

**GESUNDHEIT ÖSTERREICH GMBH
GESCHÄFTSBEREICH ÖBIG**



PHARMACEUTICAL SYSTEMS IN THE EUROPEAN UNION 2006

Comparative Analysis

Gesundheit Österreich GmbH
Geschäftsbereich ÖBIG



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Sabine Vogler

Danielle Arts

Claudia Habl

Christine Leopold

Supported by

Romana Landauer

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Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG, Stubenring 6, 1010 Vienna, Austria
phone +43/1/51561-0, fax: +43/1/5138472, e-mail: lastname@oebig.at

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I. Foreword

The Health Economics team of the Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG has a long tradition of surveying and analysing health care and pharmaceutical systems in Europe.

The studies "Pharmaceuticals - Market Control in Nine European countries" (1998), "Pharmaceutical Expenditure - Cost-Containment Strategies in the European Union" (2001) and "Pharmaceutical Systems in the New EU Member States" (2005) are just three examples of reports providing concise information on reimbursement, pricing and distribution of pharmaceuticals in several European countries (see also the list of publications in the Annex to this report).

Additionally, ÖBIG runs the Pharmaceutical Price Information (PPI) service, which offers independent and up-to-date information on the prices of pharmaceuticals at all price levels (ex-factory price, pharmacy purchase price, pharmacy retail price) in the 25 EU Member States (year 2006) plus Norway and Switzerland. More details on our service may be obtained from the Annex to this report.

To keep the PPI service up to date, ÖBIG continually keeps track of the developments in the European pharmaceutical systems. As a result of this continuous monitoring, ÖBIG is pleased to present the report called "Pharmaceutical Systems in the European Union 2006".

The report consists of two parts:

- For each EU Member State, part 1 provides in 25 fact sheets concise, country-specific information on market authorisation, pricing, reimbursement and distribution of pharmaceuticals in 2006.
- The present part 2 offers a comparative analysis of pharmaceutical systems (market authorisation, pricing, reimbursement and distribution of pharmaceuticals) with key information displayed in tables and figures.

For better understanding, a glossary with relevant terms used in this study is included in the Annex to this report. The exchange rates used for all calculations of non-Euro national currencies into € are the average annual rates for the year 2005 as published by the Austrian National Bank / European Central Bank.¹

Further in-depth information on the European pharmaceutical systems will be provided by the PPRI "Pharma Profiles", which are comprehensive country reports on pharmaceutical pricing and reimbursement. The PPRI Pharma Profiles will be published in the course of the summer of 2007. The Pharmaceutical Pricing and Reimbursement Information (PPRI) project (<http://ppri.oebig.at>) is funded by the European Commission, Public Health and Consumer

¹ www.oenb.at/de/stat_melders/datenangebot/zinssaetze/wechselkurse/wechselkurse.jsp

Protection Directorate-General and co-funded by the Austrian Ministry of Health and Women's Issues, and aims to increase transparency in the field of pharmaceuticals.

The coordination of the PPRI project is in the hands of the Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (the main partner) and the Regional Office for Europe of the World Health Organisation, WHO Europe (the associate partner).

A total of 44 national institutions (mainly competent authorities) in the field of pharmaceuticals from all Member States and Albania, Bulgaria, Canada, Norway and Turkey, as well as international institutions such as the EMEA and OECD participate in the PPRI network.

II. Acknowledgements

The present report is based on the country-specific expertise of the members of the Health Economics team at Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG:

Katja Antony

Danielle Arts

Claudia Habl

Barbara Fröschl

Christine Leopold

Ingrid Rosian-Schikuta

Heidi Stürzlinger

Sabine Vogler

Marion Weigl

In order to keep track of the ongoing developments, the members of the Health Economics team constantly monitor any changes in the EU Member States and keep contact to the experts in the countries.

We would like to genuinely thank all our contacts in administration and research institutes as well as in the industry, wholesale and pharmacy sectors of the EU Member States, who have always been willing to help us by providing information and answering our questions.

Additionally, we thank Margarida Azedo who supported us in compiling the information during her internship at Gesundheit Österreich GmbH / Geschäftsbereich. At ÖBIG, the Health Economics team was supported by Romana Landauer and Friederike Windisch, whom we are also very grateful for their help.

III. List of Abbreviations

ABPI	Association of the British Pharmaceutical Industry (United Kingdom)
AEMPS	Agencia Española de Medicamentos y Productos Sanitarios / Spanish Agency for Pharmaceuticals and Medical Devices (Spain)
AFSSAPS	Agence Française de Sécurité Sanitaire des Produits de Santé / French Agency for Security for Medical Products (France)
AGES PharmMed	Österreichische Agentur für Gesundheit und Ernährungssicherheit / Austrian Agency for Health and Foodsafety (Austria)
AIFA	Agenzia Italiana del Farmaco / Italian Medicines Agency (Italy)
ARSZMP	Agencija Republike Slovenije za zdravila in medicinske pripomočke / Agency of Medicinal Products and Medical Devices of the Republic of Slovenia
ATC	Anatomic, therapeutic, chemical classification of the WHO
BASG	Bundesamt für Sicherheit im Gesundheitswesen / Austrian Federal Agency for Safety in Health Care (Austria)
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte / Federal Institute for Drugs and Medical Devices (Germany)
BGMA	British Generic Manufacturers Association (United Kingdom)
BMG	Bundesministerium für Gesundheit / Ministry of Health (Germany)
BMGF	Bundesministerium für Gesundheit und Frauen / Federal Ministry of Health and Women's Issues (Austria)
CBG	College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board (Netherlands)
CEPS	Comité Economique des Produits de Santé / Pricing Committee (France)
CIP	Cost, Insurance and Packaging
CFH	Commissie Farmaceutische Hulp / Pharmaceutical Care Committee (Netherlands)
CRM	Commission de Remboursement des Médicaments / Medicines Reimbursement Commission (Belgium)
DGE	Direcção-Geral da Imprensa / Directorate-General Enterprise (Portugal)
DH	Department of Health (United Kingdom)
DMA	Lægemiddelstyrelsen / Danish Medicines Agency (Denmark)
DoHC	Department of Health and Children (Ireland)
DP	Drugs Payment (Ireland)
DTC	Drugs and Therapeutic Committee (Malta)
EEC	European Economic Community
EHIF	Eesti Haigekassa / Estonian Health Insurance Fund (Estonia)
EOF	National Organisation for Medicines (Greece)
EU	European Union
EüM	Egészségügyi Minisztérium / Ministry of Health (Hungary)
FD	Farmacijos departamentas prie Sveikatos apsaugos ministerijos / Department of Pharmacy under the Ministry of Health (Lithuania)
FPS	Service Public Fédéral / Federal Public Service (Belgium)
G-BA	Gemeinsamer Bundesausschuss / Federal Joint Committee (Germany)
GmbH	Gesellschaft mit beschränkter Haftung / Public limited liability company (Austria)

GMS	General Medical Services (Ireland)
GÖG/ÖBIG	Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG
HILA	Lääkkeiden hintalautakunta / Pharmaceuticals Pricing Board (Finland)
HEK	Heilmittel-Evaluierungskommission / Pharmaceutical Evaluation Board (Austria)
HPSS	Health Care Procurement and Supplies Services (Malta)
HVB	Hauptverband der österreichischen Sozialversicherungsträger / Federation of the Austrian Social Insurance Institutions (Austria)
IMB	Irish Medicines Board
INFARMED	Instituto Nacional da Farmácia e do Medicamento / Medicines Agency (Portugal)
IPHA	Irish Pharmaceutical Health Care Association
KELA	Kansaneläkelaitos / The Social Insurance Institution (Finland)
LFN	Läkemedelsförmånsnämnden / Pharmaceuticals Pricing Board (Sweden)
MA	Medicines Agency (Malta)
MHRA	Medicines and Healthcare Products Regulatory Agency (United Kingdom)
MoH	Ministry of Health
N. a.	Not available
NAM	Lääkelaitos / National Agency for Medicines (Finland)
NCPE	Irish National Centre of Pharmacoeconomics' St. James' Hospital
NHS	National Health Service
NHSBSA	National Health Service Business Service Authority (United Kingdom)
NICE	National Institute for Health and Clinical Excellence (United Kingdom)
NRT	Nicotine Replacement Therapy
OEP	Országos Egészségbiztosítási Pénztár / National Health Insurance Fund (Hungary)
OGYI	Országos Gyógyszerészeti Intézet / National Institute of Pharmacy (Hungary)
OTC	Over-the-Counter pharmaceutical
PK	Preiskommission / Pricing Committee (Austria)
POM	Prescription-only medicines
PPI	Pharma Price Information (service on price information offered by GÖG/ÖBIG)
PPRI	Pharmaceutical Pricing and Reimbursement Information (EU project coordinated by GÖG/ÖBIG)
PPRS	Pharmaceutical Price Regulation Scheme (United Kingdom)
SAM	Lietuvos Respublikos Sveikatos Absaugos Ministerija / Ministry of Health of the Republic of Lithuania (Lithuania); Ravimiamet / State Agency of Medicines (Estonia)
SM	Sotsiaalministeerium / Ministry of Social Affairs (Estonia)
SMEs	Self-employed and Energy - Market regulation - Division of prices and competition (Subdivision of Belgian FPS)
SUKL	Státní Ústav pro Kontrolu Léčiv / State Institute for Drug Control (Czech Republic / Slovakia)
TÉB	Technológia Értékelő Bizottság / Technology Evaluation Committee (Hungary)
UCM	Union des Caisses de Maladie / Union of Sickness Funds (Luxembourg)
UNCAM	Union des Caisses d'Assurance Maladie / National Union of Health Insurers (France)
URPL	Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych / Office for Registration of Medicinal Products, Medical Devices and Biocides (Poland)
VAT	Value Added Tax

VLK	Valstybinė ligonių kasa prie Sveikatos apsaugos ministerijos / State Patient Fund under the Ministry of Health (Lithuania)
VVKT	Valstybinė vaistų kontrolės tarnyba / State Medicines Control Agency (Lithuania)
VZA	Valsts zalu agentura / State Agency of Medicine (Latvia)
WHO	World Health Organisation
YPAN	Ministry of Development (Greece)
ZCA	Zalu Cenu Valsts Agentura / State Medicines Pricing and Reimbursement Agency (Latvia)
ZZZS	Zavod za zdravstveno Slovenije / National Health Insurance Fund (Slovenia)

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COMPARATIVE ANALYSIS

1 Regulatory Framework

With regard to pharmaceuticals, the European Community law primarily focuses on market authorisation and distribution.

The Directive 93/39/EEC, accompanied by Council Regulation 2309/93/EEC, which introduced the centralised and the decentralised market authorisation procedure (see Chapter 2), was of major importance for the regulation of the market authorisation of pharmaceuticals in the European Union. In 2004, further key amendments were made following the so-called Pharmaceutical Review, and Directive 2004/27/EC, which strengthened the role of the European Medicines Agency (EMA), was passed.

At a national level, Medicines Agencies have been established in many Member States since the beginning of the 1990s, which are, next to their other responsibilities (such as pharmacovigilance), in charge of the market authorisation of pharmaceuticals (cf. Table 1.1). In other Member States (e.g. Belgium, Cyprus and Luxembourg), market authorisation lies in the hands of the Ministry of Health. In some Member States where the Ministry of Health takes the final decision, the Medicines Agency has an advisory role (Poland, UK).

