pharmaceuticals (so-called Läkemedelskom-

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1199 Hälso- och Sjukvårdslag (Health and Medical Service Act) 1982:763 as amended with Swedish Code of statutes 2002:163, Section 2b

1200 AESGP 2005

1201 http://www.fass.se

1202 http://www.lfn.se/LFNTemplates/Page 246.aspx

1203 http://www.lif.se

1204 Redman 2006

mittén (Pharmaceutical Committees)). As over the years the county councils decisions on eligibility of pharmaceuticals drifted apart - leading to different availability of pharmaceuticals for patients throughout the country - LFN was introduced to re-centralise reimbursement decisions.[1205]

The government and the county councils have reached an agreement concerning the subsidy for the years 2005 to 2007, that is allocated according to need, age, sex and socioeconomic factors: For 2005 the county councils received SEK 19.8 billions / € 2 billions, for 2006 they will get SEK 20.7 billions / € 2.23 billions and for 2007 the budget foresees SEK 21,5 billions / € 2.32 billion. If the actual costs substantially exceed the fixed subsidy, the government and the SALAR together will decide whether the agreement should be re-negotiated or not.[1206]

25.3.1 Pharmaceutical Lists and Reimbursement Categories

25.3.1.1 Reimbursement Price

The introduction of the LFN on 1 October 2002 has markedly changed the principles of pricing and reimbursement of pharmaceuticals in Sweden. Before that time every POM that had an approved price[1207] automatically qualified for reimbursement.

Since that time reimbursement of pharmaceuticals depends on the decision on LFN which is undertaken following market authorisation together with an approval of a reasonable wholesale price, provided that market authorisation holder, i.e. the pharmaceutical company has applied for reimbursement eligibility.

The key feature of the current system is that an independent Pharmaceutical Benefits Committee on behalf of LFN assesses the pharmaceutical's eligibility for reimbursement according to a set of criteria, including marginal benefit (cf. 25.3.1.2).

When LFN has granted a pharmaceutical reimbursement status it is placed on the Swedish positive list, the so-called "Pharmaceuticals Benefits Scheme". This qualifies patients to get their expenses for such pharmaceuticals - if prescribed by a doctor - reimbursed by the respective county council.[1208]

Usually pharmaceuticals are either eligible for the whole of its approved area of use or not at all. But in exceptional cases LFN can circumvent this and choose to limit the reimbursement to a limited area of use, i.e. specific indications or to a particular patient group. An example of

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1205 PPR 2005

1206 Redman 2006

1207 The term “reasonable price” is a little misleading as is the cost of using the pharmaceutical that shall appear reasonable from medical humanitarian and economic aspects.

1208 Lag om läkemedelsförmåner m.m. (Act on Pharmaceutical Benefits, etc.) 2002:160 as amended with SFS 2003:76, Section 15 and 18

this are e.g. obesity treatment pharmaceuticals like Xenical® that are only reimbursable for diabetes type 2 patients with a Body Mass Index of at least 28 or for patients with a Body Mass Index above 35.[1209]

The actual reimbursement rate is calculated on basis of the pharmacy retail price of each pharmaceutical and depends on the consumption of each patient and not on the product. The reimbursement rate ranges from 0% (for patients with expenses below a threshold of SEK 900.- / € 97.-) to 100% (for patients having a so-called "free card", i.e. those who have reached their 12-month co-payment ceiling), cf. section 25.2.3 for details.[1210]

For on-patent branded originals and their parallel imports the respective reimbursement rate is calculated from the pharmacy retail price, whereas for substitutable off-patent pharmaceuticals the reimbursement rate is calculated from the cheapest available product (i.e. the former branded original, a generic or a parallel import) containing the same amount of the same active ingredient (identified by the International Non-Proprietary Name, INN) in this group (cf. 25.3.1.4).

25.3.1.2 Selection Criteria

In general, each decision of LFN has to be based on the following principles, that have been established by the Swedish Parliament in 1997 when introducing so-called prioritising in health care:[1211]

- Principle of Human Value
- Principle of Need and Solidarity
- Principle of Cost-Effectiveness
- Principle of Marginal Benefit

Once a pharmaceutical is included in the positive list it is always granted reimbursement, meaning that the patient is reimbursed a specific share (between 0 and 100%) of the cost of the pharmaceutical (see 25.3.1.1), i.e. it's pharmacy retail price or the retail price of the cheapest product with the same amount of the same active ingredient. Thus, the actual amount of money reimbursed by the county councils to the single patient depends on his/her co-payment status. The patient's co-payment status depends on the consumed quantity of pharmaceuticals within a 12-month-period, expressed in terms of cost (~ out-of-pocket payments), cf. section 25.2.3 for details.

1209 LFN 2006

1210 Lag om högkostnadsskydd vid köp av läkemedel (The Cost Limitation (Purchases of medicinal products etc.) Act) 1996:1150) Art. 4 http://www.notisum.se/rnp/sls/lag/19961150.HTM as amended by Lag om läkemedelsförmåner (Pharmaceutical Benefits Act) 2002:160

1211 Hälso- och Sjukvårdslag (Health and Medical Service Act) 1982:763, as amended; Sections 2, 2a and 28

Concretely, LFN applies according to Section 15 of the Act on Pharmaceutical Benefits following three main criteria:[1212]

- Principle of Human Value
- Principle of Need and Solidarity
- Principle of Cost-Effectiveness

To assess cost-effectiveness the marginal principle *("..reasonable costs of using the pharmaceutical … considering medical, humanitarian and economic aspects"*)[1213] and added therapeutic value (*"... that there are no other available drugs or treatment methods which after overall consideration of the intended effects and harmful effects … can be judged as significantly more suitable for the purpose."*) are considered.[1214]

Hitherto, a less effective pharmaceutical might still be eligible for reimbursement if the difference in treatment outcomes are compensated by a difference in price..[1215]

According to the IHE the LFN gives the principle of cost-effectiveness a prominent role, as pharmaceutical companies shall submit pharmaco-economic evaluations (cf. 25.2.2.1) when asked for as part of their applications for reimbursement.[1216] LFN itself says, that the cost should be *"reasonable in relation to the achieved health advantages"*.[1217]

However, OTC may be reimbursed to the discretion of LFN even if they haven't been approved a reimbursement price.[1218]

25.3.1.3 Pharmaceuticals on Positive List

Because of deviations in the decisions of the single regional Pharmaceutical Committees on county the scope of reimbursement slightly differs throughout the counties as the Pharmaceutical Committees developed different strategies to curb pharmaceutical expenditure. This doesn't mean, that pharmaceuticals have a different reimbursement status, but the Pharmaceutical Committees tend to recommend different products.[1219]

With the establishment of LFN, that currently has completed its review of all pharmaceuticals against diseases caused by stomach acid (cf. 25.3.1.7) the general eligibility of pharmaceuticals for reimbursement is still decided rather on a central than a regional level. Anyway, the

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1212 Lag om läkemedelsförmåner m.m. (Act on Pharmaceutical Benefits, etc.) 2002:160 as amended with SFS 2003:76, Section 15

1213 Hälso- och Sjukvårdslag (Health and Medical Service Act) 1982:763 as amended, Section 2

1214 Läkemedelslagen (Medicinal Products Act) 1992:859, Section 4

1215 LFN 2006

1216 IHE 1/2005

1217 LFN w. y.

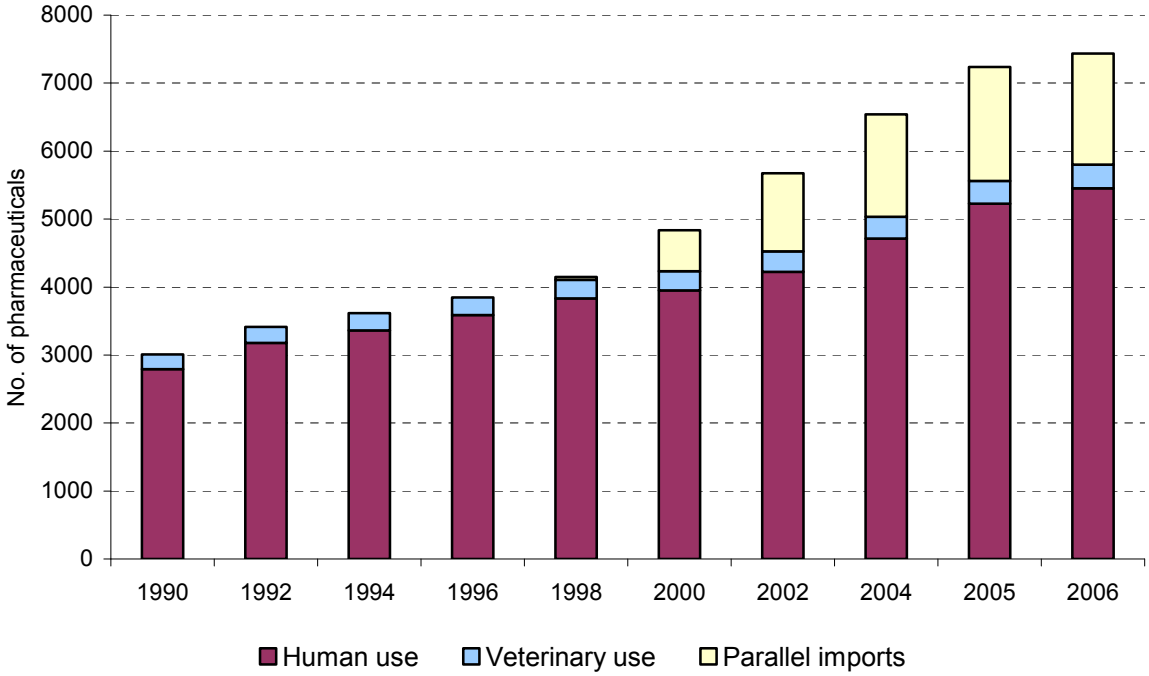
1218 Lag om läkemedelsförmåner m.m. (Act on Pharmaceutical Benefits, etc.) 2002:160 as amended with SFS 2003:76, Section 16

1219 LFN 2006

single counties are allowed to publish their own lists with "preferred" pharmaceuticals and/or define specific rules for prescribing doctors. Such specific rules comprise indicative prescribing budgets for doctors (cf. 25.3.3).

In the beginning of 2006 7,434 pharmaceuticals (thereof 346 for veterinary use only) with an approved wholesale price, i.e. reimbursable ones, were included in the Swedish positive list (so-called Pharmaceutical Benefits List). Figure 25.2 shows the development since the beginning of the 1990s.

