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Pharmaceutical Pricing and Reimbursement Information

AUSTRIA

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Pharma Profile

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Executive Summary

Background

In Austria, health care is based on a social insurance system, which includes health, accident, pension as well as unemployment insurance. The underlying law is the Austrian Social Insurance Law (Allgemeines Sozialversicherungsgesetz, ASVG), effective since 1955. The implementation of social insurance is ensured by the umbrella organisation the Federation of Austrian Social Insurance Institutions (Hauptverband der österreichischen Sozialversicherungsträger, HVB) and its 19 sickness funds. Approximately 98% of the population is covered by the social health insurance (SHI); health care contributions are based on the income of the insured person. Exemptions are made for socially disadvantaged persons and persons with communicable diseases.

Besides health insurance contributions, accounting for about 50%, health care in Austria is funded through a mix of personal contributions (30%; out-of-pocket payment (OPP) and private health insurance) and general taxation (20%).

In the year 2004, total spending for health care was around 9.6% of gross domestic product (GDP). While public health expenditure accounts for two-thirds of total health expenditure (THE), private expenditure (co-payments, private health insurance fees and other out-of-pocket expenditure) amounts to one-third of THE.

The Federal Ministry of Health and Women's Issues (Bundesministerium für Gesundheit und Frauen, BMGF¹) is the main policy-maker in health care at federal level. Further key actors in this field are the Federation of Austrian Social Insurance Institutions (HVB) and the Austrian Federal Agency for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen, BASG) acting as the Austrian Medicines Agency.

In 2005, a total of 39,519 medical doctors provided in-patient and out-patient care for the Austrian population. General practitioners (GPs) offer primary care and act as gatekeepers. In general they have contracts with one or more social health insurance (SHI) plans and are remunerated by flat-rate fees and by fee-for-service payments. Specialist care is either administered in hospitals or in consultation offices. The basis for remuneration of public and non-profit-making general hospitals and public specialised hospitals is the diagnosis-related group (DRG) (Leistungsorientierte Krankenanstaltenfinanzierung, LKF / DRG) system.

Pharmaceutical System

The legislative framework of the production, market authorisation and distribution of pharmaceuticals is the Medicines Act. The classification of pharmaceuticals is laid down in the Prescription Act. The Price Act builds the overall legal framework for the pricing of reimbursable

¹ From 1 March 2007 the Ministry has been renamed the Federal Ministry of Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ)

pharmaceuticals, and the reimbursement of pharmaceuticals is regulated in the Austrian Social Insurance Law (ASVG).

The main actors in the pharmaceutical system in Austria are: the Federal Ministry of Health and Women's Issues (BMGF) assisted by the Pricing Committee (Preiskommission, PK), and the Federation of Austrian Social Insurance Institutions (HVB) taking decisions on the reimbursement of pharmaceuticals on the basis of the recommendations of the Pharmaceutical Evaluation Board (Heilmittel-Evaluierungskommission, HEK). Another body dealing with pharmaceuticals is the Austrian Federal Agency for Safety in Health Care (BASG), being responsible for granting market authorisation and for the classification of pharmaceuticals according to prescription status.

Total pharmaceutical expenditure (TPE) amounted to € 2,967 million (Mio.) in 2004 (2003: € 2,878 Mio.). The proportion of public pharmaceutical expenditure as a share of total health care expenditure rose from 6.1 % in 1995 to 11.9 % in 2003, whereas the share of private pharmaceutical expenditure has been kept relatively stable (5% in 2003). In 2004, pharmaceutical sales at ex-factory level amounted to € 2,311 Mio., which was an increase of 7.5 % compared to the year 2003. The share of generics is relatively low in Austria. In terms of value, generics made up 10.7 % of total pharmaceutical sales in 2006.

There are approximately 160 pharmaceutical companies based in Austria. Most of them are trading ones; 24 are manufacturing companies. The manufacturers deliver their pharmaceuticals to about 35 wholesalers, of which 8 provide a full assortment of pharmaceuticals on the market. In general the system at wholesale level is a multi-channel one. In Austria pharmaceuticals are mainly sold through pharmacies or branch pharmacies, which practise under the supervision of a community pharmacy. In 2005, there were 1,191 community pharmacies and 5 hospital pharmacies. Furthermore, Austria has quite a high number of self-dispensing doctors (Apothekenführender Hausarzt, SD-doctors), totalling 992 in 2005. Internet pharmacies are not permitted in Austria.

Pricing

The Price Act builds the overall framework for pricing in Austria. The pricing of pharmaceuticals is in the hands of the Federal Ministry of Health and Women's Issues (BMGF) advised by the Pricing Committee (PK). Furthermore, there is a price notification agreement between the Federal Chamber of Labour (Bundesarbeiterkammer, BAK) and the Federal Chamber of Commerce (Wirtschaftskammer, WKÖ) in place.

In general, non-reimbursable pharmaceuticals fall under the price notification system (at the ex-factory price level), and pharmaceuticals applying for reimbursement fall under the statutory price system, where the Federal Ministry of Health and Women's Issues (BMGF), advised by the Pricing Committee (PK), sets the European Union (EU) average price. Prices for pharmaceuticals included in the Reimbursement Code (Erstattungskodex, EKO) may be further negotiated with the Federation of Austrian Social Insurance Institutions (HVB). Furthermore, regressive mark-up schemes for both wholesalers and pharmacies are applicable to all pharmaceuticals.

In Austria, internal and external price referencing plays an important role in the pricing procedure for pharmaceuticals applying for reimbursement.

Regarding the procedure of the calculation of the European Union (EU) average price, the holder of the market authorisation applying for the inclusion of the pharmaceutical into the Reimbursement Code (EKO) has to provide information on whether the pharmaceutical is on the market in the other EU Member States and if so has to submit the manufacturing price and wholesale price of the pharmaceutical in each of these countries (external price referencing). The Austrian Health Institute (now GÖG/ÖBIG) is responsible for checking the price submitted by the industry; the average price is then calculated by the Pricing Committee (PK).

Both, wholesalers and pharmacists, are remunerated via degressive margins, cf. 3.5.1 and 3.5.2.

Since 1997 the sale of pharmaceuticals bears the standard-rate Austrian 20 % value-added tax (VAT).

In Austria different pricing-related cost-containment measures have been taken. Among these, different margin schemes for “privileged customers” (i.e. sickness funds) and private customers have been introduced.

Reimbursement

Pharmaceuticals are granted in kind to the 98% of Austrian’s eight million inhabitants who are covered by statutory health insurance.

There are 19 sickness funds, being represented in their umbrella organisation the Federation of Austrian Social Insurance Institutions (HVB). The Federation of Austrian Social Insurance Institutions (HVB), consulted by the Pharmaceutical Evaluation Board (HEK), is responsible for deciding whether a pharmaceutical should be reimbursed or not. Eligibility criteria for reimbursement are based on pharmacological analysis, medical-therapeutic evaluations and health-economic considerations.

The pricing and reimbursement systems are very closely linked, since there are special pricing rules for pharmaceuticals applying for inclusion in the Reimbursement Code (EKO).

In Austria, there is a positive list of pharmaceuticals, the Reimbursement Code (EKO). All pharmaceuticals included in the EKO qualify for general reimbursement; however, there are different conditions regarding the prescription. The Reimbursement Code (EKO) has three main segments: the red box, the yellow box (subgroup: light yellow) and the green box. The red box includes newly launched pharmaceuticals and all pharmaceuticals that apply for reimbursement. Pharmaceuticals stay in the red box for 24-36 months and then they are transferred to either the yellow or the green box. The yellow box includes pharmaceuticals fulfilling certain criteria (e.g. specific disease or age group). For pharmaceuticals in the red and the yellow boxes, an ex-ante approval of a sickness fund “head physician” has to be sought by the prescribing doctor. In the subgroup of the light yellow box, the ex-ante approval is re-

placed by a possible ex-post volume control of the prescribing doctor. The green box includes pharmaceuticals qualifying for automatic reimbursement; these are prescribed by any contract doctor. Inclusion is based on certain criteria relating to drug usage, such as disease group or mode of application. In addition to the positive list, there is a kind of negative list, which includes pharmaceuticals not eligible for reimbursement.

The Reimbursement Code (EKO) is only relevant for out-patient care. Pharmaceuticals used in hospital care are included in the diagnosis-related remuneration system of hospitals, i.e. there is no separate reimbursement of pharmaceuticals in hospitals. For pharmaceuticals used with in-patient treatment no extra co-payment is charged.

Pharmaceuticals are either fully reimbursed or not reimbursed at all. If pharmaceuticals are reimbursed, patients have to pay out-of-pocket a fixed prescription fee amounting to € 4.60 (in 2006). In Austria, there is no reference price system.

The most recent change in the reimbursement list has occurred in 2005, when the new Reimbursement Code (EKO) and the system of different boxes was introduced. The pharmaceuticals that have been listed in the old reimbursement list (Heilmittelverzeichnis) are now included in the green box of the EKO.

Rational Use of Pharmaceuticals

In Austria, there are “Guidelines on Economic Prescribing of pharmaceuticals and medical products” (Richtlinie über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen, RöV). These guidelines were published in 2004 by the Federation of Austrian Social Insurance Institutions (HVB) on the basis of the Austrian Social Health Insurance Law (ASVG) and set criteria for the coverage of pharmaceuticals by the sickness funds. These guidelines intend to safeguard the appropriate and economical prescribing of pharmaceuticals.

Advertising and industry behaviour towards health professionals are regulated by the Austrian Medicines Act, which is in line with the Directive 2001/83/EC. The Austrian Federal Agency for Safety in Health Care (BASG) is the authority responsible for supervising pharmaceutical advertising activities.

Although there are no explicit pharmacoeconomic guidelines in place in Austria, rules and criteria are set for the so-called health-economic evaluation within the Procedural Rules for the (new) Reimbursement Code (VO-EKO), which is relevant for pharmaceuticals that apply for reimbursement.

The share of generics in Austria has been rather low for a long time. In 2006, according to figures of the Austrian Generics Association (Österreichischer Generikaverband, OEGV) the share of generics in the out-patient market was 10.7 % in terms of value and 18,6 % in terms of volume (counted by packs sold).

One of the reasons for the relatively low market share of generics is that neither voluntary nor obligatory generic substitution is allowed for pharmacists.

Current challenges and future developments

One of the main challenges facing the Austrian pharmaceutical system is, as in many other countries, the rising pharmaceutical expenditure. The major reasons for the growing costs are an ageing population and the uptake of new, more expensive pharmaceuticals (e.g. in oncology treatment).

In 2004, therefore, the Government announced that the annual growth rate of pharmaceutical reimbursement expenditure was to be limited to approximately 3-4 percent. This is to be achieved through a reform of the reimbursement system by introducing the so-called “box-model” and the new Reimbursement Code (EKO), cf. 4.2 for details.

According to a Governmental Declaration of spring 2007 the existing fixed co-payment per prescription shall be capped by an annual maximum. This maximum co-payment shall be introduced by 1 January 2008 and should be about 2 percent of the annual income of a patient.

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List of abbreviations

AEG	Apothekeneinkaufsgremium / Pharmacy Purchasing Committee (Austria)
AGES	Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH / Austrian Agency for Health and Food Safety (Austria)
APG	Allgemeines Pensionsgesetz / General Retirement Income Act (Austria)
ARGE Pharmazeutika	Association of Austrian Pharmaceutical Wholesalers
ASVG	Allgemeines Sozialversicherungsgesetz / Austrian Social Insurance Law (Austria)
ATC	Anatomic Therapeutic Chemical classification
BAK	Bundesarbeiterkammer / Federal Chamber of Labour (Austria)
BASG	Bundesamt für Sicherheit im Gesundheitswesen / Austrian Federal Agency for Safety in Health Care (Austria)
BfA	Bundesinstitut für Arzneimittel / National Institute of Pharmaceuticals (Austria)
BMBWK	Bundesministerium für Bildung, Wissenschaft und Kultur / Federal Ministry for Education, Science and Culture (Austria)
BMF	Bundesministerium für Finanzen / Federal Ministry of Finance (Austria)
BMGF	Bundesministerium für Gesundheit und Frauen / Federal Ministry of Health and Women's Issues (Austria), from 1 March 2007 re-named to Bundesministerium für Gesundheit, Familie und Jugend (Federal Ministry of Health, Family and Youth, BMGFJ)
BMI	Bundesministerium für Inneres / Ministry of the Interior (Austria)
BMLF	Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft / Federal Ministry for Agriculture, Forestry, Environment and Water Management (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)
DG SANCO	Health and Consumer Protection Directorate General of the European Commission
DRG	Diagnosis-related group
EKO	Erstattungskodex / Reimbursement Code (Positive list) (Austria)
EU	European Union

GDP	Gross Domestic Product
GGE	General Government Expenditure
GGP	Österreichischer Großgeräteplan / Austrian Major Equipment Plan
GmbH	Gesellschaft mit beschränkter Haftung / Public limited liability company (Austria)
GÖG/ÖBIG	Gesundheit Österreich GmbH / Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen (Austria) / Austrian Health Institute
GP	General Practitioner
HE	Health Expenditure
HEK	Heilmittel-Evaluierungskommission / Pharmaceutical Evaluation Board (Austria)
HOM	Hospital-Only Medicine
HVB	Hauptverband der österreichischen Sozialversicherungsträger / Federation of Austrian Social Insurance Institutions (Austria)
IMS	Institut für Medizinische Statistik / Insitut for Medical Statistics (Austria)
IPF	Institut für Pharmaökonomische Forschung / Institute for Pharmacoeconomic Research (Austria)
KAKuG	Krankenanstalten- und Kursanstaltengesetz / Hospitals Law
LDF	Leistungs- und Diagnoseorientierte Fallgruppen / Hospitals' lump-sum remuneration (Austria)
LKF	Leistungsorientierten Krankenhausfinanzierung / DRG system (Austria)
Mio.	Million
n.a.	not available
n.appl.	not applicable
NCU	National Currency Unit
ÖAK	Österreichische Apothekerkammer / Chamber of Pharmacists (Austria)
ÖÄK	Österreichische Ärztekammer / Chamber of Medical Doctors (Physicians) (Austria)
OECD	Organisation for Economic Co-operation and Development
OEGV	Österreichischer Generikaverband / Austrian Generics Association (Austria)
ÖKAP	Österreichischer Krankenanstaltenplan / Austrian Hospitals Plan (Austria)
OPP	Out-of-Pocket Payment
ÖSG	Österreichischer Strukturplan Gesundheit / Austrian Health Care Structural Plan (Austria)
OTC	Over-The-Counter pharmaceuticals

ÖVP	Österreichische Volkspartei / Austrian People`s Party (Austria)
PE	Pharmaceutical Expenditure
PK	Preiskommission / Pricing Committee (Austria)
POM	Prescription-Only Medicines
PPPa	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
R&D	Pharmaceutical Research & Development
RöV	Richtlinie über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen / Guidelines on Economic Prescribing (Austria)
SD-doctor	Apothekenführender Hausarzt / Self-dispensing doctor (Austria)
SHI	Social Health Insurance
SPC	Supplementary Protection Certificate
SPÖ	Sozialdemokratische Partei Österreichs / Austrian Social-Democratic Party (Austria)
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
UHK	Unabhängige Heilmittelkommission / Independent Pharmaceutical Commission (Austria)
VAT	Value-Added Tax
VHI	Voluntary Health Insurance
VO-EKO	Verfahrensordnung Erstattungskodex / Reimbursement Code (decree)
WHO	World Health Organization
WKÖ	Wirtschaftskammer / Federal Chamber of Commerce (Austria)
WVZ	Warenverzeichnis / Medicines Price Register (Austria)

Introduction

The Pharmaceutical Pricing and Reimbursement Information (PPRI) project is a 31 month-project (2005-2007) commissioned by the Health and Consumer Protection Directorate-General (DG SANCO) of the European Commission and co-funded by the Austrian Federal Ministry of Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ). The project was coordinated by the main partner Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG) and the associated partner World Health Organisation (WHO) Regional Office for Europe. The PPRI project has established a network of 46 participating institutions (competent authorities and other relevant organisations) in the field of pharmaceuticals.

The PPRI project seeks to increase transparency and knowledge and facilitate the exchange of experience in the field of pharmaceuticals by

- establishing and maintaining a network of relevant institutions in the field of pharmaceuticals in the enlarged European Union (EU), in order to facilitate a regular exchange of information and allow a process of learning from each other,
- producing country reports on pharmaceutical pricing and reimbursement systems, the “PPRI Pharma Profiles”,
- developing indicators for the comparison of pharmaceutical pricing and reimbursement information,
- providing a comparative analysis on pharmaceutical pricing and reimbursement in the European Union (EU) and,

disseminating the outcomes of the project.

The PPRI Pharma Profiles are country-specific reports that provide detailed descriptions of the countries pharmaceutical systems and policies. The profiles are written by PPRI participants (country experts from competent authorities, Medicines Agencies, Social Insurance Institutions, research institutes) and edited by experts of the PPRI project coordination.

This Pharma Profile is one of the many PPRI Pharma Profiles, which all are available on the PPRI website at <http://ppri.oebig.at>. The information and data provided in the PPRI Pharma Profiles refer, in general, to the year 2006.

In order to improve readability and allow for comparisons between countries, the structure of the Pharma profiles follows a template, which was developed by the project coordination team and the PPRI participants. The template is based on a large needs assessment of both national and international stakeholders. In addition to the template a glossary was developed to facilitate the writing process and the readability. The 70-page PPRI Pharma Profile Template and the PPRI Glossary are available at the PPRI website.

1 Background

1.1 Demography

Austria has 8.23 Mio. inhabitants and a land surface area of 83,871 km², which results in a population density of 98.17 inhabitants per km². The population of the capital, Vienna, exceeds 1.6 Mio. (2 Mio. with suburbs), representing about a quarter of the country's population. The second largest city, Graz, is home to 226,000 people, followed by Linz with 184,000, Salzburg with 143,000, and Innsbruck with 113,000 inhabitants.

As a result of declining mortality and persistently low fertility, the share of the population over age 64 has been increasing while the population under age 14 has been falling in the past decade (cf. Table 1.1). Austria faces major challenges in relation to population ageing and the employment of workers, which has necessitated reforms. In 2003, the Austrian Parliament adopted the pension securing reform with a long-term transition period, followed up by a further step in 2004, the General Retirement Income Act (Allgemeines Pensionsgesetz, APG). All in all, the reform package marks substantial progress in securing the sustainability of general government finances and improves incentives for working for longer or searching for a job.