Pricing and reimbursement is mainly a competence of the Member States, though overall EU provisions have to be considered. In this context, the Transparency Directive (Council Directive 89/105/EEC of 21 December 1988) plays an important role. The objective of the Transparency Directive is to guarantee a transparent procedure, based on objective and verifiable criteria, for the price setting of pharmaceuticals as well as the decision on reimbursement.

Within this EU framework, the Member States can freely develop their national legislation for pricing and reimbursement, which has resulted in 25 different pharmaceutical systems in the European Union.

In many Member States, the national legal basis for pharmaceuticals is a compound set of laws (Medicines Act, Health Insurance Law,...), enactments and further regulations (Decrees on mark-ups etc.). The relevant national regulations for market authorisation, pricing and reimbursement of pharmaceuticals are listed in Part 1 ("Fact Sheets") of this report "Pharmaceutical Systems in the European Union 2006".

In some Member States, the competent authority for pricing is the same as the one that is in charge of market authorisation, and this authority can also be involved in the reimbursement decisions. Table 1.1 provides an overview on the competent authorities for market authorisation, pricing and reimbursement of pharmaceuticals in the 25 EU Member States.

Table 1.1: Relevant authorities in the field of pharmaceuticals in the EU in 2006

Member State	Market authorisation	Pricing	Reimbursement
Austria	Austrian Federal Agency for Safety in Health Care (BASG), supported by Austrian Agency for Health and Foodsafety (AGES PharmMed)	Federal Ministry of Health and Women's Issues (BMGF), supported by Pricing Committee (PK)	Federation of Austrian Social Insurance Institutions (HVB), consulted by Pharmaceutical Evaluation Board (HEK)
Belgium	Federal Public Service (FPS) Health, Food Chain Safety and Environment - Directorate-General Medicines	FPS Economy, SMEs, Self-employed and Energy - Market regulation - Division of prices and competition, advised by the Medicines Pricing Commission	FPS Social Security, advised by the Medicines Reimbursement Commission (CRM)
Cyprus	Ministry of Health (MoH)	Ministry of Health (MoH)	MoH, advised by the Drugs Council Department of Pharmaceutical Services
Czech Republic	State Institute for Drug Control (SUKL)	Ministry of Finance	Ministry of Health, advised by Drug Categorisation Committee
Denmark	Danish Medicines Agency (DMA)	Danish Medicines Agency (DMA)	Danish Medicines Agency (DMA) together with Reimbursement Committee, consulted by Institute for Rational Pharmacotherapy
Estonia	State Agency of Medicine (SAM)	Ministry of Social Affairs (SM)	Ministry of Social Affairs (SM), advised by SAM and Estonian Health Insurance Fund (EHIF)
Finland	National Agency for Medicines (NAM)	Pharmaceuticals Pricing Board (HILA), consulted by the Social Insurance Institution of Finland (KELA)	Pharmaceuticals Pricing Board (HILA), consulted by the Social Insurance Institution of Finland (KELA)
France	Medicines Agency (AFSSAPS)	Pricing Committee (CEPS)	National Union of Health Insurers (UNCAM)
Germany	Federal Institute for Drugs and Medical Devices (BfArM)	Federal Joint Committee (G-BA)	Ministry of Health (BMG) and Federal Joint Committee (G-BA)
Greece	National Organisation for Medicines (EOF)	Ministry of Development (YPAN) advised by Pricing Committee	Ministry of Health and Social Solidarity, advised by EOF
Hungary	National Institute of Pharmacy (OGYI)	Ministry of Health (EüM)	National Health Insurance Fund (OEP), advised by the Technology Evaluation Committee (TÉB)
Ireland	Irish Medicines Board (IMB)	Department of Health and Children (DoHC), in co-operation with the Irish Pharmaceutical Health Care Association (IPHA)	Product Committee of DoHC, advised by Irish National Centre for Pharmacoeconomics' St. James' Hospital (NCPE)
Italy	Medicines Agency (AIFA)	Medicines Agency (AIFA)	Medicines Agency (AIFA)

Member State	Market authorisation	Pricing	Reimbursement
Latvia	State Agency of Medicine (VZA)	State Medicines Pricing and Reimbursement Agency (ZCA)	State Medicines Pricing and Reimbursement Agency (ZCA)
Lithuania	State Medicines Control Agency (VVKT)	Ministry of Health (SAM), advised by Department of Pharmacy (FD)	Ministry of Health (SAM), advised by Reimbursement Committee and Council of State Sickness Fund (VLK)
Luxembourg	Ministry of Health on advice of the Department for Pharmacy and Pharmaceuticals within the Health-Directorate	Ministry of Economy and Foreign Trade, advised by Competition Direction	Union of Sickness Funds (UCM)
Malta	Medicines Agency (MA)	Ministry of Health (MoH), Health Care Procurement and Supplies Services (HPSS)	MoH, advised by Drugs and Therapeutics Committee (DTC)
Netherlands	Medicines Evaluation Board (CBG)	Ministry of Health, Welfare and Sport, advised by Pharmaceutical Care Committee (CFH)	Ministry of Health, Welfare and Sport
Poland	Ministry of Health on recommendation of the National Office for Registration of Medical Products, Medical Devices and Biocides (URPL)	Ministry of Health, advised by Drug Committee (in consultation with Ministry of Finance)	Ministry of Health, advised by Drug Committee
Portugal	Medicines Agency (INFARMED)	Directorate-General Enterprise (DGE)	Medicines Agency (INFARMED)
Slovakia	State Institute for Drug Control (SUKL)	Ministry of Health, advised by Categorisation Committee	Ministry of Health, advised by Categorisation Committee
Slovenia	Agency of Medical Products and Medical Devices (ARSZMP)	Agency of Medical Products and Medical Devices (ARSZMP)	Drug Committee at the Health Insurance Fund (ZZZS)
Spain	Spanish Medicines Agency (AEMPS)	Interministerial Commission on Pharmaceutical Prices under the Ministry of Health	Directorate-General of Pharmacy and Health Products of the Ministry of Health
Sweden	National Agency for Medicines (NAM)	Pharmaceuticals Pricing Board (LFN)	Pharmaceuticals Pricing Board (LFN)
United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA)	Department of Health (DH) and Association of the British Pharmaceutical Industry (ABPI) ¹	DH, consulted by the National Institute for Health and Clinical Excellence (NICE)

¹ Agreeing the PPRS (Pharmaceutical Price Regulation Scheme) for (branded) on-patent pharmaceuticals. In addition, National Health Service Business Service Authority (NHSBSA) for generics of category A, and DH and the British Generic Manufacturers Association (BGMA) for generics of category M (W)

The pricing of pharmaceuticals is often conducted by the Ministry of Health or the Ministry of Social Affairs, but also of the Ministry of Economic Affairs or the Ministry of Finance. Medicines Agencies may also play a role in the price setting. Some Member States have (inter-ministerial) Pricing Committees which take the pricing decision (France, Spain) or advise the Ministry (Austria, Belgium).

In some Member States, the decision on reimbursement is also a competence of the Ministry of Health and/or of Social Affairs (e.g. Netherlands), which may be advised by a Reimbursement Committee (e.g. Lithuania, Poland). In other countries, reimbursement decisions are taken by Medicines Agencies (e.g. Italy, Portugal) or Social Insurances (e.g. France, Hungary).

In most Member States there is not just one authority responsible for the regulation in the pharmaceutical sector, but the competences are split.

2 Market Authorisation

In the European Union, pharmaceuticals may be authorised through

- the centralised procedure with the European Medicines Agency (EMA) delivering a market authorisation valid for the whole European Union (obligatory for bio-technologically produced pharmaceuticals and new substances for HIV/AIDS, cancer, neurodegenerative diseases, diabetes and facultative for innovative pharmaceuticals and those of interest for the Community and other new substances),
- the mutual recognition procedure, in which a pharmaceutical is authorised in at least one Member State (“Reference Member State”), and by mutual recognition also in the other Member States
- the national procedure, leading to a market authorisation which is only valid for that Member State.

As described in Chapter 1, the competent authority for market authorisation is in many Member States the Medicines Agency, but it may also be the Ministry of Health.

The number of authorised pharmaceuticals varies between the Member States of the European Union, as shown in Table 2.1. These variations in the numbers of authorised pharmaceuticals result from differences in market size (e.g. significantly fewer pharmaceuticals in small markets like Cyprus, Malta or the Baltic States), but also from the different “cultures” (e.g. “traditionally” fewer pharmaceuticals in the Nordic countries). Besides, diverse counting methods (cf. footnotes in Table 2.1) have also to be taken in consideration when the numbers of authorised pharmaceuticals are compared.

From a public health perspective, especially the number of available and affordable pharmaceuticals is of relevance. In several Member States, the number of pharmaceuticals that are available on the market is lower than the number of authorised pharmaceuticals. A very strong difference is reported in the Czech Republic, where the number of authorised pharmaceuticals is relatively high but less than 20% of these pharmaceuticals are marketed.

Concerning the number of reimbursable pharmaceuticals (i.e. pharmaceuticals of which the Social Health Insurance or the National Health Service covers, at least partially, the costs, but which may still require a relatively high co-payment), there are also relevant differences between the Member States. A percentage rate of over 60% reimbursable pharmaceuticals out of all authorised pharmaceuticals is rather seldom in the new Member States and more common in the old (and richer) Member States (Spain: 80%, Finland: 67%, Ireland: 64%). In several countries only every second authorised pharmaceutical is reimbursable; in the new Member States (e.g. Poland, Slovakia, Slovenia), between 30 and 50 percent are reimbursable.

Table 2.1: Number of authorised pharmaceuticals in the EU in 2006

Member State	Total of pharmaceuticals ¹	% of POM
Austria	12,140 ²	68%
Belgium	N. a.	N. a.
Cyprus	2,209 ^{2,3}	N. a.
Czech Republic	≈ 14,000 ^{4,5}	58%
Denmark	7,393 ⁶	N. a.
Estonia	2,925 ²	N. a.
Finland	6,904	93%
France	≈ 15,000 ⁵	N. a.
Germany	8,933 ⁶	N. a.
Greece	10,521 ⁵	N. a.
Hungary	5,118 ^{2,7}	≈ 85%
Ireland	7,739 ⁵	97 %
Italy	8,587 ^{5,8}	N. a.
Latvia	4,500	71%
Lithuania	4,072	75%
Luxembourg	N. a.	N. a.
Malta	2,300 ^{3,9}	N. a.
Netherlands	N. a.	11,140
Poland	8,089 ²	73%
Portugal	N. a.	N. a.
Slovakia	14,341 ²	88%
Slovenia	3,000 ^{2,8}	65%
Spain	11,783 ⁵	85%
Sweden	8,050 ⁹	N. a.
United Kingdom	≈ 15,000	N. a.