Figure 25.2: Sweden - Number of Reimbursable Pharmaceuticals for Human and Veterinary Use, 1990 - 2006[1]



[1] Data from 1 January each year

Source: LIF 2006b

25.3.1.4 Generics

In the year 2002 obligatory generic substitution replaced the reference price system from 1993, thus leading to increased generic competition followed by price reductions for about 5,000 products during 2003[1220]

Obligatory generic substitution means that for off-patent pharmaceuticals the pharmacist must always dispense the cheapest available product - generic or parallel import - of the

[1220] Lag om läkemedelsförmåner m.m. (Act on Pharmaceutical Benefits, etc.) 2002:160 as amended with SFS 2003:76, Section 21

same package type (i.e. jar, bottle, combination pack, etc.). Substitution of a certain pack size by another pack size is only possible, if it is nearly the same (e.g. 28 tab-pack by 30 tab-pack).[1221]

The institution deciding whether a pharmaceutical qualifies for substitution or not is the MPA.[1222] The list of substitutable off-patent pharmaceuticals ("Utbytbara läkemedel")[1223] is published on the MPA web-site and up-dated on a regular basis.

The basic principles for inclusion of pharmaceuticals are:[1224]

- product is a parallel import or
- product contains the same active ingredient (= ATC-5 level) in the same amount (bio-equivalence) and is medically equivalent.

Still, generic pharmaceuticals are not subject to the same investigative demands as the manufacturers of new pharmaceuticals when applying for reimbursement, i.e. LFN doesn't ask for a pharmaco-economic evaluation (cf. 25.2.2.1).[1225]

Still, doctors and patients may deny substitution:

- Doctors may oppose substitution by clearly marking the prescription with "G"[1226] and verifying the prescription with his/her signature. However, in some counties doctors have to document clearly why substitution is not possible (mainly because of medical need of the patient) and in a few counties doctors even could be obliged to penalties in case of major over-spending of his/her pharmaceutical budget (cf. 25.3.3).[1227]
- Patients may oppose substitution without giving a reason, but then they are obliged the difference between the reimbursed cost and the actual pharmacy retail price out-of-pocket. This additional payment is not taken into account for the calculation of the 12-month co-payment ceiling and has also to be paid if the patient has a so-called free card (cf. 25.2.3).

In very specific cases, for instance, if the doctor has prescribed a divided dose (e.g. a half tablet) or especially designed calendar packs, no substitution is possible.

1221 Medical Products Agency Code of Statutes (LVFS 1997:10) as amended, Section 44

1222 Läkemedelsverket 2006; according to LFN Ordinance on Pharmaceuticals Benefits (2002:687) as amended by SFS 2003:187, Section 12

1223 List of substitutable pharmaceuticals by 7 July 2006

1224 Läkemedelsverket 2006, http://www.lakemedelsverket.se/Tpl/NormalPage 984.aspx

1225 LFN w. y.

1226 This is the reason why the system also sometime is referred to as the "inverse G-scheme".

1227 PPR 11/2004

25.3.1.5 Non-reimbursable Pharmaceuticals

In general, all pharmaceuticals - including OTC - may be reimbursed in Sweden, if LFN has decided so and has determined a price, provided that the conditions stipulated in Section 15 of the Act on Pharmaceutical Benefits, etc. (2002:160) (cf. 25.3.1.2) are fulfilled.[1228]

Nonetheless, the following OTC pharmaceutical groups are explicitly excluded from reimbursement:[1229]

- Nicotine replacement therapy products,
- Herbal and homoeopathic pharmaceuticals,
- Certain pharmaceuticals for external use approved by NAM.[1230]

Examples for new pharmaceuticals that have not been granted reimbursement status by LFN include Cialis® and Viagra® (reason: "low degree of urgency") and a new dose of the HIV treatment Stocrin® with 600 mg ("not cost-effective, better compliance not proven" *Note from ÖBIG: Since June 2006 Stocrin® 600 mg is reimbursed again as the company applied again at LFN and asked a lower price*).[1231,1232]

25.3.1.6 Appeal Procedure

According to the Act on Pharmaceutical Benefits, etc.[1233] objections against pricing and/or reimbursement decisions of LFN and subsequently of the county councils have to be filed to the public administrative court. The same is true for appeals against decisions of MPA on substitutability of pharmaceuticals.

Currently appeals have been filed, for instance by several companies (like Hexal, Wyeth, Merck, Europharma etc.) against LFN decisions (on e.g. mandatory price cuts for some pharmaceuticals, which non-compliance would lead to de-listing of the products) in the course of the latest reimbursement review on diseases caused by stomach acid (cf. 25.3.1.7). The concerned pharmaceuticals are reimbursed until the Stockholm Court decides otherwise.[1234]

1228 Pharmaceutical Benefits Board Regulation (LFNFS 2003:2) on Non-prescription Drugs Pursuant to the Act (2002:160) on Pharmaceutical Benefits, etc., Section 3

1229 Pharmaceutical Benefits Board Regulation (LFNFS 2003:2) on Non-prescription Drugs Pursuant to the Act (2002:160) on Pharmaceutical Benefits, etc., Section 4

1230 http://www.lakemedelsverket.se/Tpl/NormalPage____1006.aspx

1231 PPR 4/2004

1232 LFN 2006

1233 Lag om läkemedelsförmåner m.m. (Act on Pharmaceutical Benefits, etc.) 2002:160 as amended with SFS 2003:76, Section 26

1234 PPR 4/2006

25.3.1.7 Reimbursement Review

An important task for the LFN is the thorough review of all pharmaceuticals that were granted reimbursement status before 2002, i.e. within the "old" system. LFN assumes that the evaluation of the about 2,000 affected pharmaceuticals shall be completed by the year 2008.[1235]

By end of January 2006 it had completed the review of two major therapeutic groups - all migraine pharmaceuticals and all products used for the treatment of diseases caused by stomach acid (Protonpump inhibitors, H2-antagonists and antacids).[1236] Following these two pilot reviews, LFN now intends to review reimbursable pharmaceuticals with the highest sales value like medicines against high blood pressure and asthma.[1237]

The review report[1238] also sheds light on the concrete criteria applied in the course of the review process. LFN claims patient need (especially loss of life expectancy) and quality of life considerations to be as relevant as cost-effectiveness. This means, that if the patient need is very small it doesn't matter if the product is cost-effective or not. The report shows further that treatment alternatives are not restricted to the same active ingredient (i.e. ATC 5 level) as all proton pump inhibitors are considered as interchangeable. LFN states that it may not only compare efficacy on ATC 4 level but also with other treatment options (e.g. diet or chirurgic interventions).

In the example of proton pump inhibitors LFN set the acceptable pricing range (~ price band) for a 1-day treatment (=1 tablet) with pharmaceuticals like Losec® (omeprazole), Pariet® (rabeprazole) or Lanzo® (lansoprazole) at SEK 1.- / € 0.11 or 25% against generic omeprazole.[1239] This means, that Losec®, Pariet® or Lanzo® could be up to 25% more expensive than the generic omeprazole and would still keep their reimbursement status.

However, the results (for potential delisting see next section) show, that many of the concerned pharmaceuticals didn't fall within this price band. Thus, manufacturers of these product had to lower their price unless they didn't want them to be delisted (cf. 25.3.1.8).

25.3.1.8 Delisting and Switches

The switch climate in Sweden is moderate, in average one to five major active ingredients have been switched from POM to OTC during the last five years. Both, pharmaceutical companies may apply for switches and also MPA may initiate switches. In, e.g. the case of Losec MUPS® (omeprazole) the county councils asked MPA to switch it to OTC as a cost-saving measure.[1240]

1235 LFN 2005, http://www.lfn.se/upload/Bakgrundsmaterial/det_nya_subventionssystemet_engelsk.pdf

1236 http://www.lfn.se/LFNTemplates/Page____478.aspx

1237 LFN 2006

1238 http://www.lfn.se/upload/genomgangen/engelsk_sammanfattning_magsyra_slutgiltig.pdf

1239 PPR 3/2006

1240 AESGP 2006

It is possible that one pharmaceutical strength of a given product is POM and - with its approved wholesale price - being included in the reimbursement system, whereas the OTC strength is not reimbursable and therefore freely priced.

The reimbursement review of all pharmaceuticals against diseases caused by stomach acid (cf. 25.3.1.7) resulted in intended delisting from the positive list by 1 May 2006. Pharmaceuticals effected are Lanzo® or Pariet® as LFN came to the conclusion that these pharmaceuticals are not cost-effective especially compared to generic omeprazole.[1241]

However, as many companies are challenging these decisions (cf. 25.3.1.6 for ongoing appeals) the concerned pharmaceuticals remain in the Pharmaceutical Benefits Scheme until the appeal court has come to a decision.

25.3.2 Reference Price System

A reference price system on ATC-5 basis was in place between 1993 and 2002 when it was replaced by the introduction of obligatory generic substitution (cf. 25.3.1.4).

25.3.3 Pharmaceutical Budgets

Since 1998 - as responsibility for pharmaceutical expenditure was shifted from the state to the counties - the central government allocates pharmaceutical budgets to the counties.

The central government subsidies depend on the budget of previous years, taking the epidemiological situation (age, gender, prevalence of disease) and socioeconomic factors in each county into consideration. If counties overspend their budget, normally neither sanctions are applied nor additional funds are granted.[1242, 1243]

However when fixing the budget 2005 to 2007 (cf. 25.3.1) the government and SALAR agreed on potential re-negotiation of the budget in case that actual costs substantially exceed the fixed subsidy. The county councils use different approaches when it comes to responsibility for reimbursement of pharmaceuticals within the organisation. Some county councils still have a centralised budget for pharmaceuticals and others have decentralised the responsibility to individual clinics and health care facilities including primary care centres. In most counties there are no prescribing budget imposed on single doctors.[1244, 1245]

1241 PPR 3/2006

1242 Anell 2005

1243 PPR 2005

1244 Redman 2006

1245 PPR 2005

The strongest regulations are imposed on doctors in the county of Östergötland, where each doctor is awarded a specific pharmaceutical budget, taking into account disease status, age and gender of his/her patients.[1246]

25.3.4 Other Volume Control Oriented Measures

25.3.4.1 Prescription Monitoring and other Doctors-related Measures

County councils are responsible for the prescribing policies in their respective region, as most doctors are salaried employees. The Läkemedelskommittén of each county is legally required to promote reliable and rational prescribing of pharmaceuticals.[1247]

However, depending on the budget situation county councils have introduced stricter or weaker monitoring measures. Among the different counties Östergötland is imposing the strictest measures by controlling the compliance of doctors to their pharmaceutical budget (cf. 25.3.3).

A very common measure is the publication of (non mandatory) recommendations for "first choice treatment" options and treatment guidelines combined with pharmaceutical tutoring for doctors.[1248] SBU and LFN provides evidence based information for such recommendations.