An Austrian born in 2005 can expect to live 79.45 years on average: 82.24 years if female and 76.65 years if male. Since the mid-1990s, Austrians have gained about 2.81 years in life expectancy, with men showing a greater increase than women: 3.35 years and 2.26 years, respectively.

Table 1.1: Austria - Demographic indicators 1995, 2000-2005

Variable	1995	2000	2001	2002	2003	2004	2005
Total population	7,948,278	8,011,566	8,043,046	8,083,797	8,117,754	8,174,733	8,233,306
Population density per km ²	94.77	95.52	95.90	96.38	96.79	97.47	98.17
Population aged 0-14 (as a % of total)	17.8	17.0	16.8	16.6	16.4	16.2	16.0
Population aged 15-64 (as a % of total)	67.1	67.5	67.7	67.9	68.1	68.0	67.7
Population aged >64 (as a % of total)	15.1	15.4	15.5	15.5	15.5	15.7	16.3
Life expectancy at birth, total	76.64	78.12	78.61	78.77	78.76	79.29	79.45
Life expectancy at birth, females	79.98	81.12	81.60	81.71	81.57	82.14	82.24
Life expectancy at birth, males	73.30	75.11	75.61	75.82	75.94	76.43	76.65

¹ estimation

Source: Statistics Austria 2005-2007

1.2 Economic background

In 2005, Austria had a gross domestic product (GDP) of € 246,466 Mio. and a GDP per capita of € 30,149. The gross domestic product (GDP) per inhabitant in Purchasing Power Parity (PPPa) reached US\$ 32,519. As apparent in Table 1.2, the GDP has constantly increased in the last decade. The annual economic growth rate was 4.0 % in 2005.

The Austrian Government spent 118,616 million Euro in General Government Expenditure (GGE) or 50 % of gross domestic product (GDP) on public spending.²The health care sector is affected by a general tendency towards privatisation as well as the formation of holding companies.

² OECD 2006

Table 1.2: Austria - Macroeconomic indicators 1995, 2000-2005

Variable	1995	2000	2001	2002	2003	2004	2005
GDP in NCU (Mio. €)	175,526	210,392	215,878	220,688	226,968	237,039	246,466
GDP / capita in NCU (€)	21,813	25,942	26,547	27,299	27,959	28,996	30,149
GDP / capita in PPPa (US \$)	22,976	28,359	28,855	29,942	30,796	32,519	n.a.
Annual economic growth rate in % ¹	3.9	5.2	2.6	2.2	2.8	4.4	4.0
GGE (Mio. €)	98,374	108,174	109,728	111,971	115,573	118,616	n.a.
GGE as a % of GDP	56.0	51.4	50.8	50.7	50.9	50.0	n.a.
Exchange rate (NCU per €), annual rate	13.0328	13.7603	13.7603	n.app.	n.app.	n.app.	n.app.

GDP = gross domestic product, GGE = general government expenditure, n.a. = not available, NCU = national currency unit, PPPa = purchasing power parity, n.app. = not applicable

¹ variance to previous year in %

Source: OECD Health Data 2006; Austrian National Bank 2006

1.3 Political context

Austria is a federal republic with a parliamentary democracy, which joined the European Union in 1995. Legislative and executive powers are divided between the federal Government and the nine provinces (Länder): Burgenland, Carinthia, Lower Austria, Salzburg, Styria, Tyrol, Upper Austria, Vorarlberg and Vienna. The latter is a province (Land) as well as the country's capital.

The federal legislation is implemented by the two chambers of Parliament – the National Council (Nationalrat) and the Federal Council (Bundesrat). The National Council, which has 183 members, holds legislative authority. The Federal Council has 64 members and reviews legislation which passes through the National Council and can delay, but not veto, its enactment.

The Federal President (Bundespräsident) is Austria's Head of State, elected by popular vote for a term of six years. The federal cabinet consists of the Federal Chancellor (Bundeskanzler) appointed by the President and also a number of Ministers appointed by the President on the recommendation of the Chancellor. The Federal President convenes and concludes parliamentary sessions and, under certain conditions, can dissolve Parliament. The Federal Chancellor is the Head of Government. Together with the Vice-Chancellor and the Federal Ministers, the Chancellor conducts government affairs.

The last parliamentary elections for the Nationalrat were held on 1 October 2006. With a voter participation of 78.49%, 4,793,780 delivered votes and 4,708,281 valid votes, the Austrian Social-Democratic Party (Sozialdemokratische Partei Österreichs, SPÖ) obtained the

majority of votes (first place, 35.34%) and the Austrian People's Party (Österreichische Volkspartei, ÖVP) took second place (34.33%). Since 11 January 2007 the two largest parties in Austria, the centre-left Sozialdemokratische Partei Österreichs (SPÖ) and the conservative Österreichische Volkspartei (ÖVP), have agreed to form a coalition government. Dr. Alfred Gusenbauer of the Sozialdemokratische Partei Österreichs (SPÖ) has become the Chancellor.

1.4 Health care system

1.4.1 Organisation

In Austria, health care is based on a social insurance model. The Austrian social security system includes health insurance and accident insurance, as well as pension insurance based on the solidarity principle. The Federation of Austrian Social Insurance Institutions (HVB), which is the umbrella organisation of 19 sickness funds and three further social insurance institutions (e.g. pension funds), is responsible for the organisation of these four divisions.

About 98% of Austria's 8 Mio. inhabitants are covered by statutory social health insurance (SHI), mainly organised according to vocational groups and regional considerations without free choice of sickness fund. Health insurance covers not only the insured person but also members of his/her family, such as children or partners, unless they pay health insurance contributions themselves. The system is characterised by income-related health insurance contributions, benefits in kind, direct access to primary, secondary and tertiary care, with co-payments at all levels of care. The Federation of Austrian Social Insurance Institutions (HVB) is a self-governing body but does not have the power to determine the amount of social insurance contributions. This important point is regulated by legislation.

The Austrian Social Insurance Law (ASVG) is the most important legal basis for the social health insurance (SHI) system, which became effective in 1955. Furthermore, defined groups such as self-employed people, civil servants, farmers, members of the army and the notaries have their own legal regulation. In accordance with the Austrian Social Insurance Law (ASVG), patients must be granted all necessary forms of medical treatment in a sufficient and appropriate way as long as adequacy of resources is guaranteed. In addition to statutory health insurance, Austrians can opt for a private health insurance policy to get, e.g., better accommodation (single rooms) in hospital, coverage of the costs of treatment by a doctor of choice, or the payment of daily benefits in case of illness.

The Government of Austria, represented by the Ministry of Health and Women's Issues (BMGF), is principally responsible for assuring health care at central level. In addition, there are other relevant public bodies like the Federal Ministry for Education, Science and Culture (Bundesministerium für Bildung, Wissenschaft und Kultur, BMBWK), the Länder and local communities, the Federation of Austrian Social Insurance Institutions (HVB), professional bodies (Doctors' Association, Pharmacists' Association), statutory associations and public hospitals, concerned with ensuring the effective running of the Austrian health care system.

Agreements in accordance with Art. 15a of the Federal Constitution Act are used for the comprehensive allocation of rights and duties, e.g., hospital care is the responsibility of the Länder.

Since January 2006, the health insurance certificates were replaced by the E-Card which is the precondition for access to health care as well as remuneration of contract doctors. The E-Card provides information including name, degree of coverage and insurance data of the insured and acts as European insurance card, too.

1.4.2 Funding

Health expenditure is financed through a mix of health insurance contributions (about 50%), personal contributions (about 30%; in the form of out-of-pocket payments (OPPs) and private health insurance) and taxes (about 20%). As already (cf. 1.4.1), the principal legal basis is the Austrian Social Insurance Law (ASVG).

The amount of social security contributions depends on the income and the employment status of the insured person. In addition, the insurance funds have their own individual regulations. Generally, the contributions for people that are not self-employed (i.e. employees) are raised equally between employees and employers. Contributions to health insurance are 7.3% for civil servants (4.1% for employees, 3.2% for employers) and 7.5% for blue-collar workers (3.95% for employees, 3.55% for employers) and white-collar workers (3.75% for employees, 3.75% for employers). In 2006, the maximum limit is € 3,750. The percentage for the self-employed is 9.1% (retired people 4.85%) and 7.5% for farmers (retired people 4.85%), with a ceiling of € 4,375.

Furthermore, personal contributions play an important part in the financing of the Austrian health system. Voluntary health insurance (VHI) is used by about one-third of the Austrian population in addition to social security contributions. Unlike the compulsory sickness insurance, premiums are calculated in accordance with health status, age and other mathematical insurance calculations. The benefits of private health insurance are, e.g., better accommodation and free choice of medical doctor. Out-of-pocket payments (OPPs) include the prescription fee, the annual fee for the E-Card, daily contributions for hospital stays, etc.

Of the total health expenditure, 20 % is funded by general taxation, which is pooled from federal, provincial and municipal budgets.

In 2004, total spending for health care was around € 17 billion or 9.6 % of the gross domestic product (GDP). Public health expenditure accounted for two-thirds of the total health expenditure (THE) (70.7 % in 2004) and private health expenditure (co-payments, private health insurance fees and other out-of-pocket expenditures) amounted to one-third of THE (29.3 % in 2004). Table 1.3 gives an overview of the development of the health expenditure in 1990 and in recent years.

Table 1.3: Austria - Health expenditure, 1995, 2000-2005

Health expenditure	1995 ¹	2000	2001	2002	2003	2004	2005
THE in NCU (in Mio. €)	17,026	19,786	20,559	21,057	21,802	22,770	n.a.
THE as a % of GDP	9.7	9.4	9.5	9.5	9.6	9.6	n.a.
THE per capita in NCU (€)	2,116	2,440	2,528	2,605	2,686	2,785	n.a.
Public HE as a % of THE	69.3	69.9	69.5	70.5	70.3	70.7	n.a.
Private HE as a % of THE	30.7	30.1	30.5	29.5	29.7	29.3	n.a.

GDP = gross domestic product, HE= health expenditure, n.a. = not available, THE = total health expenditure, NCU = national currency unit

¹ break in series

Source: OECD Health Data 2006

1.4.3 Access to health care

A total of 39,519 medical doctors (c.f. Table 1.4) provide in-patient and out-patient health care for the Austrian population. Due to the fact that there are a significant number of doctors who work in a hospital and also have their own practice, the sum of in-patient and out-patient doctors does not match with the total number of physicians. In 2005, 4.9 doctors were available per 1,000 inhabitants.

1.4.3.1 Out-patient care

Out-patient medical care is provided by 20,080 medical doctors, of which 6,999 are general practitioners (GPs), 9,270 specialists and 3,811 dentists who mainly work in private practice. Since 2001, doctors have had the opportunity to share consulting rooms or medical equipment within the framework of a group practice as independent medical care providers. Furthermore, out-patient clinics and out-patient departments in hospitals play a major role in the provision of out-patient health care for the Austrian population. Since the mid-1990s, the number of out-patient medical doctors has grown considerably. Between 1995 and 2005 the ratio of out-patient physicians to population has increased from 2.0 to 2.5 doctors per 1,000 inhabitants.

Mostly, physical therapy institutes, medical laboratories, radiological facilities and sports-related medical institutions are managed as out-patient clinics ("ambulatories"). However, out-patient clinics do not traditionally treat any particular type of patient as there are also the out-patient departments in hospitals, which specialise in acute medical care of the respective medical speciality. Out-patient departments are also responsible for investigation of difficult diagnoses as well as diagnostics that require additional or specialised equipment.

Doctors can either practise privately or publicly but there are differences in the establishment of their practices and funding arrangements. Due to the principle of freedom of choice of care provider, patients have the right to freely choose and change their public and/or private out-patient doctors quarterly.

Public doctors are not free to open a surgery without permission. The basis for payment of public out-patient doctors is contracts with one or more social health insurers. These contracts between doctors and public health insurance funds are based on comprehensive agreements between the Federation of Austrian Social Insurance Institutions and the Medical Chambers. These "contract doctors" are remunerated by flat-rate fees, guaranteeing a fixed amount per health insurance voucher and per quarter, and in addition, by fee for services. As already mentioned, the E-Card is the precondition for remuneration of contract doctors.

For private physicians, who do not need approval to set up in practice, the health insurance fund pays 80% of the cost that would have been incurred if a contract doctor had provided the treatment. The rest has to be paid by the patients. Basically, general practitioners (GPs) provide primary medical care and act as gatekeepers, referring patients to specialists, out-patient clinics or in-patient care providers. However, it is possible for patients to consult specialists without referral.

As social health insurance (SHI) does not cover all out-patient health care services, under all health insurance schemes out-of-pocket payments (OPPs) are required for, e.g., various dental services, services carried out by non-contract doctors, as well as the annual fee for the E-Card (€ 10.-) and the prescription fee for medicines prescribed by a doctor (€ 4.45 per prescription). The out-of-pocket (OOP) amount varies depending on the health insurance fund. Exemptions can apply, on social grounds.

Table 1.4: Austria – Out-patient care 1995, 2000-2005

Variable	1995	2000	2001	2002	2003	2004	2005
Total number of doctors	31,302	33,944	32,082	35,630	37,316	38,457	39,519
No. of doctors per 1,000 inhabitants	4.0	4.2	4.0	4.4	4.6	4.7	4.9
Total no. of out-patient doctors ¹	15,521	17,383	17,643	18,278	19,161	19,775	20,080
of which GPs	5,856	6,351	6,403	6,593	6,805	6,976	6,999
of which dentists	3,106	3,369	3,429	3,508	3,644	3,733	3,811
No. of out-patient doctors per 1,000 inhabitants	2.0	2.2	2.2	2.3	2.4	2.4	2.5
No. of out-patient clinics ("ambulatoires")	n.a.	n.a.	n.a.	n.a.	n.a.	114	n.a.

GPs = general practitioners, n.a. = not available, No. = number

¹ there are medical doctors who work as both in-patient and out-patient doctors

Source: Austrian Medical Chamber 2006 (Austrian list of medical doctors)

1.4.3.2 In-patient care

In-patient care is provided through 265 hospitals with around 52,600 acute care beds (2005) which results in a ratio of 6.5 acute care beds per 1,000 inhabitants. More than two-thirds of all hospital beds belong to public hospitals. Doctors are employees of the hospitals. In 2005, there were 3.1 in-patient doctors per 1,000 inhabitants. Austrian hospitals can be classified as general hospitals, or specialised hospitals for the examination and treatment of specific diseases, persons or purpose (e.g., lung diseases, neuropathy, children's hospitals, etc.). In

addition, there are University hospitals, which carry out research and offer education. Because of their specialist equipment they often treat patients with rare or cost-intensive diseases. Hospital care is the responsibility of the Länder.³

To provide out-patient health care services all over the country the Austrian Hospitals and Major Equipment Plan (Österreichischer Krankenanstalten- und Großgeräteplan, ÖKAP/GGP) has been established as an important tool. It regulates the locations and specialisation structures of fund hospitals as well as establishing upper limits for total bed numbers in hospitals and Länder. Since 2006, the Austrian Health Care Structural Plan (Österreichischer Strukturplan Gesundheit, ÖSG) has replaced these two plans and includes not only hospitals, but also the out- and in-patient health care sector as well as acute and long-term care and rehabilitation.

Until the end of 1996, financing of hospitals was carried out on the basis of a fixed daily fee. Since January 1997, medical care in hospitals has been financed on the basis of a fee-for-service and diagnosis-related group (DRG) system. Each patient is one case, which is defined with reference to illness, therapy and the age of the patient in the case of certain illnesses. The financing is based on services actually rendered to the patients. In-patient care is mainly covered by public funding, but patients have to pay co-payments for hospital stays.

The financing of hospitals is carried out by the Länder, municipalities, social insurers, private insurers and the patients (out-of-pocket). In addition, federal funds provide a fixed annual amount, and a defined percentage of value-added tax (VAT) is assigned to in-patient care funding. Table 1.5 gives an overview of the in-patient care sector in the last few years.