N. a. = not available

¹ Counted incl. different pharmaceutical forms and dosages, excl. pack sizes

² Year 2005

³ In the private system (i.e. selling of pharmaceuticals through pharmacies) in contrast to the public system with pharmaceuticals for eligible patients purchased by the state via public tendering of pharmaceuticals

⁴ Year 2003

⁵ Counted incl. different pharmaceutical forms, dosages and pack sizes

⁶ Counted excl. different pharmaceutical forms, dosages and pack sizes

⁷ Excl. centrally authorised pharmaceuticals

⁸ Year 2004

⁹ Counted incl. different pharmaceutical forms, excl. different dosages and pack sizes

Source: GÖG/ÖBIG 2006

The percentage of prescription-only medicines (POM) is, in general, higher than the share of reimbursable pharmaceuticals. In many Member States, over three quarters of the pharmaceuticals authorised are subject to the prescription status; in some countries (e.g. Finland, Ireland) even more than 90% are POM.

OTC (Over-the-Counter) products are usually non-reimbursable. In addition, some Member States have a significant number of non-reimbursable POM.

3 Pricing

3.1 Price Control

In the EU Member States, prices of pharmaceuticals are, at least for a segment of the pharmaceuticals, controlled. The most common forms of price control are:

- Statutory pricing

In the case of **statutory pricing**, prices of pharmaceuticals are set by the competent authorities on a regulatory basis. Price control of this kind may also be indirect, for example through profit controls (like the PPRS system in the UK) or a linkage to the reimbursement system / reference price system (like in Germany).

- Negotiations

Price control is also exercised by means of **negotiations** between the representatives of the state (competent authorities, Pricing Committees and/or Social Insurances) and the pharmaceutical companies.

- Public procurement

In the case of **public procurement**, the state (e.g. public hospitals) purchases pharmaceuticals on the basis of a tendering procedure, granting the contract to the best tenderer (pharmaceutical company / importer). One important criterion in the tendering procedure is usually the price.

If the state does not exercise any price control, then the manufacturers / importers may freely set the price of the pharmaceutical (at the manufacturer price level). In case that prices at the wholesale and retail level are also not controlled, the manufacturers / importers negotiate the prices / margins with the other distribution actors (wholesalers and pharmacies). A price notification, which is merely a formal price declaration, may also be classified as free pricing.

Table 3.1 summarises the key pricing procedures for pharmaceuticals in the out-patient sector of the 25 Member States of the European Union.

Table 3.1: Pricing procedures for pharmaceuticals in the EU in 2006

Member State	Statutory pricing	Price negotiations	Free pricing
Austria	Reimbursable ph.	Reimbursable ph. ¹	Non-reimbursable ph. (mainly OTC products)
Belgium	Reimbursable ph. and non-reimbursable ph. not considered as “new”	Not applied	“New” non-reimbursable ph. (price notification)
Cyprus	All ph. (locally produced and imported ph.)	Not applied ²	Not applied
Czech Republic	Reimbursable ph. and non-reimbursable POM	Not applied	Non-reimbursable OTC products
Denmark	De facto reimbursable ph.	Not applied ²	Technically all ph., de facto non-reimbursable ph.
Estonia	Reimbursable ph. ³		Non-reimbursable ph.
Finland	Reimbursable ph. ^{4,5}		Non-reimbursable ph. (mostly OTC products)
France	Not applied	Reimbursable ph. except innovative ph.	Non-reimbursable ph.; innovative ph. (price notification)
Germany	POM under the reference price system; reimbursable OTC products	Not applied	Non-reimbursable OTC products; innovative ph. (price notification)
Greece	All pharmaceuticals	Not applied	Not applied
Hungary	Not applied ⁶	Reimbursable ph. ⁶	Technically all ph., de facto non-reimbursable ph.
Ireland	Reimbursable ph. (price agreement)	Reimbursable ph. not available in the nominated 9 EU Member States for external referencing	Non-reimbursable ph. (mostly OTC products)
Italy	Not applied	Reimbursable ph.	Non-reimbursable ph.
Latvia	Reimbursable ph. ³		Non-reimbursable ph.
Lithuania	Not applied	Reimbursable ph.	Non-reimbursable ph.
Luxembourg	All pharmaceuticals	Not applied	Not applied
Malta	Not applied	Not applied	All pharmaceuticals
Netherlands	POM	Not applied	OTC products
Poland	Reimbursable ph. ³		Non-reimbursable ph.
Portugal	POM	Not applied	OTC products
Slovakia	Reimbursable ph.	Not applied	Non-reimbursable ph. (mostly OTC products)
Slovenia	All ph. except non-reimbursable OTC products	Reimbursable ph. ^{1,5}	Non-reimbursable OTC products
Spain	Reimbursable ph.	Not applied	Non-reimbursable ph., parallel exported ph.

Member State	Statutory pricing	Price negotiations	Free pricing
Sweden	Reimbursable ph. ^{4, 5}		Non-reimbursable ph. (mostly OTC products)
United Kingdom	NHS products ⁷	Not applied	Non-reimbursable OTC products and generics

NHS = National Health Service, OTC = Over-the-Counter, ph.= pharmaceuticals, POM = Prescription-only medicines

Note: This table refers to the out-patient sector and, if applicable (Cyprus, Malta), to private systems. Price negotiations refer to official negotiations between the state and an actor, not to negotiations between actors.

- ¹ Negotiations on the reimbursement price between the manufacturer and the Social Health Insurance may take place.
- ² There are no official price negotiations between the competent pricing authority and the actors. However, as there is no statutory wholesale mark-up and the price is set at the wholesale level, there are negotiations between the manufacturers/importers and the wholesalers on the price/margin.
- ³ The price is set (statutory pricing) after negotiations.
- ⁴ Prices need to be formally approved by the Pharmaceutical Pricing Board (Finnish HILA resp. Swedish LFN).
- ⁵ In addition to the official price negotiations between the state and the manufacturer, negotiations between the manufacturers/importers and the wholesalers on the price/margin take place, as there is no statutory wholesale mark-up and the price is set at wholesale level.
- ⁶ Based on statutory pricing criteria for reimbursable pharmaceuticals, price negotiations between manufacturers and the Social Health Insurance (OEP) may take place for pharmaceuticals applying for reimbursement.
- ⁷ Indirect price control for branded POM and OTC through the profit control of the PPRS (Pharmaceutical Price Regulation Scheme); for generics through so-called Scheme M. Both schemes are backed-up by law.

Source: GÖG/ÖBIG 2006

In the EU Member States, statutory pricing is the most common pricing procedure for reimbursable pharmaceuticals. Still, price negotiations also play a role in the reimbursable segment (e.g. Italy, France, Sweden). In some countries (Austria, Hungary), the Ministry of Health statutorily sets the manufacturer price of reimbursable pharmaceuticals and, additionally, price negotiations between the manufacturer and the Social Health Insurance may take place on the reimbursement price.

In several Member States (e.g. Estonia, Poland), it is difficult to split the pricing process into statutory pricing and price negotiations, as the prices are set by the competent authority after negotiations and/or the negotiations are an integral part of the (statutory) pricing procedure.

In general, free pricing is common for non-reimbursable pharmaceuticals. Some countries (e.g. Denmark, Hungary) allow free pricing for technically all pharmaceuticals, but as their pricing process is closely linked to the reimbursement procedure free pricing is, de facto, only possible for non-reimbursable products.

In the Czech Republic, Slovenia and the UK, manufacturers may freely set the prices of non-reimbursable OTC products, and in the Netherlands and Portugal free pricing is in place for all OTC products.

A special case concerns innovative pharmaceuticals, which some Member States promote by enabling a simplified pricing procedure. In Belgium (partly), France and Germany, statutory pricing is not applied for innovative pharmaceuticals and the manufacturers may decide on the price, which they only need to notify to the authorities.

In the EU, statutory pricing for all pharmaceuticals is applied in three countries (Cyprus, Greece and Luxembourg), whereas free pricing for all pharmaceuticals (in the private system) is allowed in only one Member State (Malta). The latter has to be seen in relation to the relevance of the public system, which offers free pharmaceuticals (also in the out-patient sector) to eligible patients. A similar system is also in place in Cyprus. Both in Malta and Cyprus, reimbursable pharmaceuticals are purchased by the state through public procurement. In other Member States (in particular in the new Member States, e.g. the Baltic States) public procurement also plays an important role, especially in the case of expensive pharmaceuticals for hospital use.

3.2 Pricing Criteria

In the process of setting a price (statutorily or via negotiations), different criteria are taken into consideration.

In many EU Member States, price comparisons are of utmost importance in the pricing process. Price comparisons may take the form of external and internal price referencing:

- **External price referencing** (cross-country referencing / international price comparison) involves a comparison with the prices of the same product in other (reference) countries.

20 Member States apply external price referencing. Only Denmark, Germany, Malta, Sweden and the United Kingdom do not consider the prices of the product in other countries when taking a decision on a price and / or on inclusion into reimbursement.

However, between the countries that have implemented external price referencing the baskets of reference countries and the methodologies may vary widely. Only a few countries (e.g. Austria, Finland) refer to all other Member States or to a large number of reference countries, whereas the majority of the Member States applying external price referencing take the prices from less than six countries into consideration. Several countries (e.g. Czech Republic, Slovakia) have listed the reference countries in their legislation; Cyprus has even defined (however not in law) alternative reference countries in case a product is not available in the first choice reference countries. Some Member States have precisely defined the methodology for external price referencing. For example, in Slovenia: the wholesale price of a pharmaceutical may, in general, not exceed 85% (96% in case of generics) of the average price determined by the price comparison. For imported products an extra 0.5% is added to this percentage. In Ireland, the non-availability of a product in the nominated reference countries even leads to a change in the pricing procedure: In this case, instead of statutory pricing which is laid down in price agreements between the state and the industry's association, price negotiations take place (cf. Table 3.1).

- **Internal price referencing** involves the comparison with the prices of identical or similar products (i.e. at the same ATC-5 or ATC-4 level) within a country. Internal price referencing can for example mean that specific pharmaceuticals (e.g. innovative pharmaceuticals or generics) are priced at a specific percentage rate above or below similar pharmaceuticals. A reference price system, which is more an element of the reimbursement system than the pricing process (cf. Chapter 4.3), is a typical example of internal price referencing.

Internal price referencing is used in 8 Member States as a criterion in the pricing process. In the reimbursement process, internal price referencing is applied in significantly more countries (17 Member States which have implemented a reference price system, see Chapter 4.3).

In addition to reference prices, other common criteria considered in the process of pricing are the therapeutic value/benefit of the pharmaceutical, its cost-effectiveness and further outcomes of pharmaco-economic evaluation as well as its impact on the national health system and/or on the budget. The United Kingdom has implemented an indirect price control through the PPRS (Pharmaceutical Price Regulation Scheme), which intends to control the profits of the companies. In four Member States (Cyprus, Czech Republic, Greece, Slovakia), the prices for locally produced pharmaceuticals are set by means of the “cost-plus” method, which means that the production cost are taken into consideration, and an additional mark-up is granted.

Table 3.2 lists the criteria that are applied in the pricing procedures of the EU Member States. The relevance of the criteria varies: For instance, some countries (e.g. Luxembourg and Portugal) do not consider other criteria besides external price referencing, while other Member States (e.g. Finland and Italy) consider the prices in other countries as a guidance, but not as the only criterion.