25.3.4.2 Generics and Parallel Trade

Since its introduction in October 2002 the current generic substitution scheme, that obliges pharmacists to substitute the cheapest version of the pharmaceutical in stock (cf. 25.3.1.4 for details), has led to savings in the health care system of SEK 6 billion / € 646.4 million (10/2002 - 12/2005).[1249]

A joint report from MPA, LFN and the Competition Authority has suggested amendments to the current generic substitution system that should accelerate the formal price approval for generics (cf. 25.3.1.4) and should also lead to a reduction of prices within the system of generic substitution.

The report suggests to cut the waiting time of at least one month and three weeks for the substitution decision of MPA to become effective. Instead such decisions should come into force at once, unless a court injunction is placed. The recommendations are currently analysed by Socialdepartementet.[12501251]

1246 Wettermark 2006

1247 Hälso- och Sjukvårdslag (Health and Medical Service Act) 1982:763, as amended; Sections 2, 2a and 28

1248 PPR 2005

1249 PPR 1/2006

1250 Global Insight 3/2006

1251 LFN 2006

25.4 Overview of the Reimbursement Market in Sweden

Tasks / Duties	Yes	No	Comments	Legal bases
Public Authorities (Ministry, Pricing Bodies like LFN, Medicines Agency)				
Decide on prescription status	X			Medicinal Products Act (SFS 1992:859) as amended
Decide on manufacturer price		X	Indirectly influenced via "agreed wholesale" price for reimbursable pharmaceuticals	
Agree on manufacturer price		X		
Fix wholesale margin		X		
Fix pharmacy retail price	X		Via mark-up scheme, additionally there is a pharmacy tax applied	LFN Enactment on Pharmacy Mark-ups from 1 November 2005
Decide on reimbursement status	X			Act 2001/02:63, "New Pharmaceutical Benefits Reform"
Agrees on reimbursement price		X		
Decide on reimbursement price	X			Act on Pharmaceutical Benefits etc. (2002:160) from 1 October 2002
Use Pharmacoeconomic guidelines	X			
Use Internal reference pricing	X		On ATC 5 level for determining reimbursement price of substitutable products	
Use External reference pricing		X		
Price freezes		X		
Margin cuts	X		1 January 2005	Enactment of LFN 2005
Discounts and Rebates	X		County councils try to negotiate discounts	
Company profit control			Not applicable	
Country specific:	RFV no longer plays a role in pricing or reimbursement of pharmaceuticals. Pharmaceuticals are reimbursed through the single county councils (but there is a state subsidy). Central public authority is the LFN (Pharmaceuticals Benefits Board); the Ministry of Health and Welfare only has a governing role.			
Pharmaceutical Industry				
Sets manufacturer price freely	x		Manufacturers are free to change their price any time.	
Notifies manufacturer price		x	However, products only qualify for reimbursement if they have an	

Tasks / Duties	Yes	No	Comments	Legal bases
Negotiates manufacturer price		X	approved wholesale price.	
Decides on application for reimbursement	X			
Negotiates reimbursement price			Not applicable due to LFN information	
Free to keep manufacturer price above reimbursement price	X		Usually adapts manufactory price to reimbursement price	
Free to grant rebates/ discounts to wholesalers	X			
Free to grant rebates/ discounts to pharmacies	X			
Can engage in marketing towards doctors	X		In line with code of conduct	http://www.lif.se
Can engage in public advertising	X		Only for OTC	
Can provide information toward patients	X		Only for OTC and if requested to do so by authorities	
Applies for switches and de-listing	X			
Promotional control		X		
Country specific:				
Distribution Chain				
Wholesaler				
Margins are fixed by statute		X		
Margins are subject to statutory discounts / rebates		X		
Free to grant discounts / rebates to pharmacies	X			
Pharmacists				
Margins are fixed by statute	X		Based on wholesaler maximum price	LFN Enactment on Pharmacy Mark-ups 1 November 2005
Free to set retail price		X		
Obliged to inform patient on cheaper product	X			Lag om läkemedelsförmåner m.m. (Act on Pharmaceutical Benefits, etc.) 2002:160 as amended with SFS 2003:76, Section 21
Obliged to substitute by a generic	X		If pharmaceutical is cheaper (except inverse "G" scheme)	

Tasks / Duties	Yes	No	Comments	Legal bases
Allowed to substitute by a generic	X			
Obliged to substitute by a parallel import	X		If pharmaceutical is cheaper	
Allowed to substitute by a parallel import	X			
Therapeutic / analogous substitution is allowed		X		
Are subject to statutory discounts / rebates			Not applicable	
Claw back system exists			Not applicable	
May grant rebates to customers	X		only for non-reimbursable pharmaceuticals	
Country specific:	There is only 1 pharmacy chain "Apoteket" on the market, that is a non-profit state monopoly			
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			Health and Medical Service Act 1982:763 as amended with Swedish Code of statutes 2002:163, Section 2b
Are obliged to inform on co-payment	X			Health and Medical Service Act 1982:763 as amended with Swedish Code of statutes 2002:163, Section 2b
Prescription habits are monitored	X			
Are subject to prescription guidelines	X		Indicative guidelines imposed by some counties	
Budgets are controlled	X		In some counties budgets are compulsory in others only indicative	
Allowed to prescribe INN	X			
Obliged to prescribe INN		x		
Can oppose generic substitution	X		Inverse "G"-scheme	Lag om läkemedelsförmåner m.m. (Act on Pharmaceutical Benefits, etc.) 2002:160 as amended with SFS 2003:76
Can oppose therapeutic substitution			Not applicable	

Tasks / Duties	Yes	No	Comments	Legal bases
Can oppose substitution by parallel import	X			Lag om läkemedelsförmåner m.m. (Act on Pharmaceutical Benefits, etc.) 2002:160 as amended with SFS 2003:76
Country specific:				
Patients				
Can shop for cheapest price of the product	X		Only relevant for OTC	
Pay a flat rate per prescription / pack		X		
Pay a certain percentage per prescription / pack or a deductible	X			Lag om högkostnadsskydd vid köp av läkemedel (The Cost Limitation (Purchases of medicinal products etc.) Act) 1996:1150) Section 4 as amended 2002
Annual minimum co-payment		X	SEK 900.- / € 96.96 for a period of 12 months, except for insulin	Lag om högkostnadsskydd vid köp av läkemedel (The Cost Limitation (Purchases of medicinal products etc.) Act) 1996:1150) Section 4 as amended 2002
Annual maximum co-payment	X		SEK 1,800.- / € 193.9 for a period of 12 months	Lag om högkostnadsskydd vid köp av läkemedel (The Cost Limitation (Purchases of medicinal products etc.) Act) 1996:1150) Section 4 as amended 2002
May ask for substitution by a generic	X			Lag om läkemedelsförmåner m.m. (Act on Pharmaceutical Benefits, etc.) 2002:160 as amended with SFS 2003:76
May oppose substitution by a generic	X		But then has to pay difference to reimbursement price out-of-pocket	Lag om läkemedelsförmåner m.m. (Act on Pharmaceutical Benefits, etc.) 2002:160 as amended with SFS 2003:76
May ask for substitution by a parallel import	X			Lag om läkemedelsförmåner m.m. (Act on Pharmaceutical Benefits, etc.) 2002:160 as amended with SFS 2003:76
Can oppose substitution by a parallel import	X		But then has to pay difference to reimbursement price out-of-pocket	Lag om läkemedelsförmåner m.m. (Act on Pharmaceutical Benefits, etc.) 2002:160 as amended with SFS 2003:76
Can oppose substitution only on payment of price difference	X			Lag om läkemedelsförmåner m.m. (Act on Pharmaceutical Benefits, etc.) 2002:160 as amended with SFS 2003:76

Tasks / Duties	Yes	No	Comments	Legal bases
Has to pay the difference between reimbursement price and retail price	X			Lag om högkostnadsskydd vid köp av läkemedel (The Cost Limitation (Purchases of medicinal products etc.) Act) 1996:1150) Section 4 as amended 2002
Has access to full public information on prices and products	X			Hälso- och Sjukvårdslag (Health and Medical Service Act) 1982:763 as amended with Swedish Code of statutes 2002:163
Country specifics:				

Source: ÖBIG 2006

UNITED KINGDOM

26 United Kingdom

26.1 Pharmaceutical System

26.1.1 Regulatory Framework and Authorities

The main characteristic of the British healthcare system is, that nearly all healthcare services are offered by public authorities. The most important health care institution is the National Health Service (NHS), which was introduced in 1948 and covers all British residents. It is funded mainly through general taxation together with an element of national insurance contribution (an income based tax payable by employers and employees) and co-payments.[1252]

Primary care is provided by 302 Primary Care Trusts (PCT) which receive budgets directly from the NHS and influence the way pharmaceuticals are prescribed. PCT are made up of groups of local general practitioners (GP) practices, community staff and representatives of the local community. The NHS operates as "gatekeeper" system, whereby GPs determine access of patients to specialists. Most patients are exempt from co-payments.

The most relevant players in the UK pharmaceutical system are:

- The Department of Health (DH), which is the regulatory body for pharmaceuticals. DH negotiates the Pharmaceutical Price Regulation Scheme (PPRS) and the Schemes M and W for generics (cf. 26.1.4.2.2)[1253]
- The Medicines and Healthcare Products Regulatory Agency (MHRA), which is an executive agency of the DH is responsible for the authorisation of pharmaceuticals. The MHRA is also monitoring the safety and efficiency of already authorised pharmaceuticals
- The NHS Business Services Authority (NHSBSA), until 31 March 2006 known as Prescription Pricing Authority (PPA), which is a part of the NHS and is responsible for the reimbursement of pharmacists and calculates the reimbursement price of Category A generics (cf. 26.2.1.4)[1254]
- NICE by providing mandatory guidance for new technologies and pharmaceuticals to British authorities
- The Association of the British Pharmaceutical Industry (APBI), which negotiates the PPRS (cf. 26.1.4.1) with the DH
- British Generic Manufacturers Association (BGMA), which negotiates the Scheme M with the DH

[1252] Health Act 1999 (1999 c. 8), as amended

[1253] DH 2005a and b

[1254] http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/GenericMedicines/fs/en

The MHRA is responsible for the market authorisation of pharmaceuticals and is also monitoring the safety and efficiency of already authorised pharmaceuticals.

If a branded POM is authorised it is with few exceptions reimbursed. The DH and the ABPI negotiate periodically the PPRS which controls the profitability of branded pharmaceutical companies and indirectly influences prices (cf. 26.1.4.1).