Table 1.5: Austria – In-patient care 1995, 2000-2005

Variable	1995	2000	2001	2002	2003	2004	2005
No. of in-patient doctors ¹	20,013	21,703	19,066	22,862	23,503	24,202	25,075
Number of in-patient doctors per 1,000 inhabitants	2.5	2.7	2.4	2.8	2.9	3.0	3.1
Number of hospitals ²	330	315	315	280	276	275	265
No. of acute care beds	57,985	54,024	53,662	53,383	52,791	52,631	52,625
<i>of which in private sector</i>	<i>2,529</i>	<i>2,529</i>	<i>2,656</i>	<i>2,651</i>	<i>2,651</i>	<i>2,679</i>	<i>2,679</i>
Acute care beds per 1,000 inhabitants	7.3	6.7	6.7	6.6	6.5	6.5	6.5
Average length of stay in hospital ³ (days)	9.3	6.8	6.5	6.2	6.2	6.2	5.9

¹ there are medical doctors who work as both in-patient and out-patient doctors

² acute care hospitals and non-acute care hospitals

³ in acute care hospitals

Sources: Austrian Medical Chamber 2006 (Austrian list of medical doctors), BMGF 2006 (Statistics of hospitals, Register of hospitals, Documentation of diagnosis and performances)

³ Art. 12 Federal Constitution [Bundes-Verfassungsgesetz i. d. F. BGBl. I No. 100/2003]

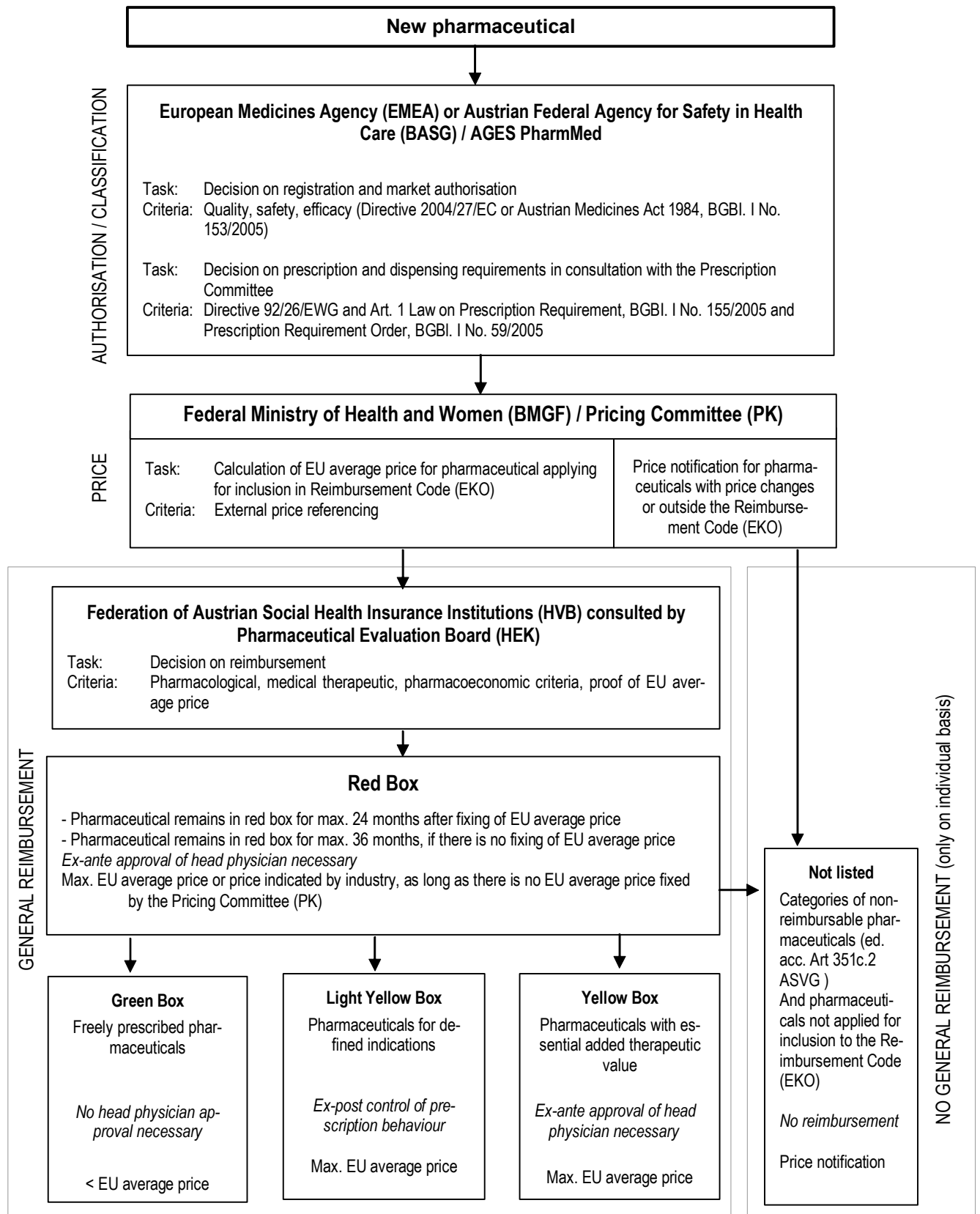
2 Pharmaceutical system

2.1 Organisation

In the following subsections we describe, on the one hand, the regulatory framework (legal basis, main authorities and their tasks) of the Austrian pharmaceutical system and, on the other hand, the Austrian pharmaceutical market (key data and players).

Figure 2.1 provides a comprehensive overview of the Austrian pharmaceutical system.

Figure 2.1: Austria - Flowchart of the pharmaceutical system, 2006



Source: GÖG/ÖBIG 2006

EU = European Union

2.1.1 Regulatory framework

This subsection includes a description of the legal framework for pharmaceutical policy, the principal authorities and important players and their roles within this framework. The main player in the Austrian pharmaceutical system at federal level is the Federal Ministry of Health and Women's Issues (BMGF), which submits bills on the extension, development and reform of the health care and social systems, which are then debated and voted upon by the Lower and the Upper Houses of Parliament (Nationalrat and Bundesrat).

Since May 2003, the Federal Ministry of Health and Women's Issues (BMGF) is the legal successor of the former Federal Ministry of Social Security and Generations and Consumer Protection (Bundesministerium für soziale Sicherheit, Generationen und Konsumentenschutz, BMSGK). The last parliamentary elections for the Nationalrat were held on 1 October 2006 and led to a change in government.

2.1.1.1 Policy and legislation

The Austrian Government has adopted a set of acts that govern the pharmaceutical sector. The legislative framework for the production, registration and distribution of pharmaceuticals is the Medicines Act (Arzneimittelgesetz)⁴. The European Union's (EU) classification provisions (laid down by in Title VI of the Community Code) were implemented in Austria by the second amendment to the Medicines Act, which came into effect on 16 February 1994. The third amendment to the Medicines Act, which came into effect on 1 August 1996, gave effect to European Union (EU) legislation on the new market authorisation system.

The classification of pharmaceuticals into prescription-only or non-prescription medicines follows the Prescription Act (Rezeptpflichtgesetz)⁵. The Pharmacy Act (Apothekengesetz)⁶ regulates the competition among pharmacies and comprises provisions for the licensing of community and hospital pharmacies.

The Price Act (Preisgesetz)⁷ builds the overall legal framework for the pricing of reimbursable pharmaceuticals. In order to set a national justified price for reimbursable pharmaceuticals, the system of the European Union (EU) average price has been introduced.

The European Union (EU) average price is calculated according to the Regulation on Procedural Rules for Calculation of the European Union (EU) average price⁸ (cf. 3.2.1). Wholesal-

⁴ Medicines Act [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]

⁵ Prescription Act [Rezeptpflichtgesetz 1972, i.d.F. BGBl. I No. 155/2005]

⁶ Pharmacy Act [Gesetz vom 18. Dezember 1906, betreffend die Regelung des Apothekenwesens (Apothekengesetz), i.d.F. BGBl. I No. 90/2006]

⁷ Price Act [Bundesgesetz, mit dem Bestimmungen über Preise für Sachgüter und Leistungen getroffen werden (Preisgesetz 1992), i.d.F. BGBl. I No. 151/2004]

ers and pharmacists are remunerated via statutory regressive mark-up schemes, which are laid down in enactments.^{9,10}

The reimbursement of pharmaceuticals is regulated through the Austrian Social Insurance Law (ASVG¹¹) According to the Austrian Social Insurance Law (ASVG) the necessary forms of medicinal and medical treatment should be reimbursed in a sufficient and appropriate way as long as adequacy of resources is guaranteed.¹²

2.1.1.2 Authorities

Since January 2006 the Austrian Federal Agency for Safety in Health Care (BASG) has taken over the responsibility for granting market authorisation, classification according to prescription status and vigilance for human and veterinary pharmaceuticals as well as medical devices from the Federal Ministry of Health and Women's Issues (BMGF). The Austrian Federal Agency for Safety in Health Care (BASG) is thus acting as a 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 Food Safety (Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH, AGES). A subdivision of this Agency, the AGES PharmMed, supports the Austrian Federal Agency for Safety in Health Care (BASG) in its work.

In the third amendment of the Medicines Act, which came into effect in 1996, a distinction is made between a normal procedure for gaining a full market authorisation and a simplified procedure for gaining a full market authorisation, with the latter only possible for certain products. According to the Austrian Association of Pharmaceutical Companies (Verband der Pharmazeutischen Industrie Österreichs, PHARMIG), new applications as well as changes in authorisation requiring approval can take one to three years, which is longer than the legally stipulated period of 210 days (2005). Authorisation by reference (a quicker turnaround for generic applications) is possible under certain conditions laid down in the Medicines Act. With the installation of the AGES PharmMed in January 2006, the authorisation process has been accelerated and has become more transparent. However, what remains is a large quantity of (about 800) applications that were submitted before January 2006, and had not been fully processed due to a shortage of personnel or the incompleteness (i.e. not compre-

⁸ Regulation on Procedural Rules for Calculation of the EU average price [Regelung für die Vorgehensweise der Preiskommission bei der Ermittlung des EU-Durchschnittspreises according to Art. 351c.6 ASVG; <http://www.bmgf.gv.at/cms/site/detail.htm?thema=CH0008&doc=CMS1078931881119>]

⁹ 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_hoehstaufschlaege_am.pdf

¹⁰ Austrian Pharmaceutical Tax 1962, amended [Österreichische Arzneitaxe, 1962 i.d.F. BGBl. II No. 433/2005]

¹¹ Austrian Social Insurance Law (ASVG 1955), amended [Art. 136.2 und 3 Allgemeines Sozialversicherungsgesetz (ASVG 1955), i.d.F. BGBl. II No. 446/2005]

¹² Art. 133 ASVG 1955, regulating the extent of medical treatment [Art. 133 ASVG 1995; BGBl. No. 189/1955]

hensive enough) of the submitted applications. Of these applications, the complete ones will be fully processed before the beginning of 2008.

Pricing activities remain in the hands of the Ministry of Health and Women's Issues (BMGF) assisted by the Pricing Committee (PK), especially in terms of the European Union (EU) average pricing system introduced in 2004. The Austrian Health Institute (GÖG/ÖBIG) is responsible for checking prices of pharmaceuticals in the other European Union (EU) Member States (cf. 3.2.1).

The Pricing Committee (PK) consists of one representative of each of the following institutions:

- the Ministry of Health and Women's Issues (BMGF) – chair of the Committee);
- the Federal Ministry of Economy and Labour (Bundesministerium für Wirtschaft und Arbeit, BMWA);
- the Federal Ministry of Finance (Bundesministerium für Finanzen, BMF);
- the Federal Ministry of Agriculture, Forestry, Environment and Water Management (Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft, Lebensmittelministerium, BMLF);
- the Federal Chamber of Commerce (WKÖ);
- the Federal Chamber of Labour (BAK);
- the Presidential Conference of the Chambers of Agriculture (Präsidentenkonferenz der Landwirtschaftskammern Österreichs).

According to the Price Act the Federal Ministry of Health and Women's Issues (BMGF) – assisted by the Pricing Committee (PK) – is basically entitled to set an economically justified price for pharmaceuticals. However, the Price Act is more of a back-up law, as manufacturing prices of new pharmaceuticals as well as price changes for existing ones do not usually need to be approved by the Federal Ministry of Health and Women's Issues (BMGF), but the Ministry must simply be notified. The maximum mark ups for wholesalers and pharmacies are statutorily regulated, nonetheless.

Separate rules are in place for the pricing of pharmaceuticals applying for reimbursement as these have to be priced according to the European Union (EU) average price. The Pricing Committee (PK) collects price notifications from companies and assesses them, as well as working out the actual calculation of the European Union (EU) average price (cf. 3.2.1).

Decisions on reimbursement status are made by the Federation of the Austrian Social Insurance Institutions (HVB) on the basis of recommendations of the Pharmaceutical Evaluation Board (HEK), a body consisting of 20 experts nominated by several Austrian public bodies, 10 of which are social health insurance (SHI) representatives. Among other parameters, such as the therapeutic value of a product and its efficacy, economic criteria (such as the price requested by the company) are also taken into consideration. The actual process of reimbursement of pharmaceuticals to patients is the responsibility of the 19 sickness funds. The sickness funds also monitor, to a greater or lesser extent, the prescription patterns of

their contracted general practitioners (GPs) and specialists, as these providers are obliged to ensure that their prescribing behaviour complies with the Federation of Austrian Social Insurance Institutions (HVB) Guidelines on Economic Prescribing (RöV).¹³

An important public body is the Independent Pharmaceutical Commission (Unabhängige Heilmittelkommission, UHK), which functions as an appeal court to whom manufacturers may turn in case their reimbursement application is refused. All members of the Independent Pharmaceutical Commission (UHK) are independent experts nominated by several public bodies in Austria, such as the Federal Chamber of Commerce (WKÖ), the Federal Chamber of Labour (BAK), the Chamber of Medical Doctors (Physicians) (Österreichische Ärztekammer, ÖÄK), various sickness funds or the Chamber of Pharmacists (Österreichische Apothekerkammer, ÖAK), etc.

Table 2.1: Austria - Authorities in the regulatory framework in the pharmaceutical system 2006

Name in local language (Abbreviation)	Name in English	Description	Responsibility
Bundesministerium für Gesundheit und Frauen (BMGF)	Federal Ministry of Health and Women's Issues	Ministry of Health	Regulatory body for pharmaceuticals. Decides on prices of pharmaceuticals
Preiskommission (PK)	Pricing Committee	A committee consisting of representatives of the BMGF and a number of other institutions	Assists the BMGF in its decisions regarding the prices of pharmaceuticals
Hauptverband der österreichischen Sozialversicherungsträger (HVB)	Federation of Austrian Social Insurance Institutions	Association of Third Party Payers	Decides on the reimbursement status of pharmaceuticals
Heilmittel-Evaluierungskommission (HEK)	Pharmaceutical Evaluation Board	A board consisting of 20 experts nominated by several Austrian public bodies	Provides the HVB with recommendations concerning the reimbursement status of pharmaceuticals
Bundesamt für Sicherheit im Gesundheitswesen (BASG)	Austrian Federal Agency for Safety in Health Care (Austrian Medicines Agency)	Medicines Agency	Responsible for market authorisation and classification of pharmaceuticals and for vigilance/security

Source: GÖG/ÖBIG 2006

Further bodies dealing with pharmaceuticals at federal level are the Prescription Committee (Rezeptpflichtkommission) and the Restriction Committee (Abgrenzungskomitee). The Prescription Committee meets on an annual basis and makes general suggestions for

¹³ Guideline on Economic Prescribing of pharmaceuticals and medicinal products [Richtlinie über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005)], www.avsv.at

changes in prescription status. The Restriction Committee is an advisory body to the Ministry of Health and Women's Issues (BMGF) and is responsible for decisions on pharmaceutical distribution channels.

The former National Institute of Pharmaceuticals (Bundesinstitut für Arzneimittel, BfA), including the official Medicines Control Laboratory, which used to support the work of the Federal Ministry of Health and Women's Issues (BMGF) by revising the information and sample molecules handed in by pharmaceutical companies with regard to quality, safety and efficacy standards, has also become part of the AGES PharmMed.

2.1.2 Pharmaceutical market

This subsection gives an overview of the availability of pharmaceuticals as well as market figures.

2.1.2.1 Availability of pharmaceuticals

In 2006 a total of 15,527 pharmaceuticals were authorised in Austria (counting different pharmaceutical forms and dosages and including homeopathics, but excluding different pack sizes). Of these, 8,733 pharmaceuticals are subject to the Prescription Act,¹⁴ which means that a doctor's prescription is required for selling these pharmaceuticals to patients. According to the Prescription Act pharmaceuticals shall only be classified as over-the-counter (OTC) or non-prescription in cases where even applications not in accordance with the specifications do not constitute any risk for patients. The Austrian Federal Agency for Safety in Health Care (BASG) is the authority responsible for the classification of pharmaceuticals into prescription-only and non-prescription.

¹⁴ Prescription Act [Rezeptpflichtgesetz (1972), i. d. F. BGBl. I No. 122/2006]

Table 2.2: Austria - Number of pharmaceuticals 1995, 2000-2006¹

Pharmaceuticals ²	1995	2000	2001	2002	2003	2004	2005	2006
Authorised	9,671 ³	12,394	12,633	12,443	15,339	15,144	14,347	15,527
On the market	n.a.	n.a.	n.a.	n.a.	n.a.	~ 60%	6,155 ³	n.a.
POM	6,910	8,062	7,904	8,320 ⁴	8,693 ⁴	8,758 ⁴	8,733 ⁴	n.a.
Reimbursable ⁵	2,761	2,979	2,965	3,013	3,049	3,109	3,926	n.a.
Generics	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Parallel traded	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
HOM	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	~ 20%	n.a.

n.a. = not available, POM = prescription-only medicines, ~ = estimate, HOM: hospital-only medicine

¹ as of 1 January

² Counted including different pharmaceutical forms and dosages, excluding different pack sizes and including homeopathic products

³ as of 31 December 1995

⁴ excluding homeopathics

⁵ as of 1 July

Source: HVB 2006b, Pharmig 2006, data gathering by GÖG/ÖBIG 2006

The number of reimbursable pharmaceuticals has increased substantially since 1 January 2005 when the new reimbursement scheme for pharmaceuticals (“Erstattungskodex”, EKO) was introduced (cf. 4.2). However, most of the pharmaceuticals that have been added to the list of reimbursable pharmaceuticals can only be prescribed under very specific circumstances (for example only by a specialist, rather than a general practitioner (GP)). Decisions on reimbursement status are made by the Federation of Austrian Social Insurance Institutions (HVB) and based on certain criteria, described later (cf. 4.2.1).

In Austria, only 40-60% of the authorised pharmaceuticals are available on the market, partly due to the fact that pharmaceutical companies apply for a decentralised market authorisation without having the intention to actually bring the product onto the market in Austria. A second reason is that consultancy businesses frequently submit multiple (even as many as seven) applications for the same product. After receiving the market authorisations, the consultancy firms sell these to generics companies. A third reason could be the cancellation of an authorisation, e.g. when a company has chosen to take a pharmaceutical from the market, this takes some time or is simply not submitted to the responsible authority at all.

Switches from prescription-only to non-prescription status can be initiated by the manufacturer or by the competent national authority. Since 13 August 2003 – due to an amendment to the prescription law – pharmaceuticals are switched automatically if their substance is ruled non-prescription by the Prescription Committee and the product and its authorised indications could be regarded as suitable for self-medication.

It is also possible that a manufacturer could independently apply for a switch of the prescription status of a specific pharmaceutical at the AGES PharmMed. In this case, the Austrian Agency for Health and Food Safety’s (AGES) decision is not applicable for pharmaceuticals from manufacturers other than the one who has applied for the switch.

Since the mid-1990s, many substances have received the non-prescription status. However, several switched substances have not yet reached the market in the form of over-the-counter (OTC) pharmaceuticals.

2.1.2.2 Market data

Table 2.3 presents pharmaceutical market data for Austria. In 2005 the total pharmaceutical sales at consumer price level amounted to € 3,588.2 Mio. Between 2004 and 2005 total pharmaceutical sales rose by 4%, whereas between 2001 and 2002 total pharmaceutical sales increased by 10.4%. Pharmaceutical sales at ex-factory level amounted to € 2,311.8 Mio. in 2004, an increase of 7.5% compared to 2003.