3.3 Price Levels

In the out-patient sector, pharmaceuticals are usually supplied by manufacturers and/or importers, and distributed via pharmaceutical wholesale to community pharmacies where they are dispensed to the patients (see also Chapter 6). Thus, typical price levels for pharmaceuticals are:

- the **manufacturer price** (ex-factory price) or the CIP (cost, insurance, packaging) price in case of an imported pharmaceutical,
- the **wholesale price** (pharmacy purchase price), and
- the **pharmacy retail price** (excluding and including taxes such as VAT)

For the wholesale and pharmacy retail level, mark-ups are normally used which may be statutorily regulated or freely negotiated between the actors.

In the hospital sector, there is usually just one price level, the trade price, at which the pharmaceuticals are purchased (e.g. in a tender).

Table 3.2: Criteria for the pricing of pharmaceuticals in the EU in 2006

Member State	Price Level	Criteria	
		Prices	Other
Austria	Manufacturer price	External price referencing	Affordability for consumers, national economic situation
Belgium	Manufacturer price	External and internal price referencing	Pharmaco-economic evaluation
Cyprus	Wholesale price for imported ph., manufacturer price for locally produced ph.	External price referencing (for imported ph.)	Production cost (for locally produced ph.)
Czech Republic	Manufacturer price	External price referencing (for imported ph.)	Cost-benefit analysis (for imported ph.), production cost (for locally produced ph.)
Denmark	Wholesale price	Internal price referencing (for reimbursed off-patent and parallel imported ph.)	Therapeutic value, cost-effectiveness, budget impact
Estonia	Manufacturer price	External price referencing, price-volume agreements between the Ministry and the ph. companies	-
Finland	Wholesale price	External and internal price referencing	Therapeutic value, budget impact, economic evaluation for innovative products
France	Manufacturer price	External price referencing	Evaluation of medical benefit, improvement of medical benefit, expected sales
Germany	Manufacturer price	Internal price referencing	-
Greece	Manufacturer price	External price referencing (for imported ph.)	Production cost (for locally produced ph.)
Hungary	Manufacturer price	External and internal price referencing	Proof of cost-effectiveness
Ireland	Manufacturer price	External price referencing	-
Italy	Manufacturer price	External price referencing	Cost-effectiveness for pharmaceuticals where no effective therapy exists, risk-benefit ratio, therapy costs per day; evaluation of the economic impact on national health system, estimated market share

Member State	Price Level	Criteria	
		Prices	Other
Latvia	Wholesale price	External and internal price referencing	Budget impact analyses, pharmaco-economic evaluation
Lithuania	Manufacturer/CIP price	External and internal price referencing	Pharmaco-economic evaluation
Luxembourg	Pharmacy retail price	External price referencing	-
Malta	- ¹	-	-
Netherlands	Wholesale price	External price referencing	Pharmaco-economic evaluation
Poland	Wholesale (and pharmacy retail) price	External and internal price referencing	Impact on treatment costs, volume of sales, production costs, efficacy, impact on public health
Portugal	Manufacturer price	External price referencing	-
Slovakia	Pharmacy retail price	External price referencing (for imported ph.)	Production cost (for locally produced ph.)
Slovenia	Wholesale price	External price referencing	-
Spain	Manufacturer price	External price referencing	Therapeutic value of the ph., sales forecast
Sweden	Wholesale price	-	Medical value of the ph., human value principle, needs/solidarity principle, pharmaco-economic evaluation
United Kingdom	Wholesale price ²	-	Expected profit, capital investments, R&D expenditure and promotional cost (profit control)

CIP = Cost, Insurance, Packaging, NHS = National Health Service, ph. = pharmaceutical, R&D = Research and Development

Note: The column "Price Level" informs at which price level the price is set in first instance. In addition, mark-ups may be applied (see Table 3.3 and Table 3.4) to control the price at further price levels.

This table refers to the out-patient sector in private systems (no public procurement considered).

External price referencing involves a comparison with the prices of the same products in other (reference) countries.

Internal price referencing involves a comparison with the prices of similar products within the same country.

¹ No control at the manufacturer price level, but at the wholesale and pharmacy level through mark-ups

² NHS price

Source: GÖG/ÖBIG 2006

Usually, in the pricing procedure undertaken by the state, the price is set at the manufacturer level. As displayed in Table 3.2, 14 Member States determine the manufacturer (or CIP) price. Nine Member States (Cyprus - for imported pharmaceuticals, Denmark, Finland, Latvia, the Netherlands, Poland, Slovenia, Sweden, UK) set the price at the wholesale level, and in two countries (Luxembourg, Slovakia) prices are only set at pharmacy retail level.

Table 3.3: Wholesale margins for pharmaceuticals in the EU in 2006

Member State	Statutory maximum mark-ups	Scope
Austria	Regressive mark-up schemes	All ph. - two mark-up schemes depending on the reimbursement category
Belgium	Regressive mark-up scheme	All pharmaceuticals
Cyprus	No statutory mark-up	Imported pharmaceuticals
	Linear mark-up	Locally produced pharmaceuticals
Czech Republic	Combined linear mark-up for wholesalers and pharmacies	All pharmaceuticals
Denmark	No statutory mark-up	-
Estonia	Regressive mark-up scheme	All pharmaceuticals
Finland	No statutory mark-up	-
France	Regressive mark-up scheme	Reimbursable pharmaceuticals
Germany	Regressive mark-up schemes	One scheme for all POM and one scheme for reimbursable OTC products
Greece	Linear mark-up	All pharmaceuticals
Hungary	Regressive mark-up scheme	All pharmaceuticals
Ireland	Different mark-ups	Pharmaceuticals under Community Drug Schemes ¹ - different mark-ups for pharmaceuticals, depending on the reimbursement status and the Community Drug Scheme
Italy	Linear mark-up	Reimbursable pharmaceuticals
Latvia	Regressive mark-up scheme	Reimbursable pharmaceuticals
	Linear mark-up	Non-reimbursable pharmaceuticals
Lithuania	Regressive mark-up scheme	Reimbursable pharmaceuticals
Luxembourg	Different linear mark-ups and regressive mark-up schemes	All pharmaceuticals - different mark-ups / mark-up schemes depending on country of origin or provenance of the pharmaceutical
Malta	Linear mark-up	All pharmaceuticals ²
Netherlands	No statutory mark-up	-
Poland	Linear mark-up	Reimbursable pharmaceuticals
Portugal	Linear mark-up	POM
Slovakia	Different linear mark-ups	All pharmaceuticals - different mark-ups depending on kind of pharmaceutical
Slovenia	No statutory mark-up	-
Spain	Regressive mark-up scheme	All pharmaceuticals
Sweden	No statutory mark-up	-
United Kingdom	Up to 12.5% of the NHS price	Branded pharmaceuticals under the PPRS

NHS = National Health Service, OTC = Over-the-Counter, ph. = pharmaceuticals, POM = prescription-only medicines, PPRS = Pharmaceutical Price Regulation Scheme

¹ Pharmaceuticals which are reimbursable for eligible persons

² All pharmaceuticals in the private system. No mark-ups are applied in the public system (=purchase of pharmaceuticals for eligible patients by the Ministry of Health via a public tendering)

Source: GÖG/ÖBIG 2006

Table 3.4: Pharmacy margins for pharmaceuticals in the EU in 2006

Member State	Statutory maximum mark-ups	Scope
Austria	Regressive mark-up schemes	All ph. - one scheme for privileged customers (e.g. sickness funds) and one scheme for private customers
Belgium	Regressive mark-up scheme	All pharmaceuticals
Cyprus	Linear mark-up	All pharmaceuticals
Czech Republic	Combined linear mark-up for wholesalers and pharmacies	All pharmaceuticals
Denmark	Regressive mark-up scheme	Reimbursable pharmaceuticals
Estonia	Regressive mark-up scheme	All pharmaceuticals
Finland	Regressive mark-up scheme	All pharmaceuticals (except NRT)
France	Regressive mark-up scheme	Reimbursable pharmaceuticals
Germany	Flat pharmacy fee and linear mark-up	POM
	Regressive mark-up scheme	Reimbursable OTC products
Greece	Linear mark-up	All pharmaceuticals
Hungary	Regressive mark-up scheme	All pharmaceuticals
Ireland	Different mark-ups and fixed dispensing fees	Pharmaceuticals under Community Drug Schemes ¹ - different mark-ups / fixed dispensing fees depending on reimbursement status & the Community Drug Scheme
Italy	Linear mark-up	Reimbursable pharmaceuticals
Latvia	Regressive mark-up schemes	All ph. - one scheme for reimbursable ph. and one for non-reimbursable ph.
Lithuania	Regressive mark-up scheme	Reimbursable pharmaceuticals
Luxembourg	Different linear mark-ups and regressive mark-up schemes	All pharmaceuticals - different mark-ups / mark-up schemes depending on country of origin or provenance of the pharmaceutical
Malta	Linear mark-up	All pharmaceuticals ²
Netherlands	Fixed pharmacy fee per prescription ³	POM
Poland	Regressive mark-up scheme	Reimbursable pharmaceuticals
Portugal	Linear mark-up	POM
Slovakia	Different linear mark-ups	All pharmaceuticals - different mark-ups depending on kind of pharmaceutical
Slovenia	Fee-for-service remuneration	All pharmaceuticals
Spain	Regressive mark-up scheme	All pharmaceuticals

Member State	Statutory maximum mark-ups	Scope
Sweden	Regressive mark-up schemes	All pharmaceuticals - one scheme for POM and one for OTC products
United Kingdom	Fixed fee per dispensed pack plus the net ingredient cost of the pharmaceutical at the NHS price	NHS pharmaceuticals (= reimbursable pharmaceuticals)

NHS = National Health Service, NRT = Nicotine-Replacement Therapy, OTC = Over-the-Counter, ph. = pharmaceuticals, POM = prescription-only medicines

¹ Pharmaceuticals which are reimbursable for eligible persons

² All pharmaceuticals in the private system. No mark-ups are applied in the public system (=purchase of pharmaceuticals for eligible patients by the Ministry of Health via a public tendering)

³ The pharmacy retail price for POM and usually also for OTC products is based on the price in the price list ("taxe").

Source: GÖG/ÖBIG 2006

In case of statutory wholesale (and pharmacy) mark-ups, the manufacturer price is indirectly regulated even if the price is determined at the wholesale (or pharmacy retail) level. Table 3.3 provides an overview on the wholesale margin regulations in the 25 Member States. Many EU Member States have regulated the maximum wholesale mark-ups. Only six Member States (Cyprus – for imported pharmaceuticals, Denmark, Finland, Netherlands, Slovenia and Sweden) do not have statutory wholesale mark-ups. As in these six countries the price is set at the wholesale level, pricing at the manufacturer level is free and the manufacturer price is negotiated between the manufacturer and the wholesaler.

In the EU Member States, wholesale margins are usually regulated in the form of a linear maximum mark-up, a regressive mark-up scheme, or different fixed mark-ups for different kinds of pharmaceuticals (like in Slovakia). In several Member States, the wholesale margins refer to a larger segment of the pharmaceutical market than the pricing procedure itself. For example, even though statutory pricing in Austria and Spain is in place for reimbursable pharmaceuticals, the wholesale and the pharmacy margins are applied to all pharmaceuticals.