If a (unbranded) generic POM is authorised it is (with few exceptions) reimbursed at a reimbursement price to pharmacists. The reimbursement price of Category M generics is determined by the DH together with the British Generic Manufacturers Association (BGMA) and the reimbursement price of Category A generics is calculated by the NHS Business Services Authority (NHSBSA), that is also responsible for the remuneration of pharmacists.

Table 26.1: United Kingdom - Relevant Bodies in the Pharmaceutical Sector, 2006

Institution	Task	Contact details/URL	Responsible person
Department of Health (DH) operating the National Health Service (NHS)	Regulatory Body for pricing and reimbursement of pharmaceuticals	DoH Richmond House 79 Whitehall UK-London SW1A 2NS United Kingdom Tel.: +44 20 7210 4850 dhmail@dh.gsi.gov.uk www.dh.gov.uk/	Ms. Patricia Hewitt MP Secretary of State for Health Richmond House 79 Whitehall, UK-London SW1A 2NS United Kingdom
Medicines and Healthcare Products Regulatory Agency (MHRA)	Market authorisation of pharmaceuticals	MHRA Information Centre10-2 Market Towers 1 Nine Elms Lane UK-London SW8 5NQ United Kingdom Tel.: +44 20 7084 2000 Fax: +44 20 7084 2353 info@mhra.gsi.gov.uk www.mhra.gov.uk	Mr. Kent Woods Chief Executive Information Centre10-2 Market Towers 1 Nine Elms Lane UK-London SW8 5NQ United Kingdom Tel.: +44 20 7210 3000 info@mhra.gsi.gov.uk www.mhra.gov.uk
NHS Business Services Authority (NHSBSA), formerly known as Prescription Pricing Authority (PPA)	Pricing of generic pharmaceuticals	NHSBSA 152 Pilgrim Street UK-Newcastle Upon Tyne NE 16SN United Kingdom Tel.: +44 191 2325 371 Fax: +44 191 2322 480 www.ppa.org.uk/contact/newcastle.htm	Pharmaceutical Directorate Ms. Christine Dalton 152 Pilgrim Street UK-Newcastle Upon Tyne NE 16SN United Kingdom Tel.: +44 191 2325 371 christine.dalton@ppa.nhs.uk

Institution	Task	Contact details/URL	Responsible person
The Association of the British Pharmaceutical Industry (ABPI)	Association of Pharmaceutical Industry	12 Whitehall UK-London SW1A 2DY United Kingdom Tel.: +44 20 7930 3477 Fax: +44 20 7747 1414 www.abpi.org.uk	Mr. Richard Barker General Secretary UK-London SW1A 2DY United Kingdom Tel.: +44 20 7930 3477 Fax: +44 20 7747 1414 abpi@abpi.org.uk
British Generic Manufacturers Association (BGMA)	Association of Generic Manufacturers	BGMA 26 Grosvenor Gardens UK-London SW1W 0GT United Kingdom Tel.: +44 20 7838 4800 Fax: +44 20 7838 4801 info@britishgenerics.co.uk www.britishgenerics.co.uk	BGMA 26 Grosvenor Gardens UK-London SW1W 0GT United Kingdom Tel.: +44 20 7838 4800 Fax: +44 20 7838 4801 info@britishgenerics.co.uk www.britishgenerics.co.uk
British Association of Pharmaceutical Wholesalers (BAPW)	Wholesaler Association	BAPW 90 Long Acre UK-London WC2E 9RA United Kingdom Tel.: +44 20 7031 0590 Fax: +44 20 7031 0591 mail@bapw.net www.bapw.net	Mr. Michael Watts 90 Long Acre UK-London WC2E 9RA United Kingdom Tel.: +44 20 7031 0590 Fax: +44 20 7031 0591 msawer@bapw.net
British Generic Wholesaler Association	Generic Wholesaler Association	British Generic Wholesaler Association 26 Grosvenor Gardens UK-London SW1W 0GT United Kingdom Tel.: +44 20 7838 4800 Fax: +44 20 7838 4801 info@britishgenerics.co.uk www.britishgenerics.co.uk	British Generic Wholesaler Association 26 Grosvenor Gardens UK-London SW1W 0GT United Kingdom Tel.: +44 20 7838 4800 Fax: +44 20 7838 4801 info@britishgenerics.co.uk www.britishgenerics.co.uk
Royal Pharmaceu-tical Society of Great Britain (RPSGB)	Association of Pharmacists	RPSGB 1 Lambeth High Street UK-London SE1 7JN United Kingdom Tel.: +44 17 1735 9141 Fax: +44 17 1735 7629 www.rpsgb.org.uk/	Ms. Susan Sharpe 1 Lambeth High Street UK-London SE1 7JN United Kingdom Tel.: +44 17 1735 9141 Fax: +44 17 1735 7629
British Medical Association (BMA)	Medical Doctors' Association	BMA Tavistock Square UK-London WC1H 9JP United Kingdom Tel.: +44 17 1387 4499 Fax: +44 17 1383 6454 www.bma.org.uk	Mr. Amstrong Tavistock Square UK- London WC1H 9JP United Kingdom Tel.: +44 17 1387 4499 Fax: +44 17 1383 6454 marmstrong@bma.org.uk

Institution	Task	Contact details/URL	Responsible person
The Patients' Association (PA)	Patients Association	PA, PO Box 935 UK-Harrow Middlesex HA1 3YJ United Kingdom Tel.: +44 20 8423 9111 Fax: +44 20 8423 9119 president@patients-association.co www.patients-association.org.uk	Ms. Claire Rayner PO Box 935 UK-Harrow Middlesex HA1 3YJ United Kingdom Tel.: +44 20 8423 9111 Fax: +44 20 8423 9119 president@patients-association.co
National Institute for Health and Clinical Excellence (NICE)	Guidance on the use of pharmaceuticals	NICE 71 High Holborn UK-London WC1V 6NA Unted Kingdom Tel.: +44 20 7067 5800 Fax: +44 20 7067 5801 nice@nice.org.uk www.nice.org.uk	Mr. Andrew Dillon 71 High Holborn UK-London WC1V 6NA Unted Kingdom Tel.: +44 20 7067 5800 Fax: +44 20 7067 5801 nice@nice.org.uk

Source: ÖBIG 2006

26.1.2 Market Players

26.1.2.1 Pharmaceutical Industry

The British pharmaceutical industry plays - with a pharmaceutical production of € 21,685 million[1255] in 2004 - a leading role in Europe.

The UK pharmaceutical market is highly fragmented, only one pharmaceutical company Pfizer had with 10.7% a marked share above 10% in the year 2004. The Association of the British Pharmaceutical Industry (ABPI) which plays a major role in the pricing of branded pharmaceuticals (cf. 26.1.4.1) has 82 full members which do employ 67,000 persons.[1256] However, especially during the last five to ten years parallel importers role became more important.

UK is with € 17,234 million exports compared to € 1,984 million imports rather an export than an import country.[1255]

26.1.2.2 Distribution

The wholesale sector in the United Kingdom is divided into full-line wholesalers, short-line wholesalers and self-distributors. The 14 full-line wholesalers have a comprehensive stock of POM and Over-the-Counter (OTC) pharmaceuticals (up to 8,000 different lines, some of

[1255] EFPIA 2005

[1256] ABPI 2006

which are unprofitable) whereas short-line wholesalers trade in a smaller range of profitable lines.

Currently several hundreds of short-line wholesalers ranging from national to regional players to independent pharmacists trading with just a few pharmaceuticals are operating on the market. Self-distributors are the UK's leading pharmacy chains "Boots" and "Chemists", which distribute pharmaceuticals (often under a "Boots" or "Chemists" brand name) to their own retail outlets.[1257]

All sorts of pharmaceuticals are dispensed by pharmacies (many of them operating as pharmacy chains) and self-dispensing doctors. OTC on the General Sales List, so-called GSL (cf. 26.1.3) may also be sold by pharmacy stores and supermarkets. In 2004 there where 12,200 pharmacies in UK corresponding to one pharmacy per 4,800 inhabitants.[1257]

Due to the Health Bill[1258], passed in October 2005, since 1 May 2006 pharmacists may opt to become independent prescribers, i.e. being able to prescribe any licensed pharmaceutical for any condition with the exception of some groups of pharmaceuticals (i.e. narcotics) to their customers.[1259] This situation is unique in the European Union.

26.1.2.3 Patients

Patients have no formal role in the United Kingdom but their interests are represented by the Patients' Association (PA)[1260].

However, patients may shop around for cheap pharmaceuticals, especially non-reimbursable OTC as there are a lot of dispensing outlets on the market and the pharmacy retail price may vary throughout the country.

In United Kingdom self medication is an important factor. In 2005 12.03% of all pharmaceutical sales were self medication[1261]. An example for this is the switch of pharmaceuticals containing simvastatin from a Prescription-only Medicine (POM) to a Pharmacy-only Medicine (P) (cf. 26.2.1.6).

26.1.3 Overview About the Pharmaceutical System

The sale and supply of medicines in the United Kingdom is controlled by the Medicines Act 1968 as amended should be based on the EU Directive 2001\83\EC.

All pharmaceuticals are categorised by MHRA in one of three following groups:

1257 PPR 2005

1258 http://www.dh.gov.uk/assetRoot/04/12/62/15/04126215.pdf

1259 RPSGB, http://www.rpsgb.org.uk

1260 PA, http://www.patients-association.org.uk

1261 AESGP http://www.aesgp.be

- Prescription-only Medicines (POM)
- Pharmacy-only Medicines (P), i.e. non-prescription pharmaceuticals (OTC) that only may dispensed through a pharmacy
- Pharmaceuticals on the General Sales List (GSL), i.e. OTC that also may be dispensed by other outlets, like super markets.[1262]

A major characteristic of the British market is that almost all authorised pharmaceuticals are eligible for reimbursement and are made available through the National Health Service. These products are commonly referred to as NHS-products (cf. 26.2.1 for details).

In 2005 around 14,000 to 15,000 pharmaceuticals had a market authorisation in the UK. The classification status of pharmaceuticals may change through a so called “reclassification procedure”, i.e. a switch. In general, almost all OTC (especially GSL) and pharmaceuticals prescribed by a private doctor are not reimbursed trough the NHS.