Table 2.3: Austria - Market data 1995, 2000-2005

In Mio. €	1995	2000	2001	2002	2003	2004	2005
<i>Prescriptions</i> ⁷							
No. of annual prescriptions by volume	94.512	101.432	98.454	99.130	102.028	104.130	103.614
No. of annual prescriptions by value	1.147	1.644	1.722	1.836	1.950	2.028	2.060
<i>Pharmaceutical sales</i>							
Sales at ex-factory price level ¹	n.a.	n.a.	1,726.5	1,885.3	2,149.7	2,311.8	n.a.
Sales at wholesale price level	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales at PRP level ^{2,3}	n.a.	n.a.	2,833	3,127.6	3,347.0	3,449.4	3,588.2
Sales in hospitals ^{1,5}	n.a.	n.a.	n.a.	458.9	634.9	690.7	n.a.
Sales of generics ^{4,6}	n.a.	55.5	63.7	76.3	100.2	126.2	n.a.
Sales of parallel traded pharmaceuticals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<i>Exports and imports</i> ⁸							
Total pharm. exports	471 ⁹	1,982	n.a.	3,042	3,003	2,875	n.a.
Total pharm. imports	141 ⁹	2,141	n.a.	3,092	2,947	2,996	n.a.

n.a. = not available, PRP = pharmacy retail price

¹ Source: Pharmig 2006

² Source: AESGP 2006

³ Including self-dispensing (SD-) doctors, excluding hospital sales

⁴ Source: OEGV 2006

⁵ At ex-factory price level

⁶ Sold in pharmacies

⁷ Source: HVB 2006b, data gathering by GÖG/ÖBIG

⁸ Sources: EFPIA 1998-2006

⁹ as of 1996 in ECU (European Currency Unit)

The share of generics sales is relatively low in Austria. In terms of value, generics sales made up 10.7% of the total sales of pharmaceuticals in pharmacies in 2006, cf. also 5.5.

Between 2003 and 2004 the total value of pharmaceutical imports was slightly above the total value of pharmaceutical exports, indicating a relatively balanced trade.

In 2005, the total pharmaceutical export amounted to € 2,875 Mio. In the consumption of pharmaceuticals, Austria is somewhat below the average for the European Union with 21.8 packs per inhabitant in 2004. In total, physicians in Austria wrote 104,130 prescriptions in 2004, which amounted to € 19,47 on average per prescription. Table 2.4 lists the top 10 best-selling reimbursable pharmaceuticals by active ingredient, based on their turnover in 2005.

Table 2.4: Austria - Top 10 best-selling reimbursable pharmaceuticals (highest turnover), by active ingredient, 2005 or latest available year.

Position	Pharmaceutical, by active ingredient
1	Pantoprazol
2	Alendronsäure
3	Simvastatin
4	Clopidogrel
5	Enoxaparin
6	Fluticason + Salmeterol
7	Atorvastatin
8	Risedronat
9	Lansoprazol
10	Olanzapin

Source: HVB 2006

2.1.2.3 Patents and data protection

In Austria, according to the European Patent Convention generic pharmaceuticals receive market protection for 20 years through the Austrian Patent Office (Österreichisches Patentamt). During these 20 years no manufacturer other than the one having gained the patent is allowed to produce the pharmaceutical in question. After the 20 years have passed, manufacturers can apply for an additional 10 years of market protection (Supplementary Protection Certificate, SPC). Considering the fact that up to 12 years can pass between the gaining of the patent and actually putting the pharmaceutical on the market, the “effective” patent period (i.e. after the pharmaceutical has been marketed) may not exceed 15 years. Independent from the protection against imitators (patent protection), there is also protection of the documentation of a product (“Unterlagenschutz”), which is regulated at European Union (EU) level. Within the “protection of documents”, the date is defined from when the authorisation of products that are based on the generic pharmaceutical documents is possible.

2.1.3 Market players

This subsection describes the key players in the pharmaceutical system, leaving aside the authorities introduced earlier (cf. 2.1.1.2). It gives an overview of the key players in the production, distribution, dispensing, prescription and use of pharmaceuticals and their influence on pharmaceutical policy-making.

2.1.3.1 Industry

Currently there are approximately 220 pharmaceutical companies based in Austria.¹⁵ This number includes 24 manufacturing companies¹⁶ but also companies only trading with pharmaceuticals. The Austrian Association of Pharmaceutical Companies (PHARMIG) represents the interests of the Austrian pharmaceutical industry. Generics manufacturers or generics trading companies (which are included in above number) are organised in a separate association, the Austrian Generics Association (OEGV). Representatives of the industry are represented in committees involved in pricing and reimbursement (e.g. the Pharmaceutical Evaluation Board, HEK) and the Pricing Committee (PK) through the Federal Chamber of Commerce (WKÖ).

The local pharmaceutical industry in Austria is characterised by small- and medium-sized enterprises. Approximately half of the companies employ up to nine people, another 40% having 10-250 employees. Only the remaining 10% are large companies with more than 250 employees, the biggest manufacturers in Austria being Baxter, Boehringer Ingelheim, Biochemie and Nycomed. The nine largest pharmaceutical manufacturers were responsible for 84% of the total pharmaceutical industry turnover. Furthermore, there are two bigger local Austrian generics manufacturers, though the generics market share is comparatively low with about 7.8% (2004) of the market in terms of turnover at pharmacy level.

Pharmaceutical production in Austria amounted to € 1,344 Mio. in 2003, a significant reduction compared to the year 2001 when production was € 1,862 Mio.¹⁷ The total pharmaceutical sales at ex-factory level have continued to rise over the years and amounted to € 2,311.8 Mio. in 2004. In recent years, the total value of pharmaceutical imports was slightly above the total value of pharmaceutical exports (Table 2.3), indicating a relatively balanced trade. In terms of parallel trade Austria is more a source for parallel export than the other way around. Consequently, there is no Association of Parallel Traders present in Austria. Pharmaceutical Research & Development (R&D) expenditure in Austria is low compared to other European countries, such as the United Kingdom.

Even though wholesalers supply about 95% of all deliveries to pharmacies, direct supply by pharmaceutical manufacturers is allowed (provided that the manufacturer has obtained a wholesale licence from the federal authorities). Self-dispensing (SD-) doctors may only pro-

¹⁵ PHARMIG Facts & Figures 2003

¹⁶ Statistik Austria, personal communication, 2005

¹⁷ EFPIA 2005

cure pharmaceuticals from pharmacies, but this provision is evaded in practice by wholesalers holding a pharmacy concession.

The Austrian pharmaceutical industry employed 9,523 people in 2003, which is significantly lower than in other European Union (EU) countries that have a stronger industry presence.

Table 2.5: Austria - Key data on the pharmaceutical industry 1995-2005¹

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies	105	103 ³	n.a.	160	160	~ 220	~ 220
- research-oriented	n.a.	n.a.	n.a.	n.a.	24	n.a.	n.a.
- generic producers	n.a.	n.a.	n.a.	n.a.	~ 9	n.a.	n.a.
- biotech	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Number of persons employed ²	n.a.	n.a.	n.a.	n.a.	9,523	n.a.	n.a.

n.a. = not available, ~ = estimate

¹ as of 1 January

² counted per head

³ 1999

Source: Pharmig Facts & Figures 1998-2006

2.1.3.2 Wholesalers

The manufacturers deliver their pharmaceuticals to about 35 wholesalers, of which eight provide a full range of pharmaceuticals on the market. The three leading full-range wholesalers (Herba Chemosan Apotheker-AG, Phoenix Arzneiwarengroßhandlung GmbH and Kwizda GmbH) have more than 75% market share. The eight full-range wholesalers are members of the Association of Austrian Pharmaceutical Wholesalers (ARGE Pharmazeutika). The interests of pharmaceutical wholesalers are, like those of the manufacturers, represented through committees involved in pricing and reimbursement (e.g. the Pharmaceutical Evaluation Board (HEK) and the Pricing Committee (PK) through the Austrian Federal Chamber of Commerce (WKÖ).

In general the system at the wholesale level is a multi-channel one. Pharmaceutical wholesalers deliver to pharmacies three times a day. In case of emergencies, immediate delivery is also possible. In terms of European averages, wholesalers stock 29,151 different items, of which 49% are pharmaceuticals. In Austria approximately 50,000 different products are stocked by wholesalers, of which 33,000 (approximately 66%) are pharmaceuticals.

The possibilities for wholesalers to own pharmacies are limited. In general, wholesalers may own a maximum of 49% of a pharmacy and the number of pharmacies they are able to co-own is limited. A wholesaler is only allowed to co-own pharmacies comprising a total maximum market share of 3% (i.e. about 35 average pharmacies). If there is more than one owner of a pharmacy, at least one of the owners must be a pharmacist.

Parallel trade in pharmaceuticals plays a minor role in Austria, as on the one hand the overall ex-factory price level is relatively low and on the other there are no incentives for doctors, patients or pharmacists to use parallel imports. For parallel imported pharmaceuticals, the same wholesale and pharmacy margins are applicable as for other pharmaceuticals.

Table 2.6: Austria - Key data on pharmaceutical wholesale 1995-2005¹

Wholesalers	1995	2000	2001	2002	2003	2004	2005
Total number of whole-sale companies	n.a.	10	n.a.	n.a.	n.a.	10	10
Total number of full-line wholesale companies	11	5	n.a.	n.a.	n.a.	8	8
Total number of outlets	31	27	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available

¹ as of 1 January

Source: GIRP 2005-2006

2.1.3.3 Pharmaceutical outlets / retailers

Pharmaceuticals in Austria are mainly sold through pharmacies or branch pharmacies, which practise under the supervision of a (main) community pharmacy. Every community pharmacy is allowed to operate one branch pharmacy, provided that the distance to the nearest pharmacy is more than 4 km. Branch pharmacies are allowed to dispense the full range of pharmaceuticals. In addition, if no pharmacy is established within the municipality in which a general practitioner (GP) has his/her practice, and the distance to the nearest pharmacy is more than six kilometers, both prescription-only medicines (POM) and over-the-counter (OTC) pharmaceuticals may be dispensed through self-dispensing (SD-) doctors. Drugstores are only allowed to sell a very restricted range of non-pharmacy over-the-counter (OTC) pharmaceuticals, in particular dietary supplements.

As far as health insurers are concerned, in 2004 84% of pharmaceutical prescriptions (85% of expenditure) were sold through pharmacies and 16% (15% of expenditure) through self-dispensing (SD-) doctors.

2.1.3.3.1 Pharmacies

The establishment of a new pharmacy in Austria requires authorisation by regional authorities, which is granted provided that the pharmacy fulfills statutory prerequisites as defined in the Austrian Pharmacy Act (Apothekengesetz)¹⁸. The establishment of a new pharmacy requires:

- that the minimal distance between the new pharmacy and the nearest existing pharmacy is at least 500 m;

¹⁸ Pharmacy Act [Gesetz vom 18. Dezember 1906, betreffend die Regelung des Apothekenwesens (Apothekengesetz), i. d. F. BGBl. I No. 90/2006]

- that the number of people who continue to be supplied by adjoining pharmacies does not drop below 5,500 as a result of establishing the new pharmacy; and
- that a general practitioner (GP) has his/her practice within the same municipality.

Another criterion for the establishment of a new pharmacy is the space available in the premises. The Regulation of the Operation of Pharmacies¹⁹ defines a minimum size of 120 m² for the premises of a pharmacy, which must cover different rooms within a pharmacy, such as the material stock room, the sales office, and a laboratory. On 1 January 2006, there were 1,203 community pharmacies in Austria (of which 19 were branch pharmacies) and 5 hospital pharmacies acting as community pharmacies. This corresponds to about 1 prescription-only medicines (POM) dispensary per 3,772 inhabitants or 0.27 prescription-only medicines (POM) dispensaries per 1,000 inhabitants (data from 2005) (cf. Table 2.7).²⁰

Table 2.7: Austria - Retailers of pharmaceuticals 1995, 2000-2006¹

Retailers	1995	2000	2001	2002	2003	2004	2005	2006
Number of community pharmacies ²	1,018	1,106	1,133	1,147	1,160	1,182	1,191	1,203
<i>No. of private pharmacies</i>	<i>1,018</i>	<i>1,106</i>	<i>1,133</i>	<i>1,147</i>	<i>1,160</i>	<i>1,182</i>	<i>1,191</i>	<i>1,203</i>
<i>No. of public pharmacies</i>	<i>n.app.</i>	<i>n.app.</i>	<i>n.app.</i>	<i>n.app.</i>	<i>n.app.</i>	<i>n.app.</i>	<i>n.app.</i>	<i>n.app.</i>
<i>Number of hospital pharmacies for out-patients</i>	5	5	5	5	5	5	5	5
Number of other POM dispensaries: SD-doctors	983	987	998	982	993	989	992	n.a.
Total number of POM dispensaries ¹	2,006	2,098	2,136	2,134	2,158	2,176	2,188	n.a.
No. of internet pharmacies	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
No. of OTC dispensaries: drugstores ³	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

OTC = over-the-counter, POM = prescription-only medicines; No. = number; n.a. = not available, n.app. = not applicable, SD-doctors = self-dispensing doctors

POM dispensaries = including branch pharmacies, SD-doctors, and hospital pharmacies acting as community pharmacies

¹as of 1 January

²incl. branch pharmacies

³Drugstores are only allowed to dispense a very restricted range of OTC products, namely dietary supplements.

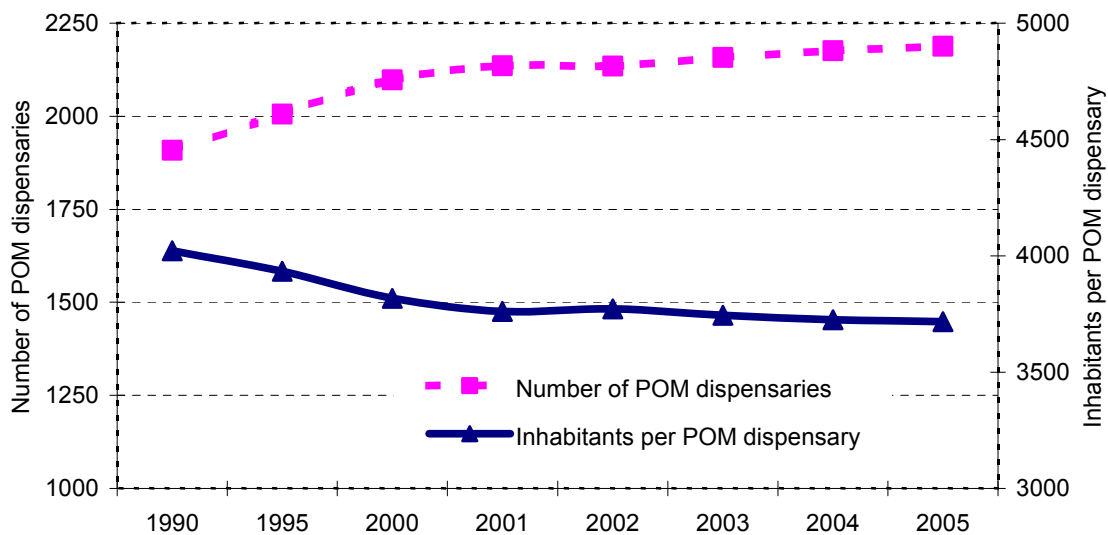
Source: ÖAK 2005-2006s

¹⁹ Regulation of the Operation of Pharmacies [Verordnung der Bundesministerin für Gesundheit und Frauen über den Betrieb von Apotheken und ärztlichen und tierärztlichen Hausapotheken (Apothekenbetriebsordnung 2005)]

²⁰ Data provided by the Austrian Chamber of Pharmacists (ÖAK 2005-2006)

Every community pharmacy is allowed to open a maximum of one branch pharmacy, provided that the distance to the nearest pharmacy is more than 4 km. This branch pharmacy is under the supervision of the (main) pharmacy. Apart from running a maximum of one branch pharmacy under the supervision of the main pharmacy, it is forbidden to fully (100%) own more than one pharmacy. The right to own a pharmacy in Austria is statutorily reserved for pharmacists with a university degree, trained according to European Union (EU) Directive 2005/36/EC.²¹ Co-ownership is allowed in so far as community pharmacies may be owned by partnerships. However, the managing pharmacist must own more than half of the shares in that partnership and has the exclusive power of management and representation of the partnership. The possibilities for vertical integration (i.e. wholesalers owning pharmacies) are thus very limited.

Figure 2.2: Austria - Number of retail pharmacies, prescription-only medicines dispensaries and number of inhabitants per prescription-only medicines dispensary 1990, 1995 and 2000-2005



POM = prescription-only medicines; All POM dispensaries = including branch pharmacies, self-dispensing (SD-) doctors, and other university pharmacies, polyclinic pharmacies and hospital pharmacies acting as community pharmacies

Source: Data gathering by GÖG/ÖBIG 2005

All Austrian pharmacies are in private ownership, whereby 51% of the pharmacy has to be owned by a pharmacist. All pharmacists, irrespective of whether they work in a community pharmacy or in a hospital pharmacy, are represented by the Austrian Chamber of Pharmacists (ÖAK). Through the ÖAK pharmacists are also represented in the Pharmaceutical Evaluation Board (HEK) and the Prescription Committee (Rezeptpflichtkommission).

²¹ Directive 2005/36/EC of the European Parliament and of the Council on the recognition of professional qualifications. 7 September 2005, Strasbourg

In general, hospitals are not allowed to run pharmacies for out-patients. However, five public hospitals do, for historical reasons, have a licence to act as a community pharmacy.

According to the Austrian Pharmaceutical Tax Enactment (Österreichische Arzneitaxe)²² pharmacies are remunerated via a statutorially fixed mark-up scheme for all pharmaceuticals (on- and off-patent, prescription-only medicines (POM) and over-the-counter (OTC) pharmaceuticals, cf. 3.5.2). Rebates (in cash) from wholesalers to pharmacies are quite common in Austria, whereas rebates from manufacturers to pharmacies are not.

Of the packages sold by pharmaceutical manufacturers in 2004, 85% went to community pharmacies and self-dispensing (SD-) doctors, and 11% went to the hospital pharmacies. Indicated in value (ex-factory price level), the share of pharmaceuticals dispensed by community pharmacies and self-dispensing (SD-) doctors was 70% (€ 1,621.1 Mio.) in 2004. The remaining 30% (€ 690.7 Mio.) is dispensed in hospital pharmacies.²³

2.1.3.3.2 Other pharmacy outlets

Apart from the branch pharmacies, which provide the same range of pharmaceuticals and services as their supervising pharmacies and are thus not just “outlets”, the Austrian pharmaceutical distribution system has no other pharmacy outlets.