Pharmacy margins are regulated, at least for some pharmaceuticals (e.g. reimbursable or prescription-only medicines), in all 25 Member States. The majority of the Member States apply statutory pharmacy margins to all pharmaceuticals (cf. Table 3.4).

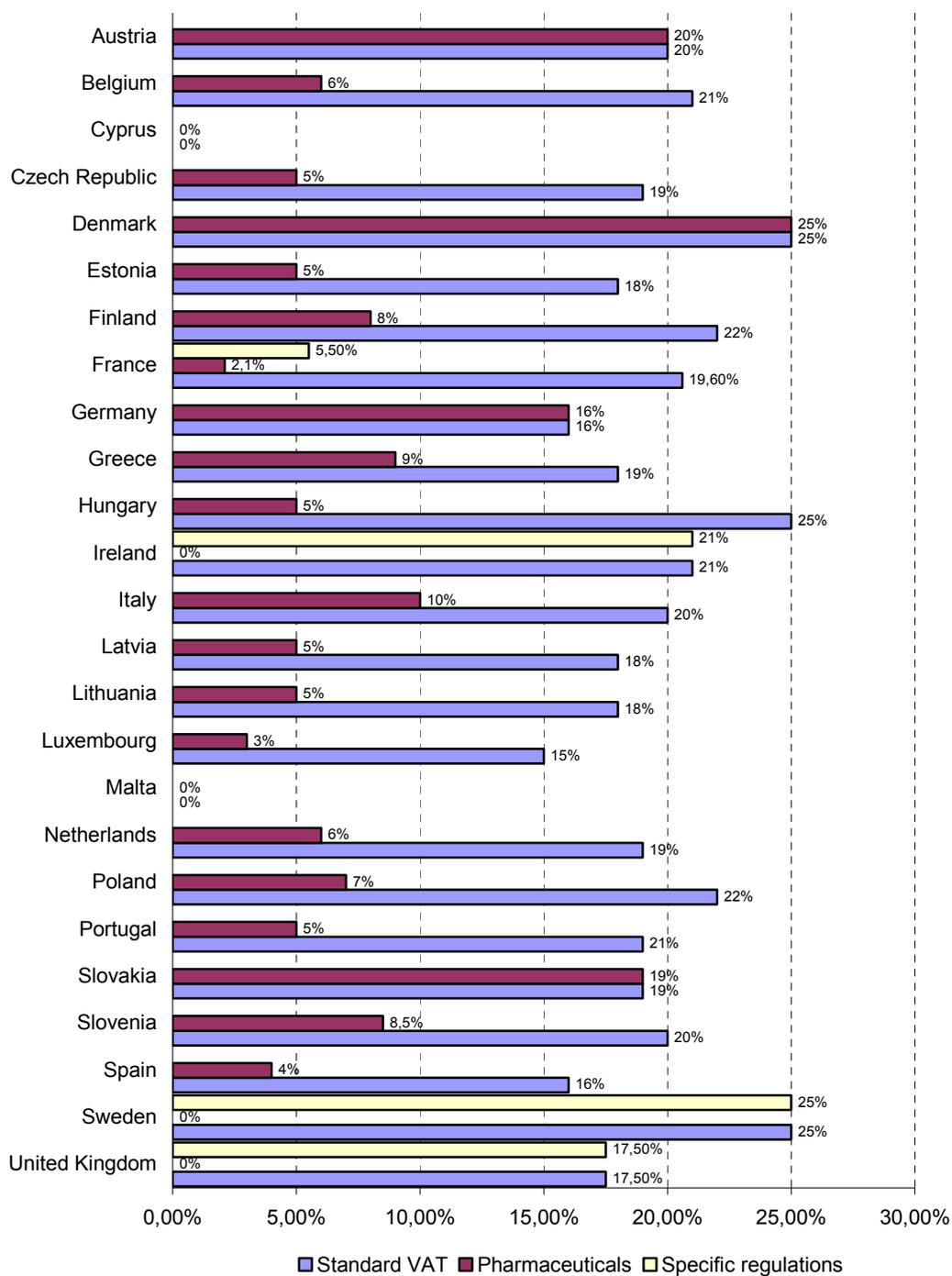
Regarding pharmacy margins, regressive mark-up schemes are more common than linear mark-ups. The Czech Republic has a combined linear maximum mark-up for the wholesale and pharmacy sector, which the distribution actors have to share. In Slovenia, pharmacies are remunerated on a fee-for-service basis, and in the Netherlands, the UK and Ireland (under some Community Drug Schemes) pharmacies receive a fixed fee per dispensed (prescribed) pack.

In the EU Member States, the statutory wholesale and pharmacy margins are regulated in the form of maximum mark-ups. In the 15 old Member States, the maximum mark-ups normally equal to the actual mark-ups, while in the new Member States in the Central and Eastern Europe, in particular in the OTC market, the maximum mark-ups are sometimes not fully utilised. As a consequence, the pharmacy retail prices in these countries may differ between pharmacies, and patients (in urban areas) could shop around for the cheapest product.

Concerning the final price to be paid for a pharmaceutical, taxes are also of relevance, in particular the Value Added Tax (VAT). Figure 3.1 displays the VAT rates for pharmaceuticals compared to the standard VAT rates in all Member States. In many Member States, the VAT rate for pharmaceuticals is lower than the standard VAT rate (exceptions are e.g. Austria and Germany). Some Member States have introduced a split VAT rate (e.g. France: 2.1% for reimbursable and 5.5% for non-reimbursable pharmaceuticals) or a VAT rate which is applicable only for a segment of the market (e.g. UK: no VAT on NHS prescriptions and the standard VAT rate of 17.5% is applied for OTC products). In several countries, especially the new Member States in Central and Eastern Europe, the VAT rate for pharmaceuticals was set at 5% in the years before their accession to the EU. Cyprus and Malta are the only Member States within the EU without any VAT on pharmaceuticals; Malta plans to introduce a 5% VAT on pharmaceuticals by 2010.

In addition to the VAT, a so-called INFARMED tax of 0.4% is applied in Portugal, and a pharmacy tax of up to 11% is in place in Finland.

Figure 3.1: VAT rates for pharmaceuticals in the EU in 2006



Germany: VAT will be raised to 19% from 1.1.2007 on

Slovakia: VAT for pharmaceuticals and medical devices will be reduced to 10% from 1.1 2007 on

Source: GÖG/ÖBIG 2006

4 Reimbursement

4.1 Reimbursement Schemes

Reimbursement is the (full or partial) coverage of costs by Third Party Payers like a Social Health Insurance.

Usually, the eligibility for reimbursement directly concerns the pharmaceutical in question: A pharmaceutical is either considered as reimbursable or as non-reimbursable. Reimbursable pharmaceuticals may then be reimbursed fully or at a certain percentage (see below Chapter 4.2 on “Reimbursement Lists and Rates”).

This product-specific approach to reimbursement is the most common one in the EU; 17 Member States have, in general, a **product-specific** reimbursement scheme (cf. Table 4.1).

However, in some Member States different reimbursement schemes are in place:

- **Disease-specific** reimbursement in the Baltic states

In the three Baltic states Estonia, Latvia and Lithuania, reimbursement is linked to the underlying diseases (based on a published “list of reimbursable diseases”) for which the pharmaceuticals are prescribed. Thus, one pharmaceutical which is used in the treatment of different diagnoses may have different reimbursement rates. For instance, in Estonia diclofenac is reimbursed at 100 percent for cancer treatment, at 75 percent for the treatment of rheumatoid arthritis and at 50 percent in all other cases.

- **Consumption-based** reimbursement in two Nordic states

In Denmark and Sweden, the amount of patient co-payment (or the reimbursement covered by the Third Party Payer alternatively) depends on the expenses of the patient within a certain period of time (in these cases: 12 months). Before the patient has a claim to reimbursement s/he has to pay the full cost of his/her reimbursable medication up to a certain threshold. After this threshold has been passed, the reimbursement rate rises gradually. When a patient has paid up to a ceiling, s/he is exempted from further co-payments for the rest of that 12-month period. In Denmark, the ceiling only applies to chronically ill patients.

- **Population-group-specific** reimbursement in Cyprus, Ireland and Malta

In Cyprus and Malta, under the so-called public system reimbursable pharmaceuticals are dispensed to eligible persons in public health care facilities, whereas under the private system non-reimbursable pharmaceuticals are sold in pharmacies. Eligible for the public system are people with low income, patients with specific diseases as well as some other population groups, such as members of the army and the police in Malta and politicians in Cyprus.

The Irish reimbursement system, consisting of the so-called Community Drug Schemes, is quite similar. However, this system also includes elements of product-specific and disease-specific reimbursement. The most important Community Drug Scheme is the GMS (General Medical Services) scheme for persons under a certain income threshold and their dependants, who are eligible for free pharmaceuticals. Persons who are not eligible for the GMS scheme or other Community Drug Schemes (e.g. for patients with specific illnesses, or for high-cost pharmaceuticals) have access to reimbursable pharmaceuticals after having paid up to a monthly limited threshold.

Table 4.1: Reimbursement of pharmaceuticals in the EU in 2006

Member State	Reimbursement scheme	Reimbursement rates
Austria	Product-specific	100%
Belgium	Product-specific	100%, 75%, (and 85%) ¹ , 50%, 40%, 20%
Cyprus	Population-group-specific	100%, 50%
Czech Republic	Product-specific	100%, no fixed reimbursement rates ²
Denmark	Consumption-based	100%, 85%, 75%, 50%, 0% ³
Estonia	Disease-specific	100%, 75% (and 90%) ¹ , 50%
Finland	Product-specific	100%, 72%, 42%
France	Product-specific	100%, 65%, 35%
Germany	Product-specific	100%
Greece	Product-specific	100%, 75%, 90%
Hungary	Product-specific	100%, 90%, 70%, 50%
Ireland	Population-group-specific ⁴	100%
Italy	Product-specific	100%
Latvia	Disease-specific	100%, 90%, 75%, 50%
Lithuania	Disease-specific	100%, 90%, 80%, 50%
Luxembourg	Product-specific	100%, 80%, 40%
Malta	Population-group-specific	100%
Netherlands	Product-specific	100%
Poland	Product-specific	100%, 70% and 50%
Portugal	Product-specific	95%, 70%, 40%, 20%
Slovakia	Product-specific	100%, no fixed reimbursement rates
Slovenia	Product-specific	100%, 75%, 25%
Spain	Product-specific	100%, 90%, 60% (and 70%) ¹
Sweden	Consumption-based	100%, 90%, 75%, 50%, 0% ³
United Kingdom	Product-specific	100%

Please note that even in case of 100% reimbursement, further co-payments may be in place (see Chapter 5, in particular Table 5.1)

¹ For vulnerable population groups

² Except for anti-allergics

³ Below a determined consumption threshold

⁴ With elements of product-specific and disease-specific reimbursement

Source: GÖG/ÖBIG 2006

4.2 Reimbursement Lists and Rates

Typical criteria for the decision on the inclusion of a pharmaceutical into the reimbursement system are medical-pharmacological and (pharmaco-)economic ones.