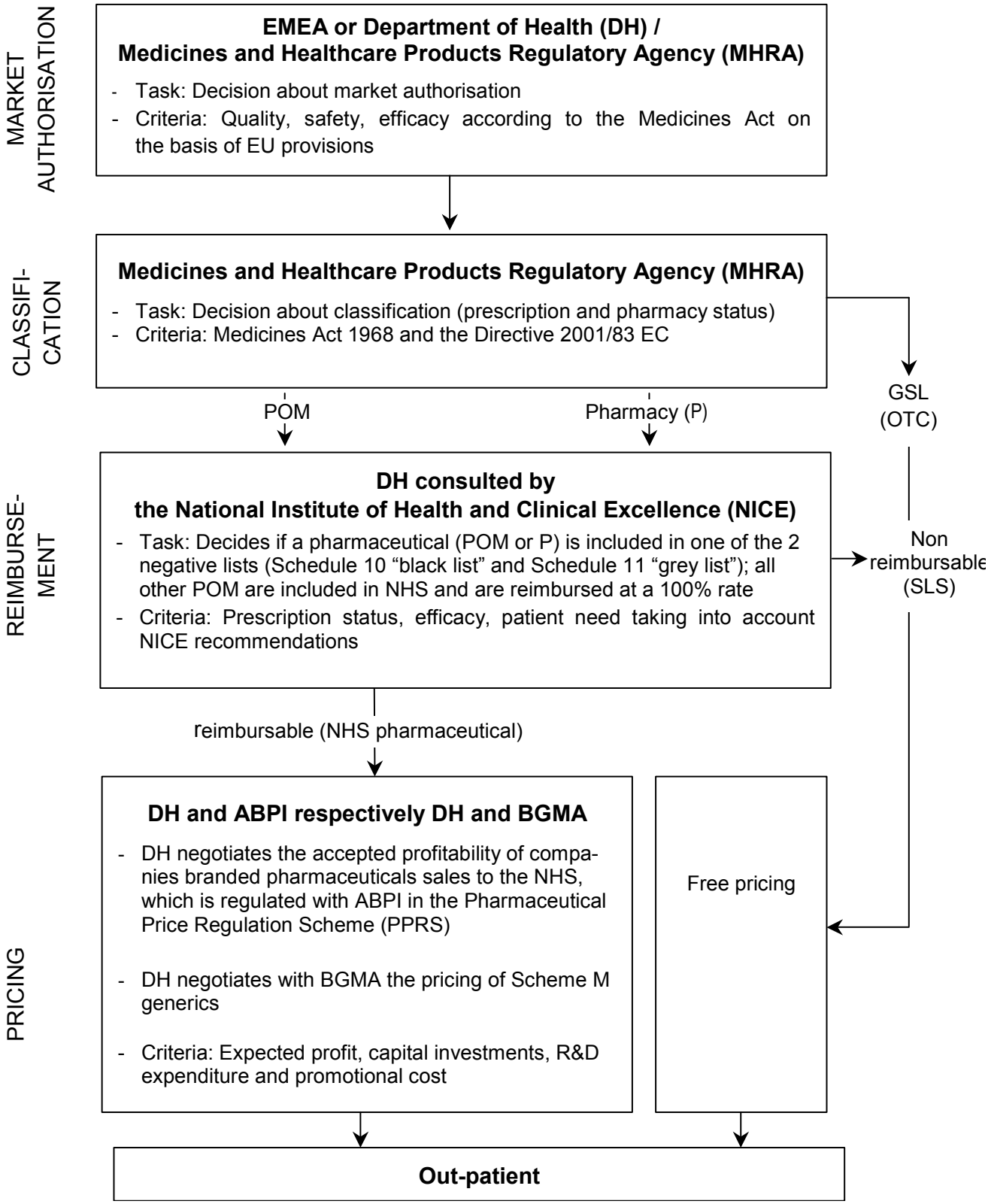
Furthermore POM included in the one of the two British negative lists (Selected List Scheme, SLS) established under the General Medical Services Regulations (GMSR)[1263] a are excluded from NHS reimbursement. The both lists are commonly called "black" and "grey" list (cf. 26.2.1.5).

Figure 26.1 shows an overview of the pharmaceutical system in United Kingdom.

[1262] Medicines Act, http://statutes.agc.gov.sg/non_version/cgi-bin/cgi_retrieve.pl?&actno=Reved-176&date=latest&method=part

[1263] GSMR, http://www.redbook.i12.com/rb/Docs/rb221.htm

Figure 26.1: United Kingdom - Pharmaceutical System, 2006



Source: ÖBIG 2006

26.1.4 Scope of Price Control

In the UK the price of GSL and Hospital-only medicines (HOM) is not controlled and can be freely set by the manufacturer. In case of GSL products, i.e. self-medication pharmaceuticals the respective shares of the manufacturer, the wholesaler and the pharmacists are negotiated on a free-market basis, but the manufacturer is likely to receive half of the pharmacy retail price.[1264] The pricing of non-reimbursable pharmaceuticals i.e. those on the Selected list scheme (SLS) - the British negative list (cf. 26.2.1.5) - is also not regulated and the price may be freely set by the manufacturer.

For pharmaceuticals reimbursed by NHS there are two different systems of pricing in place - one for branded pharmaceuticals and one for most generics.

The price build-up for branded pharmaceuticals is, generally speaking, as follows: In case of NHS pharmaceuticals the manufacturer price (cf. 26.1.4.2.1) is freely set within the within the framework of the PPRS, to which a wholesale mark-up is added (cf. 26.1.4.3). This manufacturer price together with the wholesale mark-up forms the so-called NHS price, that is the basis for the remuneration of pharmacists. In addition the pharmacist is remunerated by fee-for-services rendered, e.g. dispensation, vigilance, production of magistral formulations. In contrary to most other EU Member States no fixed mark-up schemes are applicable for pharmacists.

The NHS prices (= basis for reimbursement, also called “trade price”) for on- and off-patent pharmaceuticals are listed by the NHSBSA in the so called Drug Tariff[1265] and the prices of branded pharmaceuticals (POM and some P) are also listed in the British National Formulary (BNF).[1266]

The Drug Tariff[1267] differs between the following categories of pharmaceuticals:

- **Category A** pharmaceuticals are generics which are commonly available. Their reimbursement price (= NHS price) is calculated by NHSBSA from a basket of prices provided by generic manufacturers / suppliers.
- **Category B** pharmaceuticals are less common generics, whose NHS-price is based on the price of a particular wholesaler or generic manufacturer.
- **Category C** contains all on-patent (branded) pharmaceuticals by their generic name. However, Category C product’s prices are based on a particular brands or manufacturer and are controlled through the PPRS (see below).

1264 AESGP 2005

1265 Drug Tariff, http://www.ppa.org.uk/ppa/edt_intro.htm

1266 BNF, http://www.bnf.org/bnf

1267 Regulation 56(1) of the National Health Service (Pharmaceutical Services) Regulations 2005 and National Health Service (Pharmaceutical Services) (Wales) Regulations 2005 as amended

- **Category E** are extemporaneous preparations. NHSBSA pays an additional fee for such pharmaceuticals to the pharmacist.
- **Category M** pharmaceuticals are generics which are commonly available. Their reimbursement price (= NHS price) is set by the DH (cf. 26.1.4.2.2) based on information submitted by manufacturers.[1268]

Table 26.2 shows the various pricing policies applied in the UK.

Table 26.2: United Kingdom - Pharmaceutical Pricing System, 2006

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Non-reimbursable OTC, HOM, SLS, Generics Category A and M	Non-reimbursable OTC, HOM, SLS, Generics Category A and W	Non-reimbursable OTC, HOM, SLS, Generics Category A and M (W)
Indirect Price Control (PPRS)	Reimbursable branded POM and OTC included in NHS, backed up by law		Fee-for service plus reimbursement of net ingredient cost
Discounts/Rebates	Commercial discounts between all levels, claw-back system for NHS pharmaceuticals		
Institution in charge of pricing	(Branded) On-patent pharmaceuticals: Department of Health (DH) and The Association of British Pharmaceutical Industry (ABPI) agree on PPRS Generics Category A: NHSBSA Generics Scheme M (W): DH and the British Generic Manufacturers Association (BGMA)		
Legal Basis	- The Pharmaceutical Price Regulation Scheme (PPRS) backed by Health Act, section 33, http://www.opsi.gov.uk/acts/acts1999/99008a-a.htm#33 - Health Act, sections 35 and 36 (Regulation of generics except Scheme M and W) - Scheme M and W are based on a voluntary agreement backed by Health Act section 34-38, http://www.opsi.gov.uk/acts/acts1999/99008a-a.htm#36 - Regulation 56(1) of the National Health Service (Pharmaceutical Services) Regulations 2005 and National Health Service (Pharmaceutical Services) (Wales) Regulations 2005 as amended		

DH = Department of Health; HOM = Hospital-only-Medicine, NHSBSA = NHS Business Service Authority, formerly known as Prescription Pricing Authority, OTC = Over-the-Counter, POM = Prescription-only Medicine, PPRS = Pharmaceutical Price Regulation Scheme, SLS = Selected List Scheme

Source: ÖBIG 2006

[1268] Drug Tariff, Part VIII, http://www.ppa.org.uk/ppa/drug_tariff_guidance_notes.htm#link4

26.1.4.1 Pharmaceutical Price Regulation Scheme (PPRS)

In general there is free pricing in the UK. However, the price of pharmaceuticals reimbursable by NHS are subject to the Pharmaceutical Price Regulation Scheme (PPRS) [1269], which is backed up by the Health Act.[1270] Under this voluntary system, that is negotiated periodically between the DH and the ABPI, a profit framework is fixed for each individual manufacturer. Within this framework manufacturers and suppliers are free to set their prices.

The PPRS, that was already introduced in 1957, is also referred to as an indirect price control tool. Since 1986 the scheme has covered only those pharmaceuticals sold under brand names and has excluded those sold under generic names.[1271] The current PPRS has started in January 2005 and is valid for 5 years.

Though it is an voluntary agreement, Secretary of State for Health has statutory powers to act against companies that fail to sign up.[1272] The PPRS covers all suppliers of branded prescription pharmaceuticals that have annual sales to the NHS of more than GBP 1.- million / € 1.46 million.[1273] This includes sales through pharmacies and self-dispensing doctors as well as sales to NHS hospitals.

Sales derived predominantly from private prescriptions, unbranded generics, non-reimbursable brands, exports, GSL pharmaceuticals and In-Vitro Diagnostics are excluded from the PPRS. Since 1999 also pharmaceutical companies producing “standard” branded generics are excluded from the PPRS. A “standard” branded generic is defined as an off-patent pharmaceutical to which the manufacturer (who is not the originator company) has applied a brand name and that is comparable to a unbranded generic that is already available on the British market.[1274]

In total the PPRS covers - by value - about 80% of pharmaceuticals dispensed ob behalf of the NHS[1275]. A further characteristic of the PPRS is, that it also includes price cuts and freezes, cf. section 26.1.5.4 for details.

[1269] This system of controlling profits rather than prices is unique in Europe.