2.1.3.3.3 Internet pharmacies

Distance selling of pharmaceuticals through Internet pharmacies is not allowed for all Austrian based companies. However, private customers are allowed to order over-the-counter (OTC) pharmaceuticals through Internet pharmacies located outside Austria in the European Economic Area, provided that they obey the Austrian pharmaceutical import conditions (e.g. on declaration, etc.)

2.1.3.3.4 Dispensing doctors

In Austria, self-dispensing (SD-) doctors play an important role, as they constitute nearly half of all prescription-only medicines (POM) dispensaries, which is reflected in the quantitative figures (cf. Table 2.7).

In a municipality without a pharmacy a general practitioner (GP) (“Arzt für Allgemeinmedizin”) who has a contract with a social insurance company according to the Austrian Social Insurance Law (ASVG)²⁴ is entitled to apply for a licence for the dispensing of pharmaceuticals, if no pharmacy is established within the community in which the general practitioner (GP) has his/her practice, and the distance to the nearest pharmacy is more than 6 km. In case a new community pharmacy opens, the SD-doctor may keep his/her licence only if the distance between his/her practice and the newly established community pharmacy is more than 4 km.

²² Austrian Pharmaceutical Tax [Österreichische Arzneitaxe, 1962 i.d.F. BGBl. II No. 433/2005]

²³ PHARMIG 2006

²⁴ Austrian Social Insurance Law [(§ 342 Abs. 1 Allgemeines Sozialversicherungsgesetz (ASVG 1955), i.d.F. BGBl. II No. 446/2005]

In January 2006, the Austrian pharmaceutical distribution system included 992 self-dispensing (SD-) doctors. The self-dispensing (SD-) doctor must be the owner of the “in-house-pharmacy” and he/she must in all cases dispense the pharmaceuticals personally.

According to the Austrian Pharmaceutical Tax Enactment (Österreichische Arzneitaxe)²⁵ SD-doctors are remunerated via the same statutorily fixed mark up as pharmacies (cf. 3.5.2). Also according to the Austrian Pharmaceutical Tax,²⁶ self-dispensing doctors have to pay the Federation of Austrian Social Insurance Institutions (HVB) a 3.6% rebate (2006) on the turnover from privileged customers, above € 65,400.00, whereas for pharmacies this rebate amounts to 2.5% of the turnover above the nationwide mean turnover from privileged customers of all pharmacies payable by pharmacies (cf. 3.6.1).

Discounts in kind (“natural rebates”) granted by the pharmaceutical industry to SD-doctors are prohibited²⁷ in order to counteract the possibility of influencing the prescribing decisions of self-dispensing (SD-) doctors. Still, rebates in cash are not prohibited, especially as the pharmacy purchase price (approximate wholesale price) for SD-doctors is not fixed by law.

2.1.3.4 Hospitals

In January 2006 there were 49 hospital pharmacies in Austria, five of which operating a community pharmacy at the same time, which means that they also dispense pharmaceuticals to out-patients. According to the Hospitals Law (Krankenanstalten- und Kursanstaltengesetz, KAKuG)²⁸ all priority hospitals are supposed to have a hospital pharmacy. Currently, only 18% of hospitals have their own pharmacy. The supply of medicinal and diagnostic products and medical devices, the preparation of specific medicines and the pharmaceutical support of medical therapy and nursing (“Patient-oriented pharmacy”) are the main services offered by hospital pharmacists.

According to the Hospitals Law, hospitals are obliged to install a pharmaceutical commission, which consists of a maximum of eight people, including the head of the hospital pharmacy, the chief physician, the chief nurse, the administrative director and, in some cases, specialist physicians. The Pharmaceutical Commission is assigned to develop a list of pharmaceuticals that are bought by the hospital and can thus be applied within the hospital. Hospitals are thus autonomous in purchasing pharmaceuticals and they may also buy medicines that are not on the national reimbursement list. The choice of pharmaceuticals to be placed on the list is based on its therapeutic as well as the economic effectiveness. In case more therapeutically advantageous or equivalent pharmaceuticals are available on the market, the cheapest one

²⁵ Austrian Pharmaceutical Tax 1962, amended [Österreichische Arzneitaxe, 1962 i.d.F. BGBl. II No. 433/2005]

²⁶ Art. 3a Austrian Pharmaceutical Tax 1962, amended [Österreichische Arzneitaxe 1962, festgelegt in der 107. Änderung der Arzneitaxe, 30.12.2003 BGBl. II No. 629/2003]

²⁷ 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]

²⁸ Austrian Hospitals Law [Krankenanstalten- und Kursanstaltengesetz (KAKuG 1957) i.d.F. BGBl. II No. 65/2002]

will be placed on the hospital's pharmaceutical list. However, since the prices of pharmaceuticals for hospitals are not subject to the national law on pharmaceutical prices, manufacturers often grant (large) discounts to hospitals.

Hospitals without an in-house pharmacy are only allowed to receive their pharmaceuticals from another hospital pharmacy or from a public pharmacy.

Pharmaceutical expenditures of hospitals are included in the hospital's lump-sum remuneration (Leistungs- und Diagnoseorientierte Fallgruppen, "LDF-Pauschale"), which is calculated according to a "Leistungsorientierten Krankenhausfinanzierung" (LKF) system, comparable to the diagnosis-related group (DRG) system. Hospitals that have their own pharmacy are often united in purchasing groups and buy pharmaceuticals directly from the manufacturers. Manufacturers often grant rebates in cash of up to 99% to the hospitals, and thereby influence the composition of the hospitals' pharmaceutical lists and also (indirectly) the prescribing behaviour of doctors in the ambulatory sector for patients who have been released from hospital.

2.1.3.5 Doctors

Doctors are represented in committees such as the Pharmaceutical Evaluation Board (HEK) by the Austrian Chamber of Physicians (ÖÄK).

The prescription volume or prescribing habits of doctors are monitored by the individual sickness funds with regard to their compliance with the Federation of Austrian Social Insurance Institutions (HVB) Guidelines on Economic Prescribing (RöV),²⁹ in which doctors are encouraged to prescribe the most economical pharmaceutical out of several therapeutically similar alternatives, meaning they should preferably prescribe pharmaceuticals from the green box, and of those the cheapest generic or parallel import, if available (cf. 5.2).

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

2.1.3.6 Patients

With regard to prescription-only medicines (POM), the patient receives limited information on the price and the product. All prescription-only medicines (POM) are fully paid for by the sickness funds, independent of the type of prescription-only medicine (POM), the pack size, and dispensing pharmacy (cf. 4.4). Patients are only required to pay a fixed fee per package dispensed.

Of course, doctors are interested in establishing a good relationship with their clients so the patient does have a chance to express his/her wishes. Thus the "preferences" of patients

²⁹ Guidelines on Economic Prescribing of pharmaceuticals and medicinal products [Richtlinie über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005)], www.avsv.at

may be incorporated in the decision of the doctor as well. E.g., there are 12 different simvastatin 20mg film-coated tablets of the same pack size listed in the green box of the Reimbursement Code (EKO) besides the brand-name originator Zocord®, which also may be freely prescribed at the expense of the sickness funds.

According to the Guidelines on Economic Prescribing of pharmaceuticals and medicinal products (RöV),³⁰ only the pharmaceutical prescribed by the doctor may be dispensed at the expense of the sickness funds (thus the patient may request a generic from the doctor or a parallel import pharmaceutical from the doctor or the pharmacy – but he/she has no incentive to do so).

For patients, and formerly also for doctors or other health experts, prices of pharmaceuticals were hard to access as they were not published in a publicly available database. But nowadays the Austrian Reimbursement Code (Positive list) (EKO, cf. 4.2) is published in hard copy twice a year and monthly via the Internet (www.avsv.at).

2.2 Funding

This section provides an overview of the funding of pharmaceuticals. This includes pharmaceutical expenditure (PE) and the allocation of funds for pharmaceuticals.

2.2.1 Pharmaceutical expenditure

The Austrian pharmaceutical sector has been characterised by substantial increases in expenditure since the beginning of the 1990s. The total pharmaceutical expenditure (TPE) amounted to € 2,967 Mio. in 2004, having increased by 80% since 1995. The reasons for this large increase are demographic developments and the related factor of medical progress. Furthermore, cost increases are to a large extent accounted for by medicines which require the authorisation of “head physicians”.

The proportion of public pharmaceutical expenditure as a share of total health care expenditure rose from 5.4% in 1995 to 9.2% in 2004, whereas the share of private pharmaceutical expenditure has been kept relatively stable.

In 2004, the proportion of pharmaceutical expenditure (PE) as a share of both the gross domestic product (GDP) (1.3%) and the total health expenditure (THE) (13%) was slightly below European average (1.5% and 17.9%, respectively).

³⁰ Art. 10.2 Guidelines 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 No. 5/2005)]; www.avsv.at

Table 2.8: Austria - Total pharmaceutical expenditure 1995, 2000-2005

Pharmaceutical Expenditure	1995	2000	2001	2002	2003	2004	2005
TPE in € (Mio.)	1,569	2,490	2,526	2,697	2,847	2,967	n.a.
TPE as a % of THE	9.2	12.6	12.3	12.8	13.1	13.0	n.a.
TPE per capita in €	195	307	311	334	351	363	n.a.
Public PE as a % of THE	5.4	8.6	8.6	9.0	9.3	9.2	n.a.
Private PE as a % of THE	3.8	4.0	3.7	3.8	3.8	3.8	n.a.

n.a. = not available, TPE = total pharmaceutical expenditure, PE = pharmaceutical expenditure, THE = total health expenditure

Source: OECD 2006

2.2.2 Sources of funds

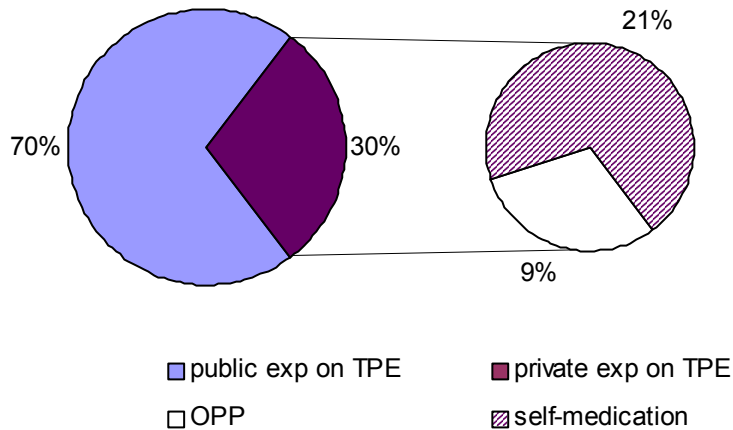
Health care expenditure is financed through a mix of health insurance contributions (50%), personal contributions (30%; in the form of out-of-pocket payments (OPPs) and private health insurance) and taxes (20%)(cf. 1.4.2).

Private pharmaceutical expenditure makes up 29.3%³¹ of the total pharmaceutical expenditure (TPE) in 2004, which can be further subdivided into expenses for self-medication (20.6%), expenses for private health insurance funds (0.3%) and out-of-pocket payments (OPPs) (8.9%).³² The proportion of public pharmaceutical expenditure as a share of TPE has risen considerably over the years, from 58.3% in 1995 to 68.4% in 2000 and 70.7% in 2004.

³¹ OECD DB 2006

³² to be up-dated

Figure 2.3: Austria - Share of private and public pharmaceutical expenditure, 2004



Source: OECD DB 2006

2.3 Evaluation

At the moment pharmaceutical policies are not regularly monitored. According to the new governmental programme (2007) it is planned to evaluate the Reimbursement Code (EKO), the EU average price system and the price notification system (cf. 6.1).

One of the last major changes in the pharmaceutical system, the establishment of the Independent Pharmaceutical Committee (cf. 2.1.1) was triggered by a legal action of the European Commission. Austria was ruled guilty of a breach of the Transparency Directive and obliged to introduce an appeal possibility for companies being denied general reimbursement eligibility for their products. This ruling also led to the introduction of the new Reimbursement Code (VO-EKO) in 2004 (cf. 4.1).

3 Pricing

3.1 Organisation

In Austria the reimbursement system and the pricing system are very closely linked. Very generally speaking, there is free pricing at the manufacturer level in Austria.

The Price Act (Preisgesetz³³) builds the overall legal framework for pricing in Austria and is considered as a sort of back-up law, as ex-factory prices of new pharmaceuticals as well as price changes to existing ones do not usually need to be approved by the Federal Ministry of Health and Women's Issues (BMGF) but the BMGF need only be notified (see details below). The authority in charge of the Price Act is the Federal Ministry for Economy and Labour (BMWA), which has delegated the task of assigning health care topics to the Federal Ministry of Health and Women's Issues (BMGF). As the Price Act does not only apply to pharmaceuticals but also to other society-related products such as raw materials, it states rather general criteria for setting prices, such as the affordability of consumers and the economic circumstances of the industry. For some areas where the Price Act is applied, such as pharmaceuticals, international price comparisons are used, among other criteria, to set prices.

Thus, the pricing of pharmaceuticals is in the hands of the Federal Ministry of Health and Women's Issues (BMGF), which is assisted by the Pricing Committee (PK) that meets once a month. The Pricing Committee (PK) consists of representatives of each of the following institutions besides the Federal Ministry of Health and Women's Issues (BMGF) itself, which also acts as chair of the Committee:

- the Federal Ministry for Economy and Labour (BMWA)
- the Federal Ministry of Finance (BMF)
- the Federal Ministry for Agriculture, Forestry, Environment and Water Management (BMLF)
- the Federal Chamber of Commerce (WKÖ)
- the Federal Chamber of Labour (BAK) and
- the Presidential Conference of the Chambers of Agriculture.

As already stated, in addition to the Price Act, since 1 September 1999 a price notification agreement between the Federal Chamber of Labour (BAK) and the Federal Chamber of Commerce (WKÖ) has been in place. Manufacturers have to notify the Federal Ministry of Health and Women's Issues (BMGF) of the ex-factory price for new products or of price changes. This pricing procedure is applied to all pharmaceuticals (on- and off-patent, prescription-only medicines (POM) or over-the-counter (OTC) pharmaceuticals).

³³ 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 No. 151/2004]

As mentioned earlier, the pricing scheme is very much linked with the reimbursement system, since there are separate pricing rules for pharmaceuticals applying for inclusion in the Reimbursement Code (EKO). Pharmaceuticals included in the EKO have to be priced either according to the European Union (EU) average price, as established by the Pricing Committee (PK), or below this price. Decisions on the reimbursement status are made by the Federation of Austrian Social Insurance Institutions (HVB) on the basis of recommendations of the Pharmaceutical Evaluation Board (HEK) (cf. 4.1).

The Federation of Austrian Social Insurance Institutions (HVB) decides in accordance with the Transparency Directive³⁴ 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 Pharmaceutical Evaluation Board (HEK). Further information on price reviews is given later (cf. 3.6.4).

Besides the European Union (EU) average price which applies for pharmaceuticals that are included in the Reimbursement Code (EKO), there is the possibility of further price negotiations with the Federation of Austrian Social Insurance Institutions (HVB) (cf. 3.2.2) and in addition there are special pricing regulations for, e.g., generics (cf. 3.4.2).

3.2 Pricing policies

As mentioned earlier (cf. 3.1), according to the Price Act of 1992³⁵, the Federal Ministry of Health and Women's Issues (BMGF) is entitled and obliged to calculate a "national price justified in terms of the national economy". The BMGF advised by the Pricing Committee (PK) therefore calculates the European Union (EU) average price for all pharmaceuticals applying for reimbursement. When doing so the PK may ask the Austrian Health Institute (GÖG/ÖBIG) to check the price information delivered by the pharmaceutical companies.

However, in practice the price notification system under the agreement between the Federal Chamber of Labour (BAK) and the Federal Chamber of Commerce (WKÖ) is the most common pricing procedure in Austria.

Table 3.1 gives an overview of the methods of pharmaceutical pricing in Austria.

³⁴ Council Directive 89/105/EEC

³⁵ 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 No. 151/2004]

Table 3.1: Austria - Ways of pricing of pharmaceuticals

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing / Price Notification	Non-reimbursable pharmaceuticals	n.app.	n.app.
Statutory Pricing	For pharmaceuticals applying for reimbursement, mostly POM (EU average price)	All pharmaceuticals regulated via a regressive mark-up scheme	All pharmaceuticals regulated via a regressive mark-up scheme
Price Negotiations	Prices for pharmaceuticals in EKO may be further negotiated with HVB (especially green box)	n.app.	n.app.
Price-volume agreements, discounts	Yes (Contribution to secure affordability of pharmaceuticals 2004-2006) - discounts by pharmaceutical industry	Yes (Solidarity contribution of pharmacists from January 2000 to December 2003; and discounts for "privileged customer" i.e. SHI)	
Institution in charge of pricing	<ul style="list-style-type: none"> - BMGF advised by PK - Ex-factory prices for reimbursable pharmaceuticals are negotiated between HVB and industry, advised by HEK on basis of EU average price or other pricing regulation (generics), price negotiations take place 		
Legal Basis	<ul style="list-style-type: none"> - Price Act 1992, as amended; - Enactment of the BMGF on the maximum mark ups in pharmaceutical wholesale 2004; - Austrian Pharmaceutical Tax Enactment (Arzneitaxe); - Verfahrensordnung Art. 351g ASVG; - 60. ASVG Novelle; - 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 October 2005 		

Art. = Article, ASVG = Allgemeines Sozialversicherungsgesetz (Austrian Social Insurance Law), BGBl = Bundesgesetzblatt (Official Gazette), BMGF = Bundesministerium für Gesundheit und Frauen (Federal Ministry of Health and Women), EKO = Erstattungskodex (Austrian Reimbursement Code), HVB = Hauptverband der österreichischen Sozialversicherungsträger (Federation of Austrian Social Insurance Institutions), HEK = Heilmittel-Evaluierungskommission (Pharmaceutical Evaluation Board), PK = Preiskommission (Pricing Committee), OTC = over-the-counter pharmaceuticals, POM = prescription-only medicines, n.app. = not applicable, SHI = social health insurance, EU = European Union

Source: GÖG/ÖBIG 2006

In order to find a justified reimbursement price, external referencing pricing has been introduced in 2004 (European Union average price system). The EU average price is set according to the very detailed Regulation on Procedural Rules for Calculation of the European Union (EU) average price³⁶ (cf. 3.2.1 and 3.3.1 for further explanations).