A key medical-pharmacological criterion is the therapeutic value/benefit. Common economic criteria for reimbursement are price comparisons, as in the pricing process (cf. Chapter 3.2), in the form of external and internal price referencing. With regard to reimbursement, internal price referencing is a key method, in particular in connection with reference price systems where similar reimbursable pharmaceuticals are clustered and attributed a reimbursement price (so-called reference price) for the whole group (see below Chapter 4.3). Further economic criteria are financial and budgetary restraints. In fact, financial limitations are of relevance for all Member States; but some countries (e.g. the Baltic states) explicitly state the budget impact as a criterion in the reimbursement decision. Several Member States perform pharmaco-economic evaluations (cost-effectiveness analyses). For each EU Member State, the criteria for the reimbursement decision are listed in Part 1 ("Fact Sheets") of this report "Pharmaceutical Systems in the European Union 2006".

Those pharmaceuticals, which are included into reimbursement ("reimbursable pharmaceuticals"), are placed on so called reimbursement lists. Reimbursement lists usually take the form of positive lists, but some Member States (e.g. Spain and the United Kingdom) have introduced negative lists which explicitly mention those pharmaceuticals exempted from reimbursement. Table 4.2 shows that de facto all EU Member States have reimbursement lists.

As stated above, reimbursable pharmaceuticals may be reimbursed fully or partially. In four Member States (Austria, Italy, the Netherlands and the United Kingdom), pharmaceuticals considered as reimbursable are always for 100% reimbursed at their full price (or, if applicable, at the reference price) by the Third Party Payers. In Ireland and Malta, where population-group-specific reimbursement schemes are in place, eligible persons have access to fully reimbursed pharmaceuticals. All other Member States, except Portugal, reimburse some pharmaceuticals fully, and some pharmaceuticals partially. Usually, the reimbursement rate depends on the therapeutic benefit of the pharmaceutical and/or the seriousness of the underlying disease. For instance, some Member States have 100% reimbursement for pharmaceuticals applied for life-threatening illnesses, a reimbursement rate between 60% and 80% for "serious" and chronic diseases and a reimbursement rate between 30% and 50% for the rest of the pharmaceuticals. However, there may also be higher reimbursement rates instead of the standard rates for specific, usually vulnerable population groups (e.g. 90% or 85% instead of 75% in Belgium and Estonia, see also Chapter 5).

Portugal is the only EU Member State where none of the pharmaceuticals is fully reimbursed; in autumn 2005 the 100% reimbursement rate was abolished and replaced by a 95% reimbursement rate.

Table 4.1 lists the various reimbursement rates in the EU Member States. Only the Czech Republic and Slovakia have no fixed percentage rates for reimbursement, the reimbursement rate is determined on an individual basis as a result of the fixing of the reference price.

4.3 Reference Price Systems

In 17 EU Member States, reference price systems are in place (cf. Table 4.2). Only Austria, Cyprus, Finland, Ireland, Luxembourg, Malta, and the United Kingdom have no such system. In Sweden there is no reference price system in place but rather a system of “obligatory generic substitution” which embodies a lot of characteristics of a reference price system.

Reference price systems cover reimbursable pharmaceuticals, which are clustered at the ATC-5 level (products with the same active ingredient) or at the ATC-4-level (therapeutically equivalent products). For each reference group, a so-called reference price is set as a basis for reimbursement. If a pharmaceutical is priced above the reference price, patients have to pay the difference between the reference price and the actual pharmacy retail price (see also Chapter 5).

A prerequisite for reference price systems is a more or less high number of interchangeable pharmaceuticals on the market in order to cluster identical or similar products. Thus, reference price systems have usually developed in countries with a high number of generics (or non-bioequivalent copy-products). The first Member States to introduce a reference price system were Germany, the Netherlands and the two Nordic countries Denmark and Sweden, which already had a high share of generics at that time. In the meanwhile the reference price system in Sweden has been replaced by an “obligatory generic substitution” system. All eight new Member States in Central and Eastern Europe have also decided to introduce a reference price system. In some old Member States (e.g. Italy and Spain) the introduction of the reference price system, and in particular the reaching of a relevant share of generics, took quite some years and required a lot of preparatory work. In the last years, mainly due to cost-containment pressures, several existing reference price systems have been refined. For example, in Slovakia the number of reference groups was reduced in 2003 and in Poland pharmaceuticals in the same therapeutic group must no longer have identical mechanism of action (since 2005).

Table 4.2: Reimbursement lists and reference price systems in the EU in 2006

Member State	Positive / Reimbursement list	Reference price system
Austria	Yes	No
Belgium	Yes	Since 2001
Cyprus	Yes ¹	No
Czech Republic	Yes	Since 1995
Denmark	Yes	Since 1993 ²
Estonia	Yes	Since 2003
Finland	Yes ³	No
France	Yes	Since 2003
Germany	Yes ⁴	Since 1989
Greece	No ⁵	Since 2006
Hungary	Yes	Since 1997
Ireland	Yes	No
Italy	Yes	Since 2001
Latvia	Yes	Since 2005
Lithuania	Yes	Since 2003
Luxembourg	Yes	No
Malta	Yes ¹	No
Netherlands	Yes	Since 1991
Poland	Yes	Yes
Portugal	Yes	Since 2003
Slovakia	Yes	Since 1995
Slovenia	Yes	Since 2003
Spain	(Yes) ⁶	Since 2000
Sweden	Yes	No ⁷
United Kingdom	(Yes) ⁸	No

¹ Pharmaceuticals in the public system for which specific population groups are eligible

² The use of the term "reference price" was removed from the legislation in 2000 and was replaced with the term "reimbursement price" (tilskudspris)

³ Since 1.1.2006 the Finnish Pharmaceuticals Pricing Board has the power to introduce a negative list which has not yet occurred

⁴ Prescription-only medicines are reimbursable; in addition, a negative list is in place

⁵ All pharmaceuticals with the exception of OTC products and lifestyle products are reimbursable. Abolition of the positive list in December 2005

⁶ Not a positive list, but 2 negative lists

⁷ Reference price system was in place between 1993 and 2002. It was replaced by a system of obligatory generic substitution

⁸ National Formulary; in addition, two negative lists are in place

Source: GÖG/ÖBIG 2006

5 Co-payment

From the price of a pharmaceutical, the amount which is not reimbursed by a Third Party Payer has to be paid by the patient.

Private out-of-pocket expenses on pharmaceuticals in many Member States concern the private market of non-reimbursable pharmaceuticals, which are often OTC products. As described in Chapter 2, the share of non-reimbursable pharmaceuticals may be quite high (up to 50 and 80%) in some (especially new) Member States.

For reimbursable pharmaceuticals, out-of-pocket payments (so-called **co-payments**) are in place in several EU Member States:

- As explained in the Chapter 4.2, in many Member States (all but Austria, Italy, Ireland, Malta, the Netherlands and the UK) some reimbursable pharmaceuticals are only partially reimbursed, which means that patients have to co-pay out-of-pocket for the non-reimbursable **percentage** part of the price of the pharmaceuticals. Due to its reimbursement scheme (consumption-based), patients may have to co-pay even 100% in Denmark and Sweden.
- In the 17 EU Member States with a **reference price system** (listed in Table 4.2), patients have to co-pay the difference between the actual pharmacy retail price of the pharmaceutical which they purchase and the (percentage share of the) reference price which is reimbursed.
- **Fixed co-payments** are rather rare in the EU. In only seven Member States (Austria, Estonia, Finland, Italy - in some regions, Poland, Slovakia and the United Kingdom) prescription fees are charged.
- In the field of pharmaceuticals, a **deductible** (i.e. a fixed amount which the patient must pay for a defined period before the cost is (fully or partially) covered by the state) is applied in the consumption-based reimbursement schemes in Denmark and Sweden, as well as in one of Community Drug schemes (the quite common Drug Payment scheme) in Ireland. In Finland, patients have to pay a flat fee deductible per purchased prescribed pharmaceutical after the annual co-payment limit has been exceeded.

Table 5.1 provides an overview of the different co-payments for pharmaceuticals in the reimbursement markets of the 25 EU Member States, and of limits on co-payments, which are in place in eight Member States. Besides these limits, many EU Member States have exemptions from co-payments (e.g. lower co-payment rates) for specific population groups, in particular chronically ill patients, people with low income, pensioners and children, and/or for specific illnesses. Denmark is the only EU Member State where there are no exemptions for vulnerable patient groups.

The information on co-payments in this chapter refers to the out-patient sector; in the hospital sector pharmaceuticals are, in general, given to in-patients free of charge.

Table 5.1: Co-payment for reimbursable pharmaceuticals in the EU in 2006

Member State	Co-payment for reimbursable pharmaceuticals			Co-payment
	Prescription fee	Deductible	Percentage rates	Limit
Austria	€ 4.60	-	0%	-
Belgium	-	-	80%, 60%, 50%, 25% (and 15% resp. ¹), 0%	Annual threshold plus max. co-payment per pr. of € 6.70 to € 26.10 ²
Cyprus	-	-	50%, 0%	-
Czech Republic	-	-	Different rates ³	-
Denmark	-	€ 64.40 per 12 months	100%, 50%, 25%, 15%, 0%	Max. € 472.37 per 12 months
Estonia	€ 1.28 and € 3.20 resp. ⁴	-	50%, 25% (and 10% resp. ¹), 0%	-
Finland	€ 3.- ⁵	€ 1.50 / pr. for ph. above max. annual limit	58%, 28%, 0%	Max. limit of € 616.72 per year
France	-	-	65%, 35%, 0%	-
Germany	-	-	10% (between € 5.- at least and max. € 10.-)	Max. 1% and 2% resp. of annual gross income ⁶
Greece	-	-	25%, 10%, 0%	-
Hungary	-	-	50%, 30%, 10%, 0%	-
Ireland	-	€ 85.- per month (DP scheme)	0%	-
Italy	Regional fees ⁷	-	0%	-
Latvia	-	-	50%, 25%, 10%, 0%	-
Lithuania	-	-	50%, 20%, 10%, 0%	-
Luxembourg	-	-	60%, 20%, 0%	Max. 2.5% of annual net income
Malta	-	-	0%	-
Netherlands	-	-	0%	-
Poland	€ 0.80 and € 1.24 resp. ⁸	-	50%, 30%, 0% ⁸	-
Portugal	-	-	80%, 60%, 30%, 5%	-
Slovakia	€ 0.48	-	Different rates ³	-
Slovenia	-	-	75%, 25%, 0%	-
Spain	-	-	40% (and 30% resp. ¹), 10%, 0%	Max. € 2.64 for ph. for chronic illnesses ⁹

Member State	Co-payment for reimbursable pharmaceuticals			Co-payment
	Prescription fee	Deductible	Percentage rates	Limit
Sweden	-	€ 97.- per 12 months	100%, 50%, 25%, 10%, 0%	Max. € 194.- per 12 months
United Kingdom	€ 9.70 ¹⁰	-	0%	€ 48.80 for 4 months and € 134.25 for 12 months resp. ¹⁰

DP = Drug Payment (one of the Irish Community Drug schemes), max. = maximum, ph. = pharmaceutical, pr. = prescription, resp. = respectively

Note: In all Member States, the percentage co-payment refers to the pharmaceutical, except in Denmark and Sweden, where a consumption-based reimbursement scheme is in place.