[1270] Health Act section 33, http://www.opsi.gov.uk/acts/acts1999/99008a-a.htm#33

[1271] Tilson/Barry 2005

[1272] Health Act section 33, http://www.opsi.gov.uk/acts/acts1999/99008a-a.htm#33

[1273] Please note that exchange rate used for all further calculations was: € 1 = GBP 0.6838 (Annual rate 2005 as published by the Austrian National Bank on basis of European Central Bank, cf. http://www.oenb.at/de/stat_melders/datenangebot/zinssaetze/wechselkurse/wechselkurse.jsp

[1274] DH 2004, http://www.dh.gov.uk

[1275] Tilson/Barry 2005

26.1.4.2 Manufacturer Price

26.1.4.2.1 Branded Pharmaceuticals

The PPRS regulates the British manufacturer prices indirectly by controlling the profits of the pharmaceutical companies (cf. 26.1.4.1).

Under the terms of PPRS pharmaceutical companies are allowed a defined return on capital (ROC) each year. All companies have a ROC target of 17% for assessing price increase applications (ROC level 1) and a 21% target for assessing profits (ROC level 2). If the profit percentage is higher than the approved amount, the company either

- has to pay back excess profits to the NHS, or
- reduce the prices of its pharmaceuticals and postpone any planned price increases.

The upper margin of tolerance on the ROC target is 140%, but only if the concerned manufacturer didn't increase the price of any of his products in the same year[1276].

The lower margin of tolerance on the ROC target is 40%. In this case, the manufacturer may apply for a price increase. There are several allowances for pharmaceutical companies (i.e. additional expenses accepted by DH) for both ROC levels, which are listed in Table 26.3 on the next page.

[1276] DH 2004, Tilson/Barry 2005

Table 26.3: United Kingdom - Allowances to Pharmaceutical Companies, 2006

Allowance	Form of allowance		Level 1 (price increase)	Level 2 (profit)
Marketing Allowance	Fixed element		GBP 500,000.- / € 731,208.-	GBP 1,000,000.- / € 1,462,416.-
	Standard element		2%	4%
	Product Servicing Allowances	For each active substance with sales to the NHS of GBP 1,000,000/ € 1,462,416.- or more	- GBP 58,000.- / € 84,420.- for each of the first three eligible products - GBP 46,000.- / € 67,271.- for each of the next three - GBP 35,000.- / € 51,185.-for each of the next three - GBP 23,000.- / € 33,635.- each for all others	
Information Allowance	Standard element		2%	4%
Research and Development Allowance	Flat rate		15%	20%
	Variable rate[1]	Innovation[2]	20 active substances (NHS sales of GBP 300,000.- / € 438,724.- or more) at 0.25% each	20 active substances (NHS sales of GBP 300,000.- / € 438,724.- or more) at 0.25% each
		Paediatrics		1.0% per product (up to 3%) in any one year
	Maximum Total		20%	28%

[1] Definition of on-patent to include 10 years from date of marketing authorisation for new active substances where no patent exists

[2] or New Entrant Flexibility (for 1st 3 years in the AFR):

- 2.0% of NHS sales for active substance 1
- 1.0% for active substance 2
- 0.25% for each active substance thereafter = 5% max

AFR =Annual financial return; NHS = National Health Service

Source: PPRS 2005

Within this framework manufacturers are in principle allowed to set prices at their own discretion. Irrespectively of the general 7% price freeze for pharmaceuticals included in the PPRS (cf. 26.1.5.4) manufacturers may even increase the price of new pharmaceuticals (i.e. those introduced after 1 January 2005) up to a maximum of 20% after 1 January 2006. A limitation, however, is that any reduction in the price of a new pharmaceutical cannot be used to offset price increases on other NHS products until the new pharmaceutical has been on market in the UK for two years.[1277]

[1277] DH 2004

26.1.4.2.2 Generics

Pricing of most generics is different to those of on-patent pharmaceuticals as unbranded generics (POM, P and OTC), GSL generics and reimbursable "standard" branded generics (cf. 26.1.4.1) are not included in the PPRS.

In general, also the prices of generics may be freely set by the manufacturers, but to qualify for reimbursement their price has to - depending on their category (cf. 26.1.4) - be either negotiated between the Department of Health (DH) and the British Generic Manufacturers Association (BGMA) (for Category M and W) or to be calculated by the NHSBSA (for Category A).

On 1 April 2005 a new category for generics, Category M, was introduced in the Drug Tariff[1278]. This Category M applies to some pharmaceuticals previously listed in Category A (i.e. most common generics). Category A and M contains all reimbursable generics which are readily available on the British pharmaceutical market. Pharmaceutical companies that supply NHS pharmaceuticals and do not opt for Scheme M remain in Category A.[1279]

Generics Category A

The pricing of generics in Category A is free. It is only indirect restricted trough the reimbursement price (cf. 26.2.1.1). The standard way of pricing generics is the statutory scheme for Category A generics.[1280]

Generics Category M

In April 2005 a new generic category - Category M - was added to the Drug Tariff as part of the governments reforms to the supply and reimbursement of generics. This is the result of negotiations between the government, industry, suppliers and dispensers of generic pharmaceuticals.

Pricing for Category M pharmaceuticals is based on a voluntary agreement (so-called Scheme M for Manufacturers) between the DH and the BGMA, which differs from the statutory scheme for Category A in the calculation of the reimbursement prices by the DH (for its calculation cf. 26.2.1.1). In addition to Scheme M there is a Scheme W (for Wholesalers, cf. details in 26.1.4.3).

[1278] Part VIII of the Drug Tariff

[1279] DH 2005a

[1280] Health Act section 33, http://www.opsi.gov.uk/acts/acts1999/99008a-a.htm#33

Both schemes are covered by voluntary arrangements under Section 33 of the Health Act 1999 and are expected to operate for not less than 5 years.[1281] Those manufacturers that decide not to join the relevant scheme will be subject to a statutory scheme under Sections 34-38 of the Health Act 1999.[1282]

Exemptions include pharmaceuticals available to the public without a prescription and pharmaceuticals that cannot be prescribed on the NHS. In principle manufacturers are free to set prices at their discretion as long as the price does not exceed the original branded products price. The pricing of pharmaceuticals in Category M is only indirectly restricted by the NHS price (cf. 26.2.1.1)[1283].

Under the new two voluntary schemes M and W manufacturers and wholesalers will provide information that will allow quarterly revisions to the new Category M in part VIII of the Drug Tariff. Where this data is not received from manufacturers, the prices may be determined from information provided by wholesaler members of Scheme W. Members of Schemes M and W will provide quarterly information on volumes, net sales values and net acquisition costs (cf. 26.2.1.4). This information will be used to calculate the reimbursement prices of category M generic medicines.[1284]

26.1.4.3 Wholesale Price

Branded Pharmaceuticals

The wholesale margins for branded pharmaceuticals are determined within the scope of the PPRS (cf. 26.1.4.1) and may be at a maximum of 12.5% off the NHS price (the price which is reimbursed by the NHS). This percentage has remained unchanged since 1983. However, the wholesaler is free to set a lower margin and in practice wholesalers give a proportion of their margin as a discount to pharmacies.

Generics Category A, B, C, E

Wholesale margins for generics included in Category A, B, C and E of the Drug Tariff (cf. 26.1.4) are unregulated and are ranging between 15 -25%[1285].

Generics Category W

Category W (for Wholesaler) corresponds to Category M on manufacturer level (cf. 26.1.4.2.2) for details. Wholesalers are allowed to set margins in their own discretion, as long as they provide the DH with information sufficient to explain the reason for charging prices.

1281 PPR 5/2005

1282 Health Act section 34-38, http://www.opsi.gov.uk/acts/acts1999/99008a-a.htm#36

1283 Health Act section 33, http://www.opsi.gov.uk/acts/acts1999/99008a-a.htm#33

1284 DH 2005c

1285 PPR 2005

Non-reimbursable pharmaceuticals

Wholesale margins for pharmaceuticals not reimbursed by the NHS (cf. 26.2.1.5) are unregulated and are ranging approximately between 15-25%.[1285]

26.1.4.4 Pharmacy Retail Price

The Pharmacy Retail Price (PRP) may vary throughout the country. As mentioned above wholesalers forward a proportion of their margin for branded NHS pharmaceuticals as a discount to pharmacies.[1286] For all other pharmaceuticals pharmacy margins are unregulated, but it is assumed that they may be up to 50% for unbranded generics or OTC.

The remuneration of pharmacists is not based on mark-ups or margins but on a fee-for-service principle. Pharmacists are remunerated the net ingredient cost of the pharmaceutical as listed in the Drug Tariff plus a dispensing fee of GDP 0.9 / € 1.296 per item dispensed by the NHSBSA.[1287] For some pharmaceuticals there are additional fees payable to the pharmacists. These fees are listed in part IIIA of the Drug Tariff.[1288]

Pharmacists may also keep the difference between the NHS reimbursement price and the purchase price (if they buy a cheaper (generic/parallel traded) product), however the NHS retains some of this money via the claw-back system (cf. 26.1.5.5).

Pharmacy contractors who dispense 2,000 prescriptions items or more per month receive additional establishment payments which are set out in the table below:

Table 26.4: United Kingdom - Annual Establishment Payments, 2006

Number of items per months	Annual establishment payment by NHSBSA to pharmacies
2,000 - 2,249	GBP 20,000.- / € 29,248.-
2,250 - 2,499	GBP 20,911.- / € 30,580.-
> 2,500	GBP 21,821.- / € 31,911.-

Source: Drug Tariff 2006[1289]

26.1.4.5 Value Added Tax (VAT)

NHS prescriptions are exempt from VAT. OTC pharmaceuticals, non-reimbursed and private prescriptions and pharmaceuticals sold in hospital pharmacies are charged at the standard VAT rate of 17.5%[1290].

1286 PPR 2005

1287 Health Act section 29-32, http://www.opsi.gov.uk/acts/acts1999/19990008.htm

1288 Drug Tariff, http://www.ppa.org.uk/edt/April_2006v3/mindex.htm

1289 Drug Tariff Part VIA, http://www.ppa.org.uk

1290 DG Taxation and Trade Union 2006

26.1.5 Price Related Cost-containment Measures

26.1.5.1 Pharmaco-economic Evaluation

Currently pharmaco-economic evaluation is not taken into account when setting prices, but UK is starting to connect reimbursement eligibility decisions for new innovative pharmaceuticals with evidence of cost-effectiveness. Since its launch in 1999 the National Institute for Health and Clinical Excellence (NICE) provides guidance for the management of diseases, using cost- effectiveness appraisals for new pharmaceuticals[1291]. NICE extends to three main areas of activity:

- *Technology appraisal* to assess the evidence base of new and existing health technologies, with the view to providing a source of advice on these treatment interventions and other medical procedures
- *Clinical guidelines* to help healthcare professionals and patients to be informed about healthcare in specific clinical circumstances. These guidelines have to take clinical and cost-effectiveness into account. These guidelines are part of a computerised decision support system for doctors.
- *Clinical audit*: NICE produces tools that can be used to monitor the use of particular interventions or the care received by patients within the NHS[1292].