³⁶ Regulation on Procedural Rules for Calculation of the EU average price [Regelung für die Vorgehensweise der Preiskommission bei der Ermittlung des EU-Durchschnittspreises according to Art. 351c.6 ASVG; <http://www.bmgf.gv.at/cms/site/detail.htm?thema=CH0008&doc=CMS1078931881119>]

There are different pricing rules (cf. 3.4.2) for the inclusion of generics in the reimbursement Code (EKO). As long as the pack size of a parallel traded pharmaceutical is the same as the generic one, an “own price application” does not need to be filed (cf. 3.4.4).

Furthermore, there are special regulations on pricing of hospital-only medicine (HOM) (cf. 3.4.1).

3.2.1 Statutory pricing

In general, prices are either calculated by the Federal Ministry of Health and Women’s Issues (BMGF) advised by the Pricing Committee (PK) (European Union average price) or notified by companies (price notification at manufacturer level). These prices are maximum prices and pharmaceuticals may be priced below them. Furthermore, there are statutory wholesale and pharmacy mark ups for all pharmaceuticals (cf. 3.5).

According to the Price Act, if such a notified price is deemed too high from the perspective of the Austrian economy, the Federal Ministry of Health and Women’s Issues (BMGF) has the opportunity to start an official price-fixing process (cf. 3.6.3). However, this has not occurred during recent years. If such a process is not started within six weeks, the sought price is automatically granted. More information on price reviews is given later (cf. 3.6.4).

The European Union (EU) average price is only set for pharmaceuticals applying for inclusion into the Reimbursement Code (EKO). The regulations of the Reimbursement Code (EKO) and its system of coloured boxes are explained in more detail later (cf. 4.2.2). According to the procedure on the calculation of the EU average price³⁷, the holder of the market authorisation applying for inclusion of the pharmaceutical into the EKO must provide information, including whether the pharmaceutical is on the market in the other EU Member States and if so the ex-factory and wholesale prices of the pharmaceutical in each of these countries have to be submitted (cf. 3.3.1). The Austrian Health Institute (GÖG/ÖBIG) is responsible for checking the prices submitted by the industry on a random basis.

The Pricing Committee (PK) then calculates the EU average price of the pharmaceuticals applying for inclusion in the reimbursement system in the following way: the EU average price can be established if the pharmaceutical is marketed in at least half of the European Union Member States for on-patent products and in at least two Member States for generics. Otherwise, the EU average price cannot be established and a price evaluation will be carried out every six months. If the criteria are not met at the second re-evaluation, the EU average price will be established on the basis of the information available, i.e. the available countries.

The ex-factory price is then set at the level of the EU average price and the pharmaceutical is allowed to enter into the red box of the Reimbursement Code (EKO). The EKO is divided into different boxes (cf. Table 4.1). The European Union average price is also the maximum

³⁷ Regulation on Procedural Rules for Calculation of the EU average price [Regelung für die Vorgehensweise der Preiskommission bei der Ermittlung des EU-Durchschnittspreises according to Art. 351c.6 ASVG; <http://www.bmgf.gv.at/cms/site/detail.htm?thema=CH0008&doc=CMS1078931881119>]

limit for pharmaceuticals in the yellow box of the Reimbursement Code (EKO) and green box products must always be priced below the EU average price.

Furthermore, the Federation of Austrian Social Insurance Institutions (HVB) may negotiate ex-factory prices with pharmaceutical companies (cf. 3.2.2).

3.2.2 Negotiations

In Austria, price negotiations are a tool used in addition to the common method of setting the European Union (EU) average price. Therefore, the EU average price at manufacturer level for pharmaceuticals of the Reimbursement Code (EKO) can be further negotiated with the Federation of Austrian Social Insurance Institutions (HVB). The legal framework of the price negotiations is contained in the Procedural Rules for the publication of the EKO³⁸. The procedure for the price negotiations is based on price referencing (cf. 3.3). As soon as an agreement is reached, negotiations end and the ex-factory price is then binding for the whole market. If the negotiations with the HVB fail, companies may appeal to the Independent Pharmaceutical Commission (UHK).

3.2.3 Free pricing

Free pricing at ex-factory price level is applied for non-reimbursable pharmaceuticals, which are mostly over-the-counter (OTC) products (e.g. for contraceptives).

3.2.4 Public procurement / tendering

Public procurement is only relevant in public hospitals and for pharmaceuticals that are mainly used for vaccines or meant as strategic reserve (for armed forces or against pandemic influenza).

In 1995, a pharmacy purchasing committee (Apothekeneinkaufsgremium, AEG) of the Viennese Hospital Corporation was established. The pharmacy purchasing committee (AEG) is responsible for negotiating the cost-effective purchase of pharmaceuticals, carried out via a tendering process. In the course of the tendering process criteria such as quality, reliable delivery, and costs are taken into account (cf. 3.4.1).

3.3 Pricing procedures

In Austria, internal and external price referencing plays an important role in the pricing procedure of pharmaceuticals applying for reimbursement.

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

Table 3.2 gives an overview of the different pricing procedures in Austria and in the following subsections the procedures are explained in more detail.

Table 3.2: Austria - Pricing procedures

Pricing procedure	In use	Level of pricing ¹	Scope ²
Internal price referencing	Yes	Ex-factory price level	Only reimbursable pharmaceuticals (mainly for products of the green box and the off-patent products and the yellow box)
External price referencing	Yes	Ex-factory price level	Only reimbursable pharmaceuticals
Cost-plus pricing	n.app.	n.app.	n.app.
Indirect profit control	n.app.	n.app.	n.app.

¹ Level of pricing = at what stage of the pricing process the pricing takes place (e.g. at the retail price level)

² Scope = A pricing procedure does not always refer to all pharmaceuticals: e.g. a pricing procedure could only refer to reimbursable pharmaceuticals, whereas for over-the-counter pharmaceuticals there is free pricing.

n.app. = not applicable

Source: GÖG/ÖBIG 2006

3.3.1 External price referencing

The Federation of the Austrian Social Insurance Institutions (HVB) has been comparing prices of reimbursable pharmaceuticals in Austria with those in other European Member States during the course of the reimbursement decision since the mid-1990s.

With the introduction of the European Union (EU) average price system in 2004 the comparison method and the relevant country basket – which consist of all EU Member States – were fixed according to the Federal Ministry of Health and Women's Issues (BMGF) Regulation on Procedural Rules for Calculation of the EU average price, published on 1 October 2005³⁹. External price referencing is applied at the ex-factory price level.

The regulation states that the holder of a market authorisation applying for inclusion of a pharmaceutical to the Reimbursement Code (EKO) has to provide information, including whether the product is on the market in other European Union (EU) Member States and if so, the ex-factory and wholesale prices of the pharmaceutical in all current EU Member States have to be submitted. To do this, the companies have to use a standard form, which was developed by the Pricing Committee (PK).⁴⁰ The Austrian Health Institute (GÖG/ÖBIG) may be

³⁹ Regulation on Procedural Rules for Calculation of the EU average price [Regelung für die Vorgehensweise der Preiskommission bei der Ermittlung des EU-Durchschnittspreises according to Art. 351c.6 ASVG; <http://www.bmgf.gv.at/cms/site/detail.htm?thema=CH0008&doc=CMS1078931881119>]

⁴⁰ Price notification form according to Regulation on Procedural Rules for Calculation of the EU average price, <http://www.bmgf.gv.at/cms/site/attachments/0/7/8/CH0008/CMS1078931881119/preismeldung-roter-bereich.xls>

asked by the PK to check the prices submitted by the industry on a random basis. The prices are compared per unit with the same strength, the same pack size and the same dosage.

3.3.2 Internal price referencing

Internal price referencing is applied in the course of the application for inclusion in the Reimbursement Code (EKO). Manufacturers of pharmaceuticals that apply for inclusion in the EKO have to submit a comparison of the ex-factory prices of comparable pharmaceuticals. The potential sales of the pharmaceuticals as well as the prices in other EU Member States may also be taken into consideration. There are three comparison methods depending on the type of pharmaceutical.

- Generics: economic efficiency of the first generic product is given, if the price is at least 48% (as at 2006) below the price of the originator (now off-patent) brand (cf. 3.4.2).
- Similar treatments: economic efficiency is assumed when the treatment cost of the pharmaceutical is pitted against that of the cheapest alternative treatment already included in the Reimbursement Code (EKO).
- For a subgroup of patients: economic efficiency is assumed when the treatment costs are only slightly or reasonably above the comparable treatment costs.

Internal price referencing is especially relevant for the reimbursement price of off-patent products in the green⁴¹ and in the yellow⁴² boxes. In the case of yellow-box products where no comparable treatment is available, cost-effectiveness may be proven by pharmacoeconomic studies.

As soon as a generic (cf. 3.4.2) becomes available, the Federation of Austrian Social Insurance Institutions (HVB) re-initiates price negotiations over the price of the original product (cf. 3.1). Companies are obliged to notify the Federation of Austrian Social Insurance Institutions (HVB) of patent expiries. If no generic is launched in Austria in the wake of a patent expiry, the Federation of Austrian Social Insurance Institutions (HVB) still may – on recommendation of the Pharmaceutical Evaluation Board (HEK) – reduce the price.

3.3.3 Cost-plus pricing

Cost-plus pricing is not applied in Austria.

3.3.4 (Indirect) Profit control

In Austria, there are no explicit profit controls. The profits of pharmaceutical companies are, on basis of the VO-EKO indirectly influenced by the “Contribution to secure affordability of

⁴¹ Art. 25.2 VO-EKO

⁴² Art. 25.5 VO-EKO

the social security system” (Finanzierungs-Sicherungs-Beitrag)⁴³, a sort of ex-post discount, which is due for the years 2004 to 2006. In 2004, the flat rate payment was € 23 Mio. plus 20% value-added tax (VAT). In 2005 and 2006, the contribution amounts to 2% of the annual sales plus 20% VAT, for sales above a threshold of € 2 Mio. per company.

Additionally, the profits are influenced through the European Union (EU) average price system in the following way: in the event that the EU average price, established by the Pricing Committee (PK), 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 is only relevant for pharmaceuticals listed in the red box of the Reimbursement Code (EKO).

3.4 Exceptions

In Austria, there are some exceptions to the pricing procedures explained above. In the following subsections these exceptions for hospital-only medicine (HOM), generics, over-the-counter (OTC) products and parallel traded pharmaceuticals are explored in more detail.

3.4.1 Hospital-only medicines

As mentioned earlier, prices for hospital-only medicine (HOM) are set in a different way. Pharmaceutical companies submit their price application at the Federal Ministry of Health and Women’s Issues (BMGF). The BMGF then sets the prices at ex-factory price level. The hospitals can then purchase the pharmaceuticals at the maximum ex-factory price level.

In 1995, a pharmacy purchasing committee of the Viennese Hospital Corporation was established. There are similar committees in other Austrian Länder. These committees purchase hospital-only medicine (HOM) via tendering processes and individual negotiations.

3.4.2 Generics

For generics (defined as products containing bio-equivalent substances of off-patent original brand) different pricing rules for inclusion in the Reimbursement Code (EKO) apply. Generics are usually included in the green box; however, prior to the formal decision of the Pharmaceutical Evaluation Board (HEK) they are initially included in the red box. The Austrian Social Insurance Law (ASVG)⁴⁴ and the Procedural Rules for publication of the Reimbursement Code (EKO)⁴⁵ state that in this case economic efficiency of the first generic product is established if the price is at least 48% (2006) below the price of the now off-patent original brand.

⁴³ 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]

⁴⁴ Art. 351c.10 ASVG

⁴⁵ Procedural Rules for publication of the Reimbursement Code according to Art. 351g ASVG [Verfahrensordnung zur Herausgabe des Erstattungskodex nach § 351g ASVG (VO-EKO)], www.avsv.at

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 original has to be reduced by at least 30% within three months of the inclusion of the first generic into the green box, to ensure the economic efficiency of the original.

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. The price of the original has to be further reduced to remain in the Reimbursement Code (EKO) at the latest three months after the inclusion of the third generic product with the same active ingredient into the Reimbursement Code (EKO).

3.4.3 Over-The-Counter pharmaceuticals

In Austria most over-the-counter (OTC) products are non-reimbursable pharmaceuticals. Non-reimbursable pharmaceuticals are not listed in the red, yellow or green boxes of the Reimbursement Code (EKO), and patients therefore have to pay the full amount out-of-pocket (cf. 4.4.1). Since most over-the-counter (OTC) products are not included in the Reimbursement Code (EKO) the price notification procedure is applied (cf. 3.2.1).

However, if a product does not qualify for reimbursement on a general or individual basis, e.g. because a medicinal-therapeutic equal but cheaper treatment alternative is available but which the patient refuses, doctors still may prescribe it and patients may purchase it at their own expense or at the expense of private insurers.

3.4.4 Parallel traded pharmaceuticals

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

The legal basis for pricing parallel traded pharmaceuticals is the same as for other pharmaceuticals but, as mentioned earlier (cf. 3.2), parallel importers do not need to file a separate price application to enter the market if their price is the same as that of the original brand.

However, if they want their product to explicitly be included in the Reimbursement Code (EKO) (e.g. because of its different pack size) they have to negotiate the price with the Federation of Austrian Social Insurance Institutions (HVB). For parallel traded pharmaceuticals the same wholesale and pharmacy margins are applicable as for other pharmaceuticals (cf. Table 3.4 and Table 3.6).

3.4.5 Other exceptions

There are no other exceptions in Austria.

3.5 Margins and taxes

In Austria all pharmaceuticals are regulated via regressive mark-up schemes for both wholesalers and pharmacies.

Table 3.3 gives an overview of the methods for regulating wholesale and pharmacy mark ups.

Table 3.3: Austria - Regulation of wholesale and pharmacy mark ups 2006

Wholesale mark up			Pharmacy mark up		
Regulation (yes / no)	Content	Scope	Regulation (yes / no)	Content	Scope
Yes	Regressive mark ups	All pharmaceuticals	Yes	Regressive mark ups ¹	All pharmaceuticals

¹ different for privileged and private customers

Source: GÖG/ÖBIG 2006

3.5.1 Wholesale remuneration

In Austria, wholesalers are remunerated via a statutory regressive mark-up scheme applicable to all pharmaceuticals⁴⁶. From 1 January 2004, there are different mark-up schemes for pharmaceuticals included in the yellow or green boxes of the Reimbursement Code (EKO) and for all other pharmaceuticals. Before this, there was one single mark-up scheme for all pharmaceuticals.

The regulations are displayed in detail in Table 3.4 and Table 3.5. The wholesale mark ups are regulated as maximum mark ups and are always applied. However, wholesalers may grant discounts to pharmacies. In practice, discounts (Skonti) are rather common and sometimes promotional activities (promoting a certain pharmaceutical form of a product, etc.) are carried out.

In 2006, the average wholesale margin for the total market is 9.5% and 9% for the reimbursement market.

⁴⁶ 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_hoehstaufschlaege_am.pdf

Table 3.4: Austria - Wholesale mark-up scheme for products included in the yellow and green boxes of the Reimbursement Code, 2006

Ex-Factory Price in €	Maximum Mark Up as a % of Ex-factory Price	Pharmacy purchase 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 Federal Ministry of Health and Women's Issues (BMGF) on Maximum Wholesale Mark Ups for Pharmaceuticals for 2004

Table 3.5: Austria - Wholesale mark-up scheme for products not included in the green and yellow boxes of the Reimbursement Code, 2006

Ex-factory Price in €	Maximum Mark Up as a % of Ex-factory Price	Pharmacy Purchase 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 Federal Ministry of Health and Women's Issues (BMGF) on the maximum mark ups in pharmaceutical wholesale for 2004

3.5.2 Pharmacy remuneration

According to the Austrian Pharmaceutical Tax Enactment (Österreichische Arzneitaxe)⁴⁷ pharmacies are remunerated via a statutorially fixed mark-up scheme applicable to all phar-

⁴⁷ Austrian Pharmaceutical Taxe 1962, amended [Österreichische Arzneitaxe, 1962 i.d.F. BGBl. II No. 433/2005]

maceuticals (on- and off-patent, prescription-only medicines (POM) and over-the-counter (OTC) products).

Like wholesale mark ups, pharmacy mark ups are regressively staggered and are based on the pharmacy purchase price. Since 1 January 2004 there are two different schemes applied:

- one scheme using reduced mark ups for "privileged customers", such as the Austrian sickness funds, the State, the Austrian Länder or communities and funds and institutions held by these, as well as non-profit-making hospitals⁴⁸ (cf. Table 3.6); and
- a basic scheme for "private customers" (cf. Table 3.7), on which an additional flat "private customer mark up" of 15 % is added,⁴⁹ valid since 1 February 1997.

Table 3.6: Austria - Pharmacy mark-up scheme for privileged customers, 2006

Pharmacy Purchase Price (PPP) in €	Mark Up as a % of PPP	Pharmacy Retail Price (PRP) in €	Margin as a % 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	-
more than 357,08	3.9	-	3.8

Source: Austrian Pharmaceutical Tax Enactment, 30 December 2003

⁴⁸ Enactment of the Minister of Health and Women, changing the Austrian Pharmaceutical Tax (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]

⁴⁹ Enactment of the Minister of Health and Women, changing the Austrian Pharmaceutical Tax (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]

In 2006, according to the Austrian Chamber of Pharmacists, the average pharmacy margin for the whole market was 27.9 percent (2005: 28 %) and for the reimbursement market 19.98 % (2005: 20.47 %).

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 at his/her own expense, which is common, e.g. for contraceptives and many over-the-counter (OTC) products).

The Austrian Pharmaceutical Tax furthermore officially ensures that the 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 of the discounts are given later (cf. 3.6.1).

Prices of pharmaceuticals are published by the Chamber of Pharmacists (ÖAK) in a Medicines Price Register (Warenverzeichnis, WVZ), which is updated monthly and available by subscription in paper and electronic form.