¹ Reduced rate for vulnerable population groups

² Threshold varies depending on income, age and social status. Maximum co-payment for prescriptions in certain reimbursement categories

³ No fixed reimbursement / co-payment rates

⁴ € 1.28 per prescription in the reimbursement categories of 100% and 75% (and 90% resp.)

€ 3.20 per prescription in the reimbursement category of 50%

In the 50% reimbursement category patients have to pay the full amount if the price is above € 12.80 per pack.

⁵ In the reimbursement category of 100%

⁶ Maximum 1% of the annual gross income in general, maximum 2% of the annual gross income for chronically ill patients

⁷ Prescription fees in seven out of 20 regions. The amount of the prescription fees varies between the regions.

⁸ Prescription fees of € 0.80 for pharmaceutical specialities and € 1.24 for magistral preparations – in general only for pharmaceuticals in one of the three reimbursement lists ("Basic List", 100% reimbursement).

⁹ With a reimbursement rate of 90%

¹⁰ Patients may purchase either a four months prescription pre-payment certificate for € 48.80 or an annual prescription pre-payment certificate for € 134.25 to cover all prescription fees for that period.

Source: GÖG/ÖBIG 2006

6 Distribution

In the EU Member States, the usual distribution chain in the out-patient sector is as follows: Pharmaceuticals, which are either locally produced or imported, are delivered by wholesalers to pharmacies, which dispense the pharmaceuticals to the patients.

In many Member States, there is a great number of wholesalers (cf. Table 6.1), however, often only a few have significant market shares. As an example, in the Czech Republic and in Latvia, five wholesalers out of a total of 160 and 40 respectively dominate the market. The wholesalers dominating the market are usually full-line wholesalers, offering the full range of products, which operate country-wide (e.g. in Italy, most of the about 300 wholesalers are regionally active, while seven companies dominate the market).

The Nordic countries each have only a few wholesalers (three in Denmark and two in Finland and in Sweden). In addition, Finland and Sweden are the only two EU Member States where pharmaceutical wholesale is organised via a single channel system: This means that wholesalers have exclusive distribution contracts with individual manufacturers, and they deliver only pharmaceuticals from those companies. In the other 23 Member States wholesale is organised in a multi channel system, where wholesalers offer pharmaceuticals from different pharmaceutical companies.

All over the European Union, the key dispensaries for pharmaceuticals are the community pharmacies. A special case form both Cyprus and Malta where, in addition to the community pharmacies in the private system, special public dispensaries (hospital pharmacies in Cyprus and NHS dispensaries in Malta) dispense pharmaceuticals to eligible patients. The provision with pharmacies varies significantly between the EU Member States (cf. Figure 2).

However, when interpreting the number of pharmaceutical retailers per inhabitant, other dispensaries (especially those which are allowed to dispense prescription-only medicines) need to be considered (cf. Table 6.1). These may be:

- Branch pharmacies, which are under the supervision of a pharmacy and, in some cases, offer only a limited range of pharmaceuticals. In Finland and Sweden, pharmacies run so-called medicines chests to guarantee the provision with pharmaceuticals in remote rural areas. For the same reason Portugal has “postos”, which are also managed by pharmacies.
- Self-dispensing doctors who are also typically located in rural areas. In the EU, self-dispensing doctors are not common and their number is declining, with one exception: In Austria, self-dispensing doctors constitute nearly half of all POM dispensaries, as there are around 1,200 pharmacies and nearly 1,000 self-dispensing doctors.
- In a few Member States (e.g. in France), hospital pharmacies, which normally only provide pharmaceuticals for use within the hospital, may also dispense pharmaceuticals to out-patients.

Table 6.1: Pharmaceutical distribution in the EU in 2006

Member State	Wholesale			Pharmaceutical retail					
	< 10	10-100	>100	Phar-macies	Branch ph.	Hospi-tal ph. ¹	SD doctors	OTC shops	Internet ph.
Austria		√		√	√	√ ²	√		
Belgium		√		√					
Cyprus		√ ³		√		√ ⁴			
Czech Republic		√		√				√	
Denmark	√			√	√			√	√
Estonia		√		√				√	
Finland	√ ⁵			√	√			√	
France		√		√		√	√ ²		
Germany		√		√					
Greece			√	√					
Hungary		√		√		√	√ ²		
Ireland	√			√			√ ²	√	
Italy		√		√				√	
Latvia		√		√					
Lithuania		√		√	√	√	√ ⁶		
Luxembourg	√			√		√			
Malta		√		√		(√) ⁴			
Netherlands		√		√		√	√	√	√
Poland			√	√				√	
Portugal			√	√	√ ⁷			√	
Slovakia		√		√					
Slovenia		√		√				√	
Spain		√		√					
Sweden	√ ⁵			√ ⁸		√		√	
United Kingdom		√		√			√ ²	√	

OTC = Over-the-Counter pharmaceutical, ph. = pharmacies, SD = self-dispensing doctors

¹ Dispensing to out-patients

² Only a respectively few number

³ Importers acting as wholesalers

⁴ Acting as community pharmacies for eligible patients in the public system - in Cyprus these are hospital pharmacies, in Malta there are NHS dispensaries which may be situated on the area of a hospital

⁵ Single channel system

⁶ Health Care Centres in rural areas having a contract with a pharmacy are allowed to dispense pharmaceuticals

⁷ "Postos" - outlets run by pharmacies in rural areas

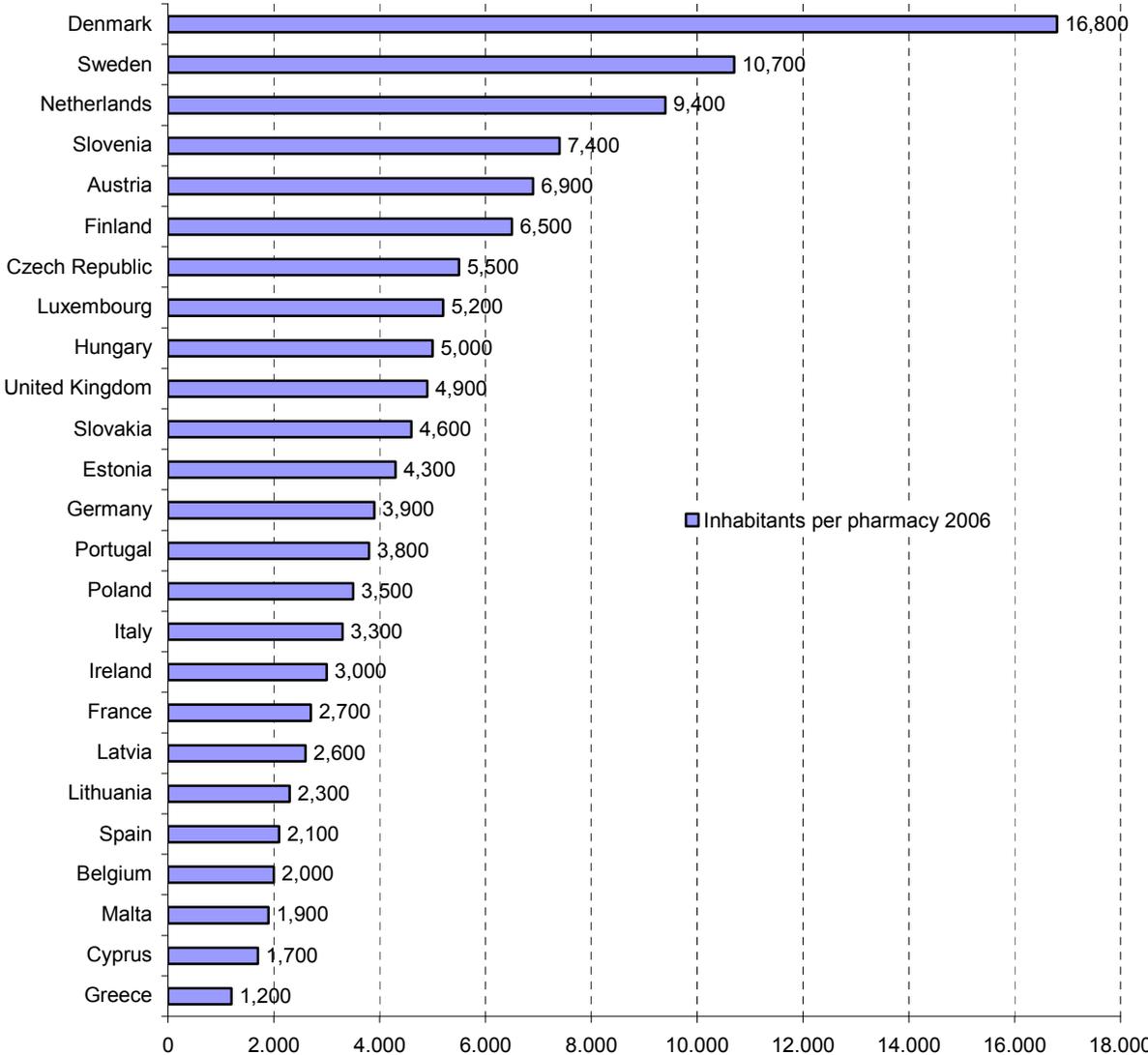
⁸ The state monopoly chain Apoteket owns all pharmacies and other distribution outlets

Source: GÖG/ÖBIG 2006

In the past years a process of liberalisation could be seen in the pharmacy sector, leading to an increase in the number of countries where other retailers, such as drugstores, corner shops, supermarkets and petrol stations, are permitted to sell OTC products (or at least a limited range of OTC products). While the United Kingdom has a longer tradition of selling specified OTC products in supermarkets, this has been allowed in Finland (for tobacco-selling shops to sell Nicotine Replacement Therapy products) and in Italy (for supermarkets to sell non-reimbursable OTC products) since 2006.

Internet pharmacies are only permitted in two EU Member States, namely the Netherlands and Denmark (only for the sale of OTC products).

Figure 6.1: Pharmacies per inhabitant in the EU in 2006¹



¹ or latest available year

Source: GÖG/ÖBIG 2006

7 Summary and Outlook

This report provides concise information on market authorisation, pricing and reimbursement for pharmaceuticals in the 25 EU Member States. In the comparative tables and figures, common elements and trends of the pharmaceutical systems were displayed, from which can be concluded:

- that statutory pricing or official price negotiations often apply to the reimbursable segment, while the price setting for non-reimbursable / OTC products is deregulated,
- that at the wholesale and the pharmacy price level, however, statutory maximum mark-ups are common in many Member States, even for non-reimbursable pharmaceuticals,
- that the majority of Member States consider the prices of the same pharmaceutical in other countries (external price referencing) or the prices of similar products in their own country (internal price referencing) in their pricing or reimbursement decision,
- that all EU Member States use reimbursement lists (usually positive lists),
- that most Member States decide on reimbursement per product, but there are also other reimbursement schemes, which are for example based on the consumption of pharmaceuticals within a time period or the reimbursement eligibility of specific population groups,
- that nearly all Member States reimburse only some pharmaceuticals fully, while for other reimbursable pharmaceuticals patients have to co-pay,
- that the VAT rate for pharmaceuticals is usually lower than the standard VAT rate,
- that in the OTC segment, the role of other dispensaries besides pharmacies is increasing.