Appraisal process

Pharmaco-economic studies are mandatory for all pharmaceuticals referred to NICE for appraisal. The appraisal process takes a minimum of 54 weeks from the start to the end of the appeal period.

The appraisal begins with NICE commissioning an independent academic centre to review the published evidence of the technology treatment and prepare an assessment report. Consultees and commentators are invited to comment this report. Then the assessment report and the comments are drawn together in an evaluation report. An independent appraisal committee then meets to consider the evaluation report and verbal evidence from clinical experts and patients. The committee then writes an Appraisal Consultation Document (ACD), which is circulated to all interested parties. Finally the committee meets again to consider the comments submitted on the ACD and prepares its final recommendations in the Final Appraisal Determination (FAD), which is submitted to NICE for approval.

[1291] Tilson/Barry 2005

[1292] Taylor 2003

NICE sends the FAD to consultees and publishes it on the internet. Consultees can appeal against the final recommendations stated in the FAD[1293]. If there are no appeals, the final recommendations becomes the basis of the guidance that NICE issues to the NHS. The implementation of NICE guidance became mandatory (e.g. for PCT) in 2001[1294].

26.1.5.2 Internal Price Referencing

The reimbursement price of Category M pharmaceuticals (cf. 26.1.4.2.2 and 26.2.1.1) is calculated as the weighted average price (charged by manufacturers after discounts) of all generics containing the same active ingredient (which complies to ATC 5 level). This price becomes the NHS "trade" price and is re-calculated by the DH on a quarterly basis.[1295]

26.1.5.3 External Price Referencing / Cross Country Referencing

United Kingdom is - together with Germany - one of the few European countries not applying any kind of external price referencing, i. e. international price comparisons.

26.1.5.4 Price Freezes / Cuts

The current PPRS (valid from 1 January 2005 to 31 December 2009) includes a voluntary price freeze for branded pharmaceuticals until 1 January 2006 and a 7% price cut for pharmaceuticals marketed by pharmaceutical companies with sales above GBP 1.- million / € 1.46 million.[1294]

Also the last PPRS, that was valid between 1 October 1999 and 31 December 2004 included a prize freeze till 1 January 2001 and a 4.5 % price cut.[1296]

26.1.5.5 Discounts and Rebates

Wholesalers are free to forward pharmacists any proportion of the 12.5% maximum wholesale margin for branded pharmaceuticals. The discounts offered vary , depending on the type of the pharmaceutical and the volume ordered by the pharmacist. Generics and parallel traded products are sold highly discounted to pharmacists.

The British Association of Pharmaceutical Wholesalers (BAPW) estimates that on average 9% of the gross margin of 12.5% is offered to the pharmacist and only 3.5% retains with the wholesaler.[1294]

A part of the additional profits pharmacists obtain through such discounts is retained by the DH in form of a "claw-back". The claw-back is calculated on the basis of a periodic discount inquiry, which samples prices in around 300 pharmacies to set an average discount level. The claw-back is set below this discount level not to discourage pharmacists with an efficient

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1293 PPR 2005

1294 PPR 2005

1295 DH 2005a

1296 ÖBIG 2001

procurement. The current claw-back rate (calculated from the potential savings pharmacists may achieve) is 11.47%.[1297]

26.1.5.6 Company Profit Controls

The UK is unique in controlling the profits of companies derived from sales of branded pharmaceuticals to NHS rather than fixing prices directly. As already explained, the profits of pharmaceutical manufacturers and suppliers are controlled through the PPRS (for further information cf. 26.1.4.1) which is negotiated periodically between the DH and the ABPI.

26.1.5.7 Parallel Trade

Parallel trade is an important factor in the pharmaceutical market in United Kingdom. It is estimated that 90% of pharmacists source pharmaceuticals through parallel trade.

One important reason for that is the so called “claw-back” system: like mentioned above pharmacists may keep the difference between the purchase price and the reimbursement price (=NHS price) of a pharmaceutical (minus the above mentioned 11.47%, cf. 26.1.5.5) That means, the cheaper a pharmacist buys a pharmaceutical the higher his/her profit. So pharmacists have a clear incentive to buy parallel traded products. The parallel traded product can be dispensed instead of the original one and the pharmacist keeps the difference to the original’s reimbursement price.

The pricing of parallel imported pharmaceuticals is also free in the UK, however the same NHS price is applied as for the original branded pharmaceuticals[1298].

26.1.6 Co-Payments

Patients who are not exempt from prescription fees pay a flat rate per prescription item. This prescription fee is increased every year along with the British Consumer Price Index. Since 1 April 2006 it amounts to GBP 6.65 / € 9.70.

Alternatively patients may purchase either a four monthly prescription prepayment certificate (PPC) for GBP 33.4 / € 48.8 or an annual PPC for GBP 91.8 / € 134.25 to cover all prescription fees for that period.[1299]

[1297] PPR 2005

[1298] Arfwedson 2003

[1299] PPA 2006

Approximately half of the UK population is exempt from the prescription fee, like persons under 16 and over 60 years, students, pregnant women, new mothers, low income groups and patients suffering from a chronic illness. There is also no prescription fee for prescribed contraceptives.[1297, 1300]

26.1.7 Information Transparency and Marketing

The UK regulations to implement the EU provisions on pharmaceutical advertising laid down in title VIII of the Community Code came into force in 1994. The Medicines Advertising Regulations (MAR) contains an advertising prohibition for POM and for pharmaceuticals for special diseases, as well as an interdiction of consumer sampling.[1301] Advertising for P and GSL pharmaceuticals is allowed in any media.[1302]

Promotional expenses are controlled under the PPRS. Under the 2004 PPRS, for instance, marketing expenses were restricted to GBP 1.- million / € 1.46 million, plus 4% of turnover, plus a small additional allowance for each pharmaceutical.[1303]

26.2 Reimbursement

26.2.1 Pharmaceutical Lists and Reimbursement Categories

In the United Kingdom pricing and reimbursement decisions are not separately negotiated, like in many other European countries[1304]. The vast majority of new POM are automatically granted reimbursement once the pharmaceutical has obtained market authorisation.

26.2.1.1 Reimbursement Price

The reimbursement price for branded pharmaceuticals under the PPRS (cf. 26.1.4.1) is the price set by the manufacturer plus the wholesale mark-up.

The reimbursement price for generics depends on their category (A or M (W)), cf. section 26.2.1.4 for a detailed explanation.

HOM are fully reimbursed by the NHS provided that the manufacturer price complies to the reimbursement price.

1300 Tilson/Barry 2005

1301 MAR, Part III http://www.opsi.gov.uk/si/si1994/Uksi_19941932_en_1.htm

1302 AESGP 2005

1303 DH 2004

1304 PPR 2005

26.2.1.2 Selection Criteria

Like already mentioned above most POM are reimbursed when obtaining market authorisation unless they are included in one of the two negative lists (black and grey list, cf. 26.2.1.5). Furthermore all GSL and most P-listed pharmaceuticals are not reimbursable.

26.2.1.3 Pharmaceuticals on Positive List

There is no real positive list in the United Kingdom, but the British National Formulary (BNF)[1305] acts as a kind of positive list, as it contains all reimbursable brands and their NHS price. In addition all pharmaceuticals are listed in the so-called Drug Tariff by their generic names (cf. 26.2.1.4).

26.2.1.4 Generics

Generics included in Category A (cf. 26.1.4.2) are reimbursed at the prevailing market prices, based on the list price of a sample of wholesalers and manufacturers. The reimbursement price is calculated from a basket of suppliers (2 wholesalers and 3 generic manufacturers) without considering discounts. This calculation is done by the NHSBSA on a monthly basis.[1306]

For Category M (W) pharmaceuticals a reimbursement price (acting as a kind of reference price) is calculated by the DH in accordance with the BGMA:

The price is calculated as the weighted average price (charged by manufacturers after discounts) of all generics with the same active ingredient in this category (which complies to ATC 5 level). For this calculation manufacturers (and respectively wholesalers) are required to submit the following information every March, June and September:

- The income generated for each generic by strength, pharmaceutical form, package size, net of all discounts and rebates (*net sales value*).
- The volume of each generic by strength, pharmaceutical form, and package size (*volume*).
- The level of any other rebate or discount not attributed to a specific pharmaceutical, but that accrues to those sales in the relevant quarter and up-to-date lists of the manufacturers i.e. trade price (*net acquisition costs*).[1307]

Under the new two voluntary schemes M and W manufacturers have to provide information that will allow the mentioned quarterly revisions of the new Category M generics. Where this data is not received from manufacturers, the prices may be determined from information provided by wholesaler members of Scheme W.[1308]

1305 http://www.bnf.org

1306 Drug Tariff, Part VIII, http://www.ppa.org.uk/ppa/drug_tariff_guidance_notes.htm#link4

1307 DH 2005a

1308 DH 2005c

The major difference between Scheme A and Scheme M (W) is that basic prices of Category M (W) pharmaceuticals reflect the average manufacturers' market prices after discount, rather than being based on the Category A system of basket prices before discount.

26.2.1.5 Non-reimbursable Pharmaceuticals

In general, almost all OTC (especially GSL) and pharmaceuticals prescribed by a private doctor are not reimbursed by the NHS.

Furthermore POM included in the one of the two British negative lists (Selected List Scheme, SLS) established under the General Medical Services Regulations (GMSR)[1309] are excluded from NHS reimbursement. This two lists are as following:

- *Black List:* Includes pharmaceuticals that GPs are not allowed to prescribe on the NHS. However, GPs can write private prescriptions for their NHS patients without charging for their consultation. The patient then has to pay the full price of the pharmaceutical. All blacklisted pharmaceuticals are stated explicitly in Schedule 10 of the GMSR[1310]. Pharmaceuticals included are, e.g., diet pills, vitamins, herbal preparations, etc.
- *Grey List:* This list refers to Schedule 11 of the GMSR[1311]. Pharmaceuticals on this list may be prescribed by a GP on the expense of the NHS for specific indications and patients groups. If a patient is not eligible, GPs can still write a private prescription. Pharmaceuticals included are for instance Viagra® or Nizoral® cream.

The black list is much more extensive than the grey list. The later only contains 12 substances, thereof four for the treatment of erectile dysfunction.

26.2.1.6 Delisting and Switches

The switching of POM to P-listed pharmaceuticals is an important cost-containment strategy by the MHRA supported by the government in United Kingdom. Also the Royal Pharmaceutical Society has also promoted the concept of POM-to-P switching and has actively and consistently lobbied for moves from prescription-only medicine to pharmacy status. Self care and self medication may be seen as an opportunity to shift costs out of the NHS onto the cionsumer. Because of such a switch pharmaceuticals lose their eligibility for reimbursement.