Table 3.7: Austria – Pharmacy mark-up scheme for private customers, 2006

Pharmacy Purchase Price (PPP) in €	Mark Up as a % of PPP	Pharmacy Retail Price (PRP) in €	Margin as a % 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	-
more than 371.37	12.5	-	11.1

Source: Austrian Pharmaceutical Tax Enactment, 14 July 2000

To calculate the pharmacy retail price (PRP) valid for customers, on top of the prices calculated through the mark-up scheme a flat 15% rate (“Privatverkaufszuschlag”) is added.

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

3.5.3 Remuneration of other dispensaries

The remuneration scheme of self-dispensing (SD-) doctors is regulated via a regressive margin scheme set out in the Austrian Pharmaceutical Tax Enactment (Art. 3 et al.) for all pharmaceuticals (on- and off-patent, prescription-only medicines (POM) and over-the-counter (OTC) products).⁵⁰ These fees are only applicable for pharmaceuticals, not for medical devices. Self-dispensing (SD-) doctors have to grant a 3.6% discount (rebate) to “privileged customers” (cf. 3.6.1).

In Austria pharmaceuticals are also dispensed in hospital pharmacies (cf. 2.1.3.3.1), but there are no other distribution channels.

3.5.4 Value-added tax

Since 1997 the sale of pharmaceuticals bears the standard Austrian 20% value-added tax (VAT) rate, the second highest rate in the European Union (EU) after Denmark. Value-added tax (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 (PRPs). The Federal Ministry of Finance (BMF) refunds part of the value-added tax (VAT) on reimbursed products to the sickness funds, but this amount has not been changed for more than five years.

3.5.5 Other taxes

There are no further taxes / fees on pharmaceuticals in Austria.

3.6 Pricing related cost-containment measures

3.6.1 Discounts / Rebates

The Federation of Austrian Social Insurance Institutions (HVB) and the Chamber of Pharmacists (ÖAK) have agreed that from the year 2000 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.

⁵⁰ Austrian Pharmaceutical Tax [Österreichische Arzneitaxe, 1962 i.d.F. BGBl. II No. 433/2005]

Growing pharmaceutical expenditure (PE) led to another agreement between the Austrian Social Insurance Institutions (HVB), pharmacists, wholesalers, and the industry to further cut margins, effective from 1 January 2004. As the former discount (rebate) for “privileged customers” was incorporated in the margin scheme, the “Solidarity Contribution” ended on 31 December 2003. In addition to the margin cuts, a further 2.5% discount (rebate) on turnover for “privileged customers” above the nationwide mean turnover was introduced payable by pharmacies.

Pharmaceuticals with a wholesale price above € 200 are exempt from the discount (rebate) calculation.⁵¹ This has resulted in different mark ups for “privileged customers” (i.e. sickness funds) and private customers. Similar regulations apply to self-dispensing (SD-) doctors.

As mentioned earlier there is a sort of pay-back system applied in Austria. The share of pharmaceutical companies to curb expenditure is the so-called “Contribution to secure affordability of system of social solidarity” (Finanzierungs-Sicherungs-Beitrag).⁵² It is a sort of ex-post discount, which is due for the years 2004 to 2006. According to the VO-EKO in 2004 the flat-rate payment was of € 23 Mio. plus 20% value-added tax (VAT). In 2005 and 2006 the contribution amounts to 2% of the annual sales plus 20% VAT, for sales above a threshold of € 2 Mio. per company.

There was a wide discussion on rebates in kind (“natural rebates”) granted by the pharmaceutical industry to self-dispensing (SD-)doctors in summer 2005. Following the public discussion these kinds of rebates were explicitly prohibited in an amendment to the Austrian Medicines Act⁵³ to counteract even the possibility of influencing the prescribing decisions of SD-doctors through the existence of rebates in kind. However, cash rebates are not prohibited, especially as the pharmacy purchase price (i.e. wholesale price) for SD-doctors is not fixed by law.

In general, hospital pharmacies receive discounts in kind from the pharmaceutical companies.

3.6.2 Margin cuts

Wholesale and pharmacy margins on pharmaceuticals are regulated through a regressive mark-up scheme (cf. 3.5.1 and 3.5.2). In 1995, 1997 and in 2004 pharmacy margins were reduced by law. In the year 2000 the the Pharmacists' Association managed to avoid a fur-

⁵¹ Art. 3a Austrian Pharmaceutical Tax 1962, amended [Österreichische Arzneitaxe 1962, festgelegt in der 107. Änderung der Arzneitaxe, 30.12.2003 BGBl. II No. 629/2003]

⁵² 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]

⁵³ 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]

ther margin cut by offering a sort of pay-back (so-called "Solidarity Contribution") to the Austrian sickness funds executed by the Federation of Austrian Social Insurance Institutions (HVB).

Wholesale margins have also been reduced by law in 1995, 1997 and in 2004, as well as being statutorially cut on 1 June 2000.

3.6.3 Price freezes / Price cuts

There is no price freezing / cutting policy applied in Austria. However, the introduction of the European Union (EU) average price system together with the new Reimbursement Code (EKO) in July 2004 has led to price reductions in some market segments, for example in the segment of highly priced pharmaceuticals (the formerly so-called "Schwarzpunkt" products) which had formerly not been included in the previous reimbursement list (Heilmittelverzeichnis). These "Schwarzpunkt" products could be only reimbursed with ex-ante approval of the so-called head physician.

In the course of the introduction of the Reimbursement Code (EKO) the Government put forward that public pharmaceutical expenditure should only be allowed to grow in the range of 3-4% annually. This goal was reached in 2004 with a growth of public pharmaceutical expenditure of 3.5%; the corresponding figure for 2005 was 2.2%.

3.6.4 Price reviews

Considering the price consultation of the Austrian Health Institute (GÖG/ÖBIG) the Pricing Committee (PK) calculates the EU average price of the products applying for inclusion in the reimbursement system in the following way: the Regulation on Procedural Rules for Calculation of the EU average price maintains that the EU average price can be established if the pharmaceutical 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 cannot be established and a price evaluation will be carried out every six months. Should the information criteria not be met at the second re-evaluation, the European Union (EU) average price will be established on the basis of information available, i.e. the available countries.

Additionally, there are further negotiations between the pharmaceutical companies and the Federation of Austria Social Insurance Institutions (HVB), which was explained in more detail earlier (cf. 3.2.2).

4 Reimbursement

4.1 Organisation

Austria is organised in a social health insurance (SHI) system. According to the Austrian Social Insurance Law (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.⁵⁴

In Austria, reimbursement of pharmaceuticals is characterised by reimbursement in kind. On a very general level all duly registered pharmaceuticals are reimbursable by social health insurance (SHI) for certain diseases if there is no treatment alternative.⁵⁵ This is called individual reimbursement but is only rarely applied (less than 1% of prescriptions). On average 45,000 prescriptions per month were approved via the individual reimbursement procedure in 2005.⁵⁶

All pharmaceuticals listed in the Reimbursement Code (EKO)⁵⁷ may be prescribed by contracting doctors on behalf of the sickness funds (general reimbursement). In specific cases, ex-ante or ex-post approval of a "head physician" (Chefarzt) of the contracting sickness fund is necessary.

As mentioned earlier (cf. 3.1), the pricing and reimbursement system are very closely linked, since there are special pricing rules for pharmaceuticals applying for inclusion in the Reimbursement Code (EKO).

In Austria, there are 19 sickness funds, being represented by their umbrella organisation the Federation of Austrian Social Insurance Institutions (HVB). The Federation of Austrian Social Insurance Institutions (HVB) consulted by the Pharmaceutical Evaluation Board (HEK) is responsible for deciding whether a pharmaceutical should be reimbursed or not. The Pharmaceutical Evaluation Board (HEK) consists of 20 experts nominated by several Austrian public bodies, 10 of which are representatives of the sickness funds.

Another body dealing with the reimbursement status of pharmaceuticals at federal level is the Independent Pharmaceutical Commission (UHK). The Independent Pharmaceutical Commission (UHK) functions as an appeal court to whom manufacturers may turn in case of reimbursement applications being turned down, etc.

⁵⁴ Art. 133 ASVG 1955, regulating the extent of medical treatment [Art. 133 ASVG 1995; BGBl. No. 189/1955]

⁵⁵ Art. 136.1 and 2 ASVG 1955, amended [Art. 136.1 und 2 ASVG 1995 i.d.F. BGBl. II No. 446/2005]

⁵⁶ Calculation by the Federation of Austrian Social Insurance Institutions (HVB), based on January-October 2005 data

⁵⁷ Art. 31.3(12), on the publication of the Reimbursement Code EKO (Art. 31.3(12) latest amended by BGBl. I No. 131/2006

In order to apply for reimbursement, the holder of a market authorisation needs to send an application for the inclusion of the pharmaceutical into the Reimbursement Code (EKO) to the Federation of Austrian Social Insurance Institutions (HVB). Since 1 September 2005 the application can be submitted electronically. The application needs to include information, including whether the pharmaceutical is on the market in other European Union (EU) Member States and if so, the ex-factory and wholesale prices of the pharmaceutical in each of these countries have to be submitted. To do this, the companies have to complete a form, which was developed by the Pricing Committee (PK).⁵⁸ The Austrian Health Institute (GÖG/ÖBIG) is - on request of the PK - responsible for checking the prices submitted by the industry.

The Federation of Austrian Social Insurance Institutions (HVB) decides within 90 days from the complete application, on the recommendation of the Pharmaceutical Evaluation Board (HEK), whether the pharmaceutical qualifies for inclusion into the Reimbursement Code (EKO) at all.

4.1.1 Appeal procedure

In the case of a negative decision, the manufacturer may appeal to the Independent Pharmaceutical Commission (UHK).⁵⁹ All committee members, including those of the Pharmaceutical Evaluation Board (HEK), are independent experts nominated by several public bodies in Austria such as the Federal Chamber of Commerce (WKÖ), the Federal Chamber of Labour (BAK), the Chamber of Physicians (ÖÄK), various sickness funds, the Chamber of Pharmacists (ÖAK), the Austrian Health Institute (GÖG/ÖBIG), etc.

The Independent Pharmaceutical Commission (UHK) was established in the course of the 60th amendment to the Austrian Social Insurance Law (ASVG) in 2002 as an appellation court to assess the decision of the Federation of Austrian Social Insurance Institutions (HVB) on the inclusion of a pharmaceutical in the Reimbursement Code (EKO) (cf. 2.3). There are monthly sessions which are open to the public.

4.1.2 Delisting

Decisions on delisting, on the change of the insertion of a pharmaceutical to a box, or on any restrictions in the wake of new pharmacological, medical-therapeutic or economic findings can be made by the Federation of Austrian Social Insurance Institutions (HVB).⁶⁰ The manu-

⁵⁸ Price notification form according to Regulation on Procedural Rules for Calculation of the EU average price, <http://www.bmgf.gv.at/cms/site/attachments/0/7/8/CH0008/CMS1078931881119/preismeldung-roter-bereich.xls>

⁵⁹ Details on the UHK, e.g. procedure regulations and topics may be found at www.bmgf.gv.at/cms/site/detail.htm?thema=CH0008&doc=CMS1096983721392

⁶⁰ Art. 35 VO-EKO

facturer has the right to comment or complain against any such decision to the Independent Pharmaceutical Commission (UHK).⁶¹

4.2 Reimbursement schemes

A total of 98 percent of Austria's eight million inhabitants are covered by statutory health insurance. Pharmaceuticals are granted through benefits in kind. Pharmacies settle their accounts 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" (cf. 3.5.2). This mark-up scheme is applicable to all pharmaceuticals dispensed on behalf of the sickness funds, regardless of the prescription or reimbursement status, i.e. regardless of whether it is included in the red box or reimbursed on individual application.

The legal basis for the current reimbursement scheme (valid from 1 January 2005) is Art. 31.3 paragraph 12 of the Austrian Social Insurance Law (ASVG) published in 2003 (61st Amendment of the ASVG)⁶² and the Procedural Rules for publication of the Reimbursement Code (EKO) are fixed by decree (Verfahrensordnung Erstattungskodex, VO-EKO).⁶³

4.2.1 Eligibility criteria

Eligibility criteria for the decision on reimbursement of a pharmaceutical are held in Art. 351c.2 and Art. 351c.4 (pack sizes) of the Austrian Social Insurance Law (ASVG).

If the pharmaceutical qualifies for inclusion on the basis of these rather formal criteria the Pharmaceutical Evaluation Board (HEK) will study the therapeutic benefits of the pharmaceutical in question, basing their analysis on pharmacological, medical-therapeutic, and health-economic data⁶⁴ (cf. 5.4).

- The pharmacological analysis mainly aims to classify and evaluate the pharmaceutical in the context of available therapeutic alternatives, determining comparable therapeutic alternatives if appropriate on Anatomic Therapeutic Chemical classification ATC 4 Level, and determining the degree of innovation for the pharmaceutical concerned.
- Medical-therapeutic evaluation aims to determine and quantify groups of patients which could be treated with the new medication, determine and quantify the added therapeutic value of the new treatment compared to alternatives and verify the validity of its medical effectiveness as shown by pharmacoeconomic evaluation. Expected duration of treatment

⁶¹ Details on the UHK, e.g. procedure regulations and topics may be found at

www.bmgf.gv.at/cms/site/detail.htm?thema=CH0008&doc=CMS1096983721392

⁶² Art. 31.5.12 ASVG 1955, amended [Art. 31.5.13 ASVG, i.d.F. BGBl. I No. 71/2005]

⁶³ Procedural Rules for publication of the Reimbursement Code according to Art. 351g ASVG [Verfahrensordnung zur Herausgabe des Erstattungskodex nach § 351g ASVG (VO-EKO)], www.avsv.at

⁶⁴ Art. 351g.2 ASVG

and frequency of administration are also taken into account. The criteria / data which are evaluated can be found in the Annex of the new Reimbursement Code (VO-EKO).

- As far as the health-economic aspect is concerned, according to the Procedural Rules for publication of the new Reimbursement Code (VO-EKO)⁶⁵ pharmacoeconomic evaluations have to be submitted by the market authorisation holder if applying for inclusion to the EKO for an innovative product, providing a substantial therapeutic benefit, or if applying for inclusion to the yellow box, if no comparable medicinal preparation is listed in this box.

After assessment of the above three categories the Pharmaceutical Evaluation Board (HEK) then recommends inclusion or not of the product into the yellow or green box. A detailed description of the different boxes that are included in the Reimbursement Code (EKO) is given later (cf. 4.2.2).

The green box comprises those pharmaceuticals that can be "freely" prescribed without prior authorisation of a "head physician". Pharmacy-manufactured pharmaceuticals are also in the green box, unless the Pharmaceutical Evaluation Board (HEK) has decided differently.

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 pharmaceuticals in the yellow and red boxes is designed to ensure the sickness funds control the volume of prescriptions of these types of pharmaceuticals.

As explained earlier (cf. 4.1), the Federation of Austrian Social Insurance Institutions (HVB) decides on the reimbursement status upon the recommendation of the Pharmaceutical Evaluation Board (HEK). If the application for reimbursement is denied the manufacturer may appeal to the Independent Pharmaceutical Commission (UHK) (cf. 4.1).

4.2.2 Reimbursement categories and reimbursement rates

In Austria, there is a positive list, the Reimbursement Code (EKO) (cf. 4.1). All pharmaceuticals included in the Reimbursement Code (EKO) qualify for general reimbursement, but prescribing doctors have to consider their prescribing habits in accordance with the Guidelines on Economic Prescribing of pharmaceuticals and medicinal products (RöV) (cf. 5.2) and the ex-ante or ex-post approval of the sickness fund "head physician" might be required.

As soon as a pharmaceutical company has completed its application for the reimbursement, the pharmaceutical is included in the red box of the Reimbursement Code (EKO), thus qualifying for full reimbursement. Nonetheless, its reimbursement status depends on its approval by a "head physician" of the sickness funds. Since there is either full reimbursement or no reimbursement, there are no reimbursement rates (such as rates depending on diseases or patient status).

⁶⁵ Art. 24.2 para 5 and 6 and Art.25.4 VO-EKO

The pharmaceuticals in the Reimbursement Code (EKO) are categorised in accordance with the World Health Organisation's Anatomic Therapeutic Chemical (ATC) classification. The Reimbursement Code (EKO) has three main segments: the red, the yellow (subgroup: light yellow) and the green boxes, as displayed in Table 4.1.