The pharmaceutical systems of the EU Member States are constantly undergoing changes. For instance, in 2007, a Health Care Reform will be implemented in Germany, the pricing system in Slovenia is planned to be modified and a new pharmaceutical law will come into force in the Netherlands.

The Health Economics team of Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG monitors these developments. In order to promote a better exchange of information we have built up the PPRI (Pharmaceutical Pricing and Reimbursement Information) network of competent authorities and relevant institutions in the field of pharmaceuticals. PPRI will produce in-depth country reports ("Pharma Profiles") on EU Member States and some non-EU countries and a comparative report. These reports are due in summer 2007 and will be presented at the Vienna PPRI conference on 29 June 2007.

ANNEX

Glossary

Anatomic Therapeutic Chemical Code (ATC)	=	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.
Community Drug Scheme	=	Different payment arrangements for services/pharmaceuticals provided in the community and financed by the Primary Care Reimbursement Service (PCRS) in Ireland
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. In case of a reference price system: any difference between the reference price and the pharmacy retail price, which has to be paid by the patient.
External Price Referencing / Cross Country Referencing	=	The practice of comparing pharmaceutical prices across countries. There are various methods applied and different country baskets relevant.
Full liner		Wholesaler offering the full range of pharmaceuticals available in a given market/country. There are no full liners in single channel distribution systems.
Free Pricing	=	Pricing system, where pharmaceutical prices may be freely set by the manufacturer / importer.
Generic	=	Bioequivalent of a branded original pharmaceutical, whose patent on the active ingredient has expired (also called off-patent or multi-source pharmaceutical). By law, a generic product must contain an identical amount of the same active ingredient(s) as the branded product. There are branded generics and unbranded generics on the market. Branded generics also have a specific trade name, whereas unbranded generics use the international non-proprietary name and the manufacturer's 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 therapeutically 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 or price to wholesalers. This price does not include any discounts or other incentives offered by manufacturers.
Mark-up	=	Wholesale mark-up: Gross profit of wholesalers, expressed as a percentage of the manufacturer/ex-factory price. Pharmacy mark-up: The gross profit of pharmacies expressed as a percentage of the wholesale/pharmacy purchase price.

Margin	= Wholesale margin: Gross profit of wholesalers, expressed as a percentage of the wholesale/pharmacy purchase price. Pharmacy margin: Gross profit of pharmacies, expressed as a percentage of the pharmacy retail price.
Market Authorisation	= A licence issued by a medicines agency approving a pharmaceutical for market use based on a determination by authorities that the pharmaceutical meets the requirements of quality, safety and efficacy for human use in therapeutic treatment. There are the following application procedures possible in the EU: "centralised procedure", "mutual recognition procedure" (MRP)/"decentralised procedure" and "national procedure". For homeopathic pharmaceuticals and medical devices no authorisation but a registration procedure is necessary.
Member States	Member States of the European Union, as of the year 2006 Old Member States: Member States of the EU-15 (Austria, Belgium, Denmark, Germany, Finland, France, Greece, Ireland, Italy, Luxemburg, Netherlands, Portugal, Sweden, Spain, United Kingdom) New Member States: those which acceded to the EU in 2004 (Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia)
Multi channel system	In a multi channel distribution system pharmaceutical companies distribute their products via several wholesalers to pharmacies. Wholesalers do not have exclusive distribution rights on specific products.
Negative List	= List of pharmaceuticals which cannot be prescribed at the expense of the social health insurance / national health service.
Original Product	= The first version of a pharmaceutical, developed and patented by an originator pharmaceutical company which has exclusive rights to marketing the product in the European Union for 15 years. An original product has a unique trade name for marketing purposes, its so-called brand name.
Over-the-Counter (OTC)	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	= Any active ingredient or combination product presented for treating or preventing disease in human beings as animals. Any active ingredient or combination product which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human being or in animals is likewise considered a pharmaceutical.
Pharmacoeconomic 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.
Prescription-only-Medicines (POM)	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 Negotiation	= A form of pricing procedure, where pharmaceutical prices are negotiated.

Pricing	= The act of setting a price for a pharmaceutical.
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 at a given ATC-4 level (similar pharmaceuticals) and/or ATC-5 level (identical pharmaceuticals) group.
Reimbursable Pharmaceuticals	= Pharmaceuticals whose costs are, at least partially, covered by the social health insurance / national health service.
Reimbursement	= Reimbursement is the percentage of costs (for a service or a pharmaceutical) which the social health insurance / national health service pays. So 100% reimbursement means that the social health insurance/national health service accept 100% of the costs for a pharmaceutical or service.
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.
Reimbursement rate	= The percentage share of the price of a pharmaceutical or medicinal service, which is reimbursed/subsidised by social health insurance / national health service. The difference to the full price of the pharmaceutical or medicinal service is paid by the patients (out-of-pocket payment).
Single channel system	In a single channel system pharmaceutical wholesalers have exclusive distribution contracts with individual pharmaceutical companies/importers. Consequently, every wholesaler - being partly assorted - is only able to offer a part range of the pharmaceuticals on the market to pharmacies .
Statutory Pricing	= Pricing system, where pharmaceutical prices are set on a regulatory basis (e.g. law, enactment, decree).
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.
Value Added Tax (VAT)	= A sales tax levied on the sale of goods and services (compulsory for EU Member States). The VAT rate of pharmaceuticals in the EU is often lower than the standard VAT rate of 15%.
Wholesale Price	= The price charged by wholesalers to the retailers (usually pharmacies). It includes any wholesale mark-up.

Further definitions can be found in the PPRI glossary, see <http://ppri.oebig.at>



Pharmaceutical Pricing and Reimbursement Information

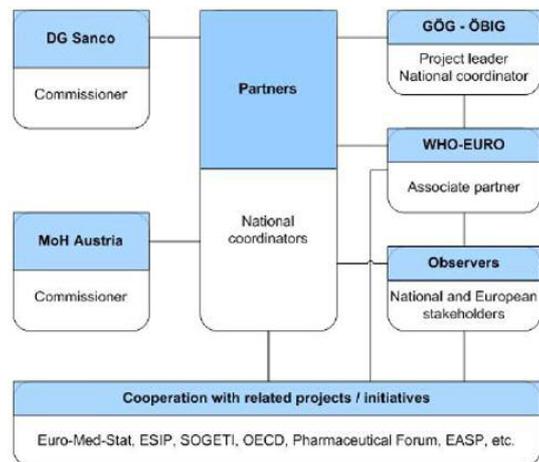
PPRI project

The pricing and reimbursement of pharmaceuticals is a national issue. Consequently there are 25 pharmaceutical pricing and reimbursement systems in the enlarged European Union which often differ greatly. Therefore, the objective of the PPRI project is to develop a network of authorities and institutions in order to improve information and knowledge about the pharmaceutical systems in the enlarged Europe, by providing comprehensive country reports on the Member States and a comparative analysis.

Project organisation

The PPRI project is commissioned and funded by the European Commission, Health and Consumer Protection Directorate-General and co-funded by the Federal Ministry for Health and Women's Issues, Austria. The project team consists of the main partner (GÖG-ÖBIG / Austrian Health Institute), an associate partner (WHO Regional Office for Europe) and a network of 20 partners and more than 20 observers from a large range of EU Member States and other countries such as Bulgaria, Norway and Canada.

The PPRI project is designed to run from April 2005 to summer 2007. The results will be disseminated during a conference in Vienna in summer 2007.



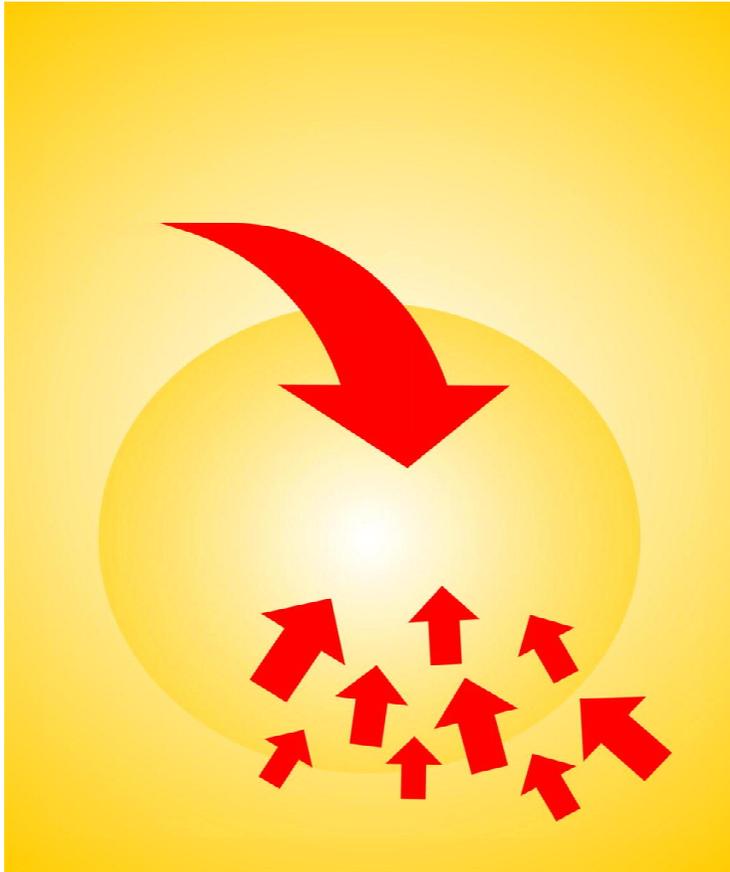
Project description

The PPRI project is subdivided into 6 work packages, which are linked to the specific objectives of the study.

Specific objective of the PPRI project:	Work package(s):	Deliverables of the PPRI project:
Strengthening the networking of institutions in the field of pharmaceuticals in Member States	WP 1 'Coordination'	Good communication and cooperation within the project, for delivering a project of high quality on time
	WP 2 'Dissemination'	A website (http://ppri.oebig.at) and a conference at the end of the project (Summer 2007, Vienna)
Assessing the information needs concerning pharmaceutical pricing and reimbursement	WP 3 'Assessment'	A questionnaire to be used in the interviews, with a list of key information and data to be collected
Collection, reporting and analysis of information on pricing and reimbursement in Member States	WP 4 'Survey'	Pharma Profiles (=country reports on the pharmaceutical pricing and reimbursement systems) of the EU Member States
Developing indicators for comparative analysis	WP 5 'Development of comparable indicators'	A list of indicators for analysing pricing and reimbursement in a comparative way
Benchmarking pharmaceutical pricing and reimbursement in the enlarged Europe	WP 6 'Comparative analysis'	Benchmarking of pricing and reimbursement in the Member States in a draft report
Dissemination of project results	WP 2 'Dissemination'	International publications and organisation of the summer 2007 conference

Contact:
GÖG-ÖBIG – PPRI
Sabine Vogler, Claudia Habl, Ingrid Rosian
Address: Stubenring 6, 1010 Vienna, Austria
Tel.: +43 1 515 61 ext. 147, 161 or 159, Fax: +43 1 513 84 72
E-Mail: ppri@oebig.at
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