Between 1992 and 2002 there were about 50 major switches. Recent examples for POM to P-switches include omeprazole and simvastatin in the 10mg strength.[1312]

1309 GSMR, http://www.redbook.i12.com/rb/Docs/rb221.htm

1310 GSMR, Schedule 10, http://www.redbook.i12.com/rb/Docs/rb221.htm

1311 GSMR, Schedule 11 http://www.redbook.i12.com/rb/Docs/rb221.htm

1312 Tilson 2005

26.2.2 Reference Price System

There is no reference price system in place in the United Kingdom, but for Category M generics their reimbursement price (cf. 26.2.1.4) could be considered as a kind of reference price.

Pharmacists receive the NHS price for a generic, which means that they are encouraged to buy the cheapest available generic.

26.2.3 Pharmaceutical Budgets

There are prescribing budgets applied in the United Kingdom. These budgets are set by the PCT (with guidance of DH), which are responsible for regional spending on primary care for a period of three years. When "earmarking" the amount of money to be spent on pharmaceuticals PCT have to keep in mind that NICE recommendations on e.g. reimbursement of a particular new medicine are binding (cf. 26.1.5.1).[1313]

The DH encourages to control costs through effective generic prescribing (INN prescription) of doctors, therefore some PCT encourage the GPs to prescribe generically by offering specific incentives to for GP practices if they achieve a target generic prescribing rate. For example a PCT may grant a GP a certain percentage of his/her potential budget surplus for reinvestment in practice service and facilities.[1314]

26.2.4 Other Volume Control Oriented Measures

26.2.4.1 Prescription Monitoring and Other Doctors-related Measures´

There are a number of different systems in the UK to improve the cost-effectiveness in prescribing:

- The prescription patterns and expenditure profiles of doctors are monitored by the NHSBSA. Monthly budgetary reports and quarterly performance reports are sent to GPs. Details of a GPs prescribing expenditure are compared with local and national averages.
- Prescribing incentive schemes: The government established the Indicative Prescribing Scheme in 1991 with the aim of improving appropriate prescribing of pharmaceuticals. GPs are given a benchmark, which is used to evaluate the overall cost of their prescribing.

[1313] The National Health Service (Pharmaceutical Services) Regulations 2005, http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/LocalPharmaceuticalBudgets/LocalPharmaceuticalBudgetsArticle/fs/en?CONTENT_ID=4000163&chk=z4uSM1

[1314] PPR 2005

- As mentioned under section 26.2.3 incentives for GP for under spending their pharmaceutical budgets are in place. However, there are no explicit sanctions for over-spending in place.
- Doctors are assisted by a computerised decision support system providing guidance on the most commonly encountered conditions and symptoms in primary care. Each guideline in this system, known as "Prescribing Rationally with Decision Support in General Practice" (PRODIGY), offers different treatment scenarios and choice of pharmaceuticals. NICE guidance can also be issued through PRODIGY.[1315]

26.2.4.2 Generics and Parallel Trade

Although generic substitution is not allowed in United Kingdom, doctors are encouraged to write INN prescriptions (a prescription with the International Non-Proprietary Name, where the pharmacist can decide which specific pharmaceutical the patient gets). Subsitution by a parallel traded product is allowed[1316].

Pharmacists are encouraged to fill INN prescriptions with cheap generic or parallel traded (cf. 26.1.5.7) pharmaceuticals as they are always reimbursed the NHS price minus the clawback. The reimbursement price is listed in Part VIII of the Drug Tariff[1317].

For prescriptions written by reference or brand name the pharmacist is allowed and financially incentiviced to substitute by a (ceaper) parallel traded product.

DH expects the introduction of the new voluntary pricing schemes for generics - M and W (cf. 26.1.4.2.2 and 26.1.4.3) to generate annual savings of GBP 300 millon / € 438.7 million as currently about 80% of prescriptions are written generically by doctors.[1318] Still, the market share of generics was 20.1% by value in 2004[1319].

Consequently the UK has a large generic and a large parallel trade market. Parallel imports account to 15 - 20 % of all NHS sales.[1320].

1315 PPR 2005, Tilson/Barry 2005

1316 Enemark 2006

1317 Drug Tariff, http://www.ppa.org.uk/ppa/edt_intro.htm

1318 DH 2005c

1319 Simoens, 2006

1320 Tilson 2005

26.3 Overview of the Reimbursement Market in United Kingdom

Public authorities	Yes	No	Comment	Legal bases
Decide on prescription status	X			Health Act 1999 as amended
Decide on manufacturer price	X		Indirectly via the PPRS	Health Act, sect. 33, http://www.opsi.gov.uk/acts/acts1999/99008a-a.htm#33
Fix wholesale margin	X		For branded NHS pharmaceuticals	PPRS
Fix pharmacy retail price		X	Retail price depends on patient, region etc.; pharmacists are remunerated by fee-for-service	
Decide on reimbursement status	X		Reimbursement is connected with pricing decision	Health Act 1999 as amended
Decide on reimbursement price	X		Only for generics in Category A and M (W)	Health Act, sect. 34-38, http://www.opsi.gov.uk/acts/acts1999/99008a-a.htm#36
Use Pharmaco-economic guidelines	X		Provided by NICE	
Use Internal reference pricing	X		For the calculation of the reimbursement price for reimbursable generics	Scheme M and W
Use External reference pricing		X		
Price freezes	X		The last price freeze was from 1 January 2005 to 1 January 2006	PPRS 2005 backed by Health Act 1999 as amended
Margin cuts		X		
Discounts and Rebates	X		Claw-back system for NHS pharmaceuticals	
Company profit control	X		For branded NHS pharmaceuticals	PPRS
Country specific:	Companies profits controlled via PPRS (Pharmaceutical Price Regulation Scheme)			
Pharmaceutical Industry				
Sets manufacturer price freely	X		For non-reimbursable OTC, HOM, SLS pharmaceuticals, Generics Category A and Category M	Health Act, sect. 33-38, http://www.opsi.gov.uk/acts/acts1999/99008a-a.htm#33
Notifies manufacturer price	X		If manufacturers of generics category A and M change prices they are obliged to notify this price change.	

Public authorities	Yes	No	Comment	Legal bases
Negotiates manufacturer price	X		Only indirect via the PPRS are maximum /minimum profits negotiated which has an influence on the price setting	
Is free to set price below fixed manufacturer price			Resale Price Maintenance is abolished, not applicable for brands	
Decides on application for reimbursement			Not applicable, as all NHS pharmaceuticals automatically are eligible for reimbursement unless they are included in the SLS	GSMR http://www.redbook.i12.com/rb/Docs/rb221.htm
Negotiates reimbursement price	(X)		Generic manufacturers negotiate the Scheme M which influences the NHS price	
Free to grant rebates/ discounts to wholesalers	X			
Can engage in marketing towards doctors	X			MAR
Can engage in public advertising	X		For GSL and P-listed pharmaceuticals	MAR
Can provide information toward patients	X			
Applies for switches and delisting	X		The Royal Pharmaceutical Society promotes the concept of POM- to P-switches	
Country specific:	Companies profits are indirectly controlled via PPRS (Pharmaceutical Price Regulation Scheme)			
Distribution chain				
Wholesaler				
Margins are fixed by statute	X		For branded NHS pharmaceuticals at 12,5%, for others it is free	PPRS
Margins are subject to statutory discounts and rebates	X		Claw-back system is applied for NHS pharmaceuticals	
Free to grant rebates and discounts to pharmacies	X		Wholesalers are free to offer pharmacists any proportion of the 12.5 % maximum wholesale margin for branded pharmaceuticals. Generics and parallel imports are sold highly discounted to pharmacists	
Pharmacists				
Margins are fixed by statute	X		For NHS pharmaceuticals pharmacists get a fixed fee per dispensed pack plus reimbursement of net ingredient cost of the pharmaceutical at NHS price	Regulation 56(1) of the National Health Service (Pharmaceutical Services) Regulations 2005 and National Health

Public authorities	Yes	No	Comment	Legal bases
Free to set retail price	X		Price can vary throughout the country	Service (Pharmaceutical Services) (Wales) Regulations 2005 as amended
Obliged to inform patient on cheaper product			Not applicable	
Obliged to substitute by a generic		X	Not applicable	
Allowed to substitute by a generic		X		
Obliged to substitute by a parallel import		X		
Allowed to substitute by a parallel import	X		Pharmacists are financially incentiviced to substitute by a parallel traded product.	
Therapeutic substitution is allowed		X		
Claw back system exists	X		In average 11.47% claw-back to the NHS	
Are subject to statutory discounts and rebates		X	None besides claw-back system	
May grant rebates to customers	X			
Country specific:	Generic substitution is not allowed, but if a prescription is written generically (by its INN) the pharmacist is encouraged to dispense the cheapest available pharmaceutical. Substitution by parallel traded products is allowed.			
Doctors				
Are obliged to inform patients on risks of treatment and treatment alternatives	X			Health and Social Care Act 2001 (Part 5)
Are obliged to inform on co-payment		X		
Prescription habits are monitored	X		Only NHS doctors	
Are subject to prescription guidelines	X		Only NHS doctors	
Budgets are controlled	X		Only NHS doctors, but not indicative	
Allowed to prescribe INN	X		Doctors are encouraged (via budget controls) to write INN prescriptions	
Obliged to prescribe INN		X		
Can oppose generic substitution			Not applicable as substitution not mandatory	
Can oppose therapeutic substitution				
Can oppose substitution by parallel import				

Public authorities	Yes	No	Comment	Legal bases
Country specific:				
Patients				
Can shop for cheapest price of the product	X		For self-medication	
Pay a flat rate per prescription/pack	X		GBP 6.65 / € 9.70 per pack, but there are different co-payment options (quarterly or annually)	
Co-payment at a certain percentage		X		
Can ask for substitution by a generic		X	Only in self-medication	
Can oppose substitution by a generic			Not applicable	
Can ask for substitution by a parallel import	X		Only in self-medication	
Can oppose substitution by a parallel import			Not applicable	
Can oppose substitution only on payment of price difference			Not applicable	
Has to pay the difference between reimbursement price and pharmacy retail price			Not applicable	
Has access to full public information on prices and products	X		BNF and Drug Tariff can be subscribed by everybody for free	Health and Social Care Act 2001 (Part 5)
Country specifics:				

NHS = National Health Service, PPRS = Pharmaceutical Price Regulation Scheme, POM = Prescription-only Medicine, GSL = General Sales List, MAR = Medicines Advertising Regulations

Source: ÖBIG 2006

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