Table 4.1: Austria - Reimbursement of pharmaceuticals

Reimbursement category ¹	Characteristics of category
Red Box	<p>Scope:</p> <ul style="list-style-type: none"> • Newly launched pharmaceuticals and all pharmaceuticals (including off-patents) that have applied for inclusion into the Reimbursement Code (EKO) the yellow or green box <p>Procedure:</p> <ul style="list-style-type: none"> • Stay in box for a period of 24 to 36 months <ul style="list-style-type: none"> ○ Max. 24 months from the establishment of the EU average price ○ Max. 36 months for products where no EU average price can be established, price as indicated by manufacturer will be used for reimbursement purposes; Pricing Committee (PK) performs price evaluation every 6 months (any difference between industry indicated and established EU average price must be paid back to the SHI ex-post) ○ Until the decision of the Federation of Austrian Social Insurance Institutions (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 <p>Conditions for reimbursement:</p> <ul style="list-style-type: none"> • Ex-ante approval of head physician sought by the doctor prescribing the pharmaceutical to the patient is needed for reimbursement <p>Price:</p> <ul style="list-style-type: none"> • Priced at the EU average price or price indicated by market authorisation holder (if no EU average price has been established); applications for price increments are decided upon by the Federation of Austrian Social Insurance Institutions (HVB) within 90 days of receipt of the Pricing Committee (PK) recommendations
Yellow Box	<p>Scope:</p> <ul style="list-style-type: none"> • Pharmaceuticals with fundamental therapeutic benefits or considered important therapeutic innovation ("essential added therapeutic value") <p>Conditions for reimbursement:</p> <ul style="list-style-type: none"> • Pharmaceuticals are only reimbursed <ul style="list-style-type: none"> ○ for specific disease or age group or ○ if prescribed by specialist doctor or ○ in limited quantities (e.g. only for 2 weeks) or for a specific method of application

Reimbursement category ¹	Characteristics of category
	<ul style="list-style-type: none"> • Ex-ante approval of head physician sought by the doctor prescribing the pharmaceutical to the patient is needed for reimbursement Price: <ul style="list-style-type: none"> • Price must not exceed the EU average price, applications for price increments are decided upon by the Federation of Austrian Social Insurance Institutions (HVB) within 90 days
Light Yellow Box	Scope: <ul style="list-style-type: none"> • Same as for other yellow box products Conditions for reimbursement: <ul style="list-style-type: none"> • Same conditions as for yellow box, but for indications as defined in the Reimbursement Code (EKO) pharmaceuticals may be "freely" prescribed by doctors on expense of sickness fund • Ex-post volume control by head physician possible, i.e. doctor has to keep a record of the reason for such prescriptions Price: <ul style="list-style-type: none"> • Same as for yellow box pharmaceuticals
Green Box	Scope: <ul style="list-style-type: none"> • "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: <ul style="list-style-type: none"> • In general no conditions, pharmaceuticals may be prescribed by any contract physician • Restrictions concerning specialist prescription or age of patient are possible Price: <ul style="list-style-type: none"> • Price must be below the EU average price • Special pricing rules for generics • Prices are usually set after price negotiations, applications for price increments are decided upon by Federation of Austrian Social Insurance Institutions (HVB) within 90 days

Reimbursement category ¹	Characteristics of category
Not listed pharmaceuticals	<p>Scope:</p> <ul style="list-style-type: none"> Contains pharmaceuticals 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 purposes⁶⁶ <p>Conditions for reimbursement:</p> <ul style="list-style-type: none"> No general reimbursement possible In very specific cases (e.g. for hospital products in cases when the patient re-enters the primary care setting) reimbursement on individual basis is possible, but ex-ante approval by head physician is required <p>Price:</p> <ul style="list-style-type: none"> The ex-factory price of such pharmaceuticals is freely determined by industry, whereas the respective statutory wholesaler and pharmacy margins (“privileged customers”) are set

¹ Reimbursement Code (EKO) is divided into different boxes, which can be seen as reimbursement categories
SHI = Social Health Insurance, EU = European Union

Source: GÖG/ÖBIG 2006

Besides the mentioned categories there are also pharmaceuticals on the market that didn't apply for reimbursement at the Social Insurance. The vast majority of these products are OTC and self-medication products. However, also some marketing authorisation holders of selected POM didn't apply for reimbursement status.

4.2.3 Reimbursement lists

As mentioned earlier (cf. 4.2.2), Austria has a positive list, the Reimbursement Code (EKO). In addition to the positive list, there is also a kind of negative list, which includes pharmaceuticals categories not eligible for reimbursement. Table 4.1 gives an overview of the pharmaceuticals included in the Reimbursement Code (EKO) and those that are not.

The eligibility criteria for whether a pharmaceutical can remain in the Reimbursement Code (EKO) or not were explained in more detail earlier (cf. 4.2.1).

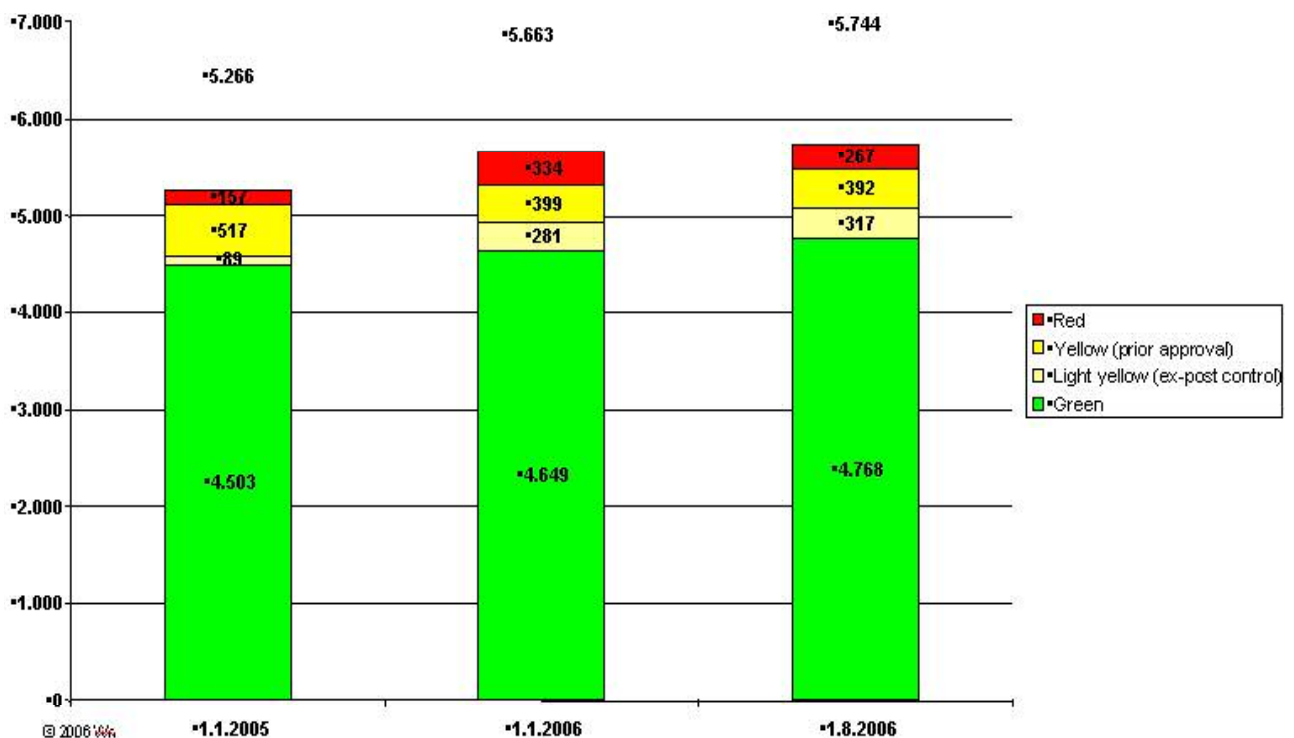
The Reimbursement Code (EKO) is updated monthly via the Internet (www.avsv.at) and is also published in hard copy (paper version) twice a year (on 1 January and 1 July). The paper version contains only the green, yellow and light-yellow boxes of the Reimbursement Code (EKO), whereas the red box is only available via the Internet as it may change daily. Besides information on the Anatomic Therapeutic Chemical (ATC) classification, brand name, available pharmaceutical forms, dosage and pack size, the Reimbursement Code

⁶⁶ List of non-reimbursable pharmaceutical categories according to Art. 351c.2 ASVG [Liste nicht erstattungsfähiger Arzneimittelkategorien nach Art. 351c.2 ASVG], www.avsv.at

(EKO) also contains prescription restrictions (e. g. may only be prescribed by a paediatrician for children under 12 years) and the reimbursement price of the pharmaceutical.

The Reimbursement Code (EKO) is only relevant for primary 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.

Figure 4.1: Austria - Development of pharmaceuticals in Reimbursement Code¹



¹ number of packages

Source: HVB 2006a

As displayed in Figure 4.1 the number of pharmaceuticals included in the new Reimbursement Code (VO-EKO) has substantially increased since it was introduced. At the beginning of 1999 there were approximately 2,950 pharmaceuticals 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 August 2006, 5,744 pharmaceuticals (counted by packs) are included in the Reimbursement Code (EKO).

However, most of the pharmaceuticals that have been added to the Reimbursement Code (EKO) can be prescribed under very specific circumstances (e.g. only by a specialist or as a second-line therapy). Thus, in comparison to the old reimbursement list (Heilmittelverzeichnis) the need for individual reimbursement applications is reduced and access for patients becomes less bureaucratic.

4.3 Reference price system

In Austria, there is currently no reference price system in place

4.4 Private pharmaceutical expenses

In Austria, all pharmaceuticals that are included in the Reimbursement Code (EKO) are fully reimbursable. The only private expense for patients, as far as pharmaceuticals that are included in the Reimbursement Code (EKO) are concerned, is the prescription fee. There are exemptions for socially disadvantaged patients and patients with communicable diseases (cf. 4.4.2.1). The fixed prescription fee does not provide incentives for patients to opt for cheaper pharmaceuticals or treatment alternatives, especially as neither a reference pricing system (cf. 4.3) nor generic substitution (cf. 5.5.1) are relevant in Austria.

4.4.1 Direct payments

As mentioned earlier (cf. 4.2.3), pharmaceuticals not listed in the red, yellow or green boxes of the Reimbursement Code (EKO) do not qualify for general reimbursement, which means that if the pharmaceutical is not reimbursed on an individual basis patients have to pay directly for those pharmaceuticals. Furthermore self-medication is paid directly by patients.

Selection criteria⁶⁷ for the exclusion of pharmaceuticals from general reimbursement include if the pharmaceutical categories are deemed unsuitable for use in out-patient care, either because they are used in a hospital setting under constant medical supervision (cf. 4.5) or because they are used for preventive purposes.

Further pharmaceutical categories which are in general excluded from reimbursement are: Nicotine Replacement Drugs, Nootropics, medical wines, contraceptives, obesity treatment drugs, some homoeopathic products and pharmaceuticals used to stimulate or increase the sexual drive.

However, patients may apply for individual reimbursement under very special circumstances (e.g., for hospital products in cases when the patient re-enters the primary care setting, as is often the case for oncology drugs). This individual reimbursement requires the ex-ante approval of a "head physician". On this occasion the reimbursement price (Kassenpreis) is again calculated on the basis of the mark-up scheme for "privileged customers" (cf. 3.5.2). On average 45,000 prescriptions per month were approved via the individual reimbursement procedure in 2005.⁶⁸

⁶⁷ List of non-reimbursable pharmaceutical categories according to Art. 351c.2 ASVG [Liste nicht erstattungsfähiger Arzneimittelkategorien nach Art. 351c.2 ASVG], www.avsv.at

⁶⁸ Calculation by the Federation of Austrian Social Insurance Institutions (HVB), based on January-October 2005 data

Thus, a pharmaceutical that is not listed, e.g. a hormonal pharmaceutical for contraception, may be reimbursed on an individual basis, e.g., on the grounds of its use for dermatological treatment, although in general contraceptives are not reimbursed.

However, if a pharmaceutical does not qualify for reimbursement on a general or an individual basis, e.g. because a medicinal-therapeutically equal but cheaper treatment alternative is available, but which the patient refuses; doctors still may prescribe it and patients may purchase it at their own expense or at expense of private insurers.

4.4.2 Out-of-pocket payments

In Austria, all pharmaceuticals that are included in the Reimbursement Code (EKO) are fully reimbursable. However, patients have to pay a fixed prescription fee out-of-pocket. This form of co-payment does not give any incentives for patients to opt for cheaper pharmaceuticals or treatment alternatives, especially as neither a reference pricing system (cf. 4.3) nor generic substitution (cf. 5.5.1) are relevant in Austria. Also, no special co-payment rules apply for parallel traded products.

There have been discussions to lower prescription fees for generics, thus encouraging demand from patients, but there is no decision yet as to whether this reduced fee will be put into place.

4.4.2.1 Fixed 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).⁶⁹ The latest extraordinary rise happened in October 2000 when the fee was changed by 22.2% to € 4.0. Patients do not have to pay any other additional payments for reimbursable pharmaceuticals.

The pharmacies collect this amount on behalf of the sickness funds and pass it on to them. Socially disadvantaged people such as old-age pensioners with an income below a certain threshold and people with communicable diseases like tuberculosis or HIV are exempt from prescription fees.⁷⁰

4.4.2.2 Percentage co-payments

There are no percentage co-payments in Austria.

⁶⁹ 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 No. 446/2005]

⁷⁰ Art. 136.4 and 5 ASVG 1955, amended [Art. 136.2 und 3 ASVG 1955, i.d.F. BGBl. II No. 446/2005]; The current values for exemption of social reasons are published on the webpage of the Federation of Austrian Social Insurance Institutions (HVB): <http://www.hauptverband.at/mediaDB/108932.PDF>

4.4.2.3 Deductibles

In Austria, there are no deductibles.

4.5 Reimbursement in the hospital sector

Since 1997, medical care in hospitals has been financed through a kind of diagnosis-related group (DRG) system. The financing of hospitals is carried out by the Länder, municipalities, social insurances, private insurers and patients (out-of-pocket). In addition, federal funds provide a fixed annual amount and a defined percentage of the value-added tax (VAT) is assigned to in-patient care funding.

Pharmaceutical expenditure (PE) of hospitals is included in the hospital's lump-sum remuneration ("LDF-Pauschale"), which is calculated according to a diagnosis-related group (DRG) system. There are no specific criteria for reimbursement decisions.

In general, each public hospital has to have a pharmaceutical committee (Arzneimittelkommission) and create internal hospital positive lists. There are specific rules set out by the Viennese Hospital Corporation.

4.6 Reimbursement-related cost-containment measures

In recent years, there have been changes in the reimbursement list. Furthermore, there are Guidelines on Economic Prescribing of pharmaceuticals and medicinal products (RöV)⁷¹ (cf. 5.2).

4.6.1 Major changes in reimbursement lists

In the year 2005, the new positive list (VO)(EKO) has been introduced. Through the introduction of the Reimbursement Code (EKO) and the system of different boxes, a more transparent way of making the decisions on reimbursement has been set up. The pharmaceuticals that have been listed in the old reimbursement list (Heilmittelverzeichnis) are now included in the green box of the Reimbursement Code (EKO). In the course of the introduction of the Reimbursement Code (EKO) the calculation of the European Union (EU) average price has been introduced.

4.6.2 Introduction / review of reference price system

At the moment, there are no plans to introduce a reference price system in Austria.

⁷¹ Guidelines on Economic Prescribing of pharmaceuticals and medicinal products [Richtlinie über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005)], www.avsv.at

4.6.3 Introduction of new / other out-of-pocket payments

In October 2000, the latest extraordinary rise of prescription fees occurred (cf. 4.4.2).

4.6.4 Claw-backs

There are no explicit claw-backs in Austria, but the Austrian Federation of Social Insurance Institutions (HVB) may recoup up to 2.5% of pharmacy profits that are above the nationwide average sales.

4.6.5 Reimbursement reviews

In Austria there is no history of regular reimbursement reviews in place on a general level (e.g. by Anatomic Therapeutic Chemical (ATC) classification, etc.). However, if a pharmaceutical included in the Reimbursement Code (EKO) positive list goes off-patent and the first followers enter the market the Federation of Austrian Social Insurance Institutions (HVB) starts a price-lowering process (cf. 3.3.2 and 3.4.2 for details).

5 Rational use of pharmaceuticals

5.1 Impact of pharmaceutical budgets

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

Still, the prescription volume or prescription habits of general practitioners (GPs) and specialists are monitored by the individual sickness funds with a view to their compliance with the Federation of Austrian Social Insurance Institutions (HVB) Guidelines on Economic Prescribing (RöV)⁷² in which doctors are encouraged to prescribe the most economical pharmaceutical out of several therapeutically similar alternatives, meaning they should preferably prescribe pharmaceuticals from the green box, and thereof the cheapest generic or parallel import, if available. The guidelines are explained in more detail later (cf. 5.2).

There are specific evaluation investigations, where the prescribing habits of doctors are evaluated. In general doctors receive the results of the evaluation.

5.2 Prescription guidelines

As mentioned earlier (cf. 5.1), there are Guidelines on Economic Prescribing of pharmaceuticals and medicinal products (RöV)⁷³ in use. These guidelines were published in 2004 by the Federation of Austrian Social Insurance Institutions (HVB) on the basis of the Austrian Social Health Insurance Law (ASVG)⁷⁴ and set criteria for the coverage of pharmaceuticals by sickness funds. Thus even pharmaceuticals not listed in the Reimbursement Code (EKO) have to be reimbursed by the sickness funds on individual application (cf. 4.4.1), if treatment is necessary for therapeutic reasons and no medication for treatment of the disease is available in the Reimbursement Code (EKO). The Guidelines on Economic Prescribing (RöV) also set out general criteria on approval by the head physician for pharmaceuticals in the reimbursement Code (EKO).

The sickness funds monitor to a greater or lesser extent the prescription patterns of their contracted general practitioners (GPs) and specialists as these are obliged to comply in their prescribing practices with the Guidelines on Economic Prescribing (RöV). These guidelines intend to safeguard the appropriate and economical prescribing of pharmaceuticals by, e.g., stating that in the event of several similar therapeutic options being available a doctor has to

⁷² Guideline on Economic Prescribing of pharmaceuticals and medicinal products [Richtlinie über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005)], www.avsv.at

⁷³ Guideline on Economic Prescribing of pharmaceuticals and medicinal products [Richtlinie über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005)], www.avsv.at

⁷⁴ Art. 31.5.13 ASVG 1955, amended [Art. 31.5.13 ASVG, i.d.F. BGBl. I No. 71/2005]

choose the most cost-effective one. This system is also called the "Red-Light System" (cf. 4.2.2), meaning that the first therapeutic option should be one from the green box, followed by a (light) yellow box pharmaceutical. Red box pharmaceuticals should be used only under special circumstances.

The most common way that sickness funds 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 pharmaceuticals that they prescribe compared to others.

According to the contracts between the sickness funds and the Austrian Chamber of Physicians (ÖÄK), in case of non-adherence, as a first measure the doctor will be informed, followed by a discussion with him/her 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 a final option – might be obliged to pay back the difference between the price of the prescribed pharmaceutical and the average prescription price. However, the latter case would be very rare and most critical cases can be solved through discussions with the arbitration board (Schlichtungsstelle).

Concerning the in-patient sector, there is no monitoring of prescribed packages. Pharmaceuticals are prescribed according to their need and purpose.

Doctors in the in-patient sector have to consult with the pharmacies in order to better monitor prescribing habits.

5.3 Information to patients / doctors

Advertising and industry behaviour towards health professionals is regulated by the Austrian Medicines Act,⁷⁵ which is in line with the European Community Directive 2001/83/EC. The Austrian Federal Agency for Safety in Health Care (BASG) is the institution responsible for supervising pharmaceutical advertising activities.

Advertising in media (broadcasting) is not allowed for prescription-only medicines (POM), but companies may provide 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 Federation of Austrian Social Insurance Institutions (HVB) together with the Austrian Chamber of Physicians (ÖÄK) and the Austrian Chamber of Pharmacists (ÖAPK) have a cooperation agreement that they will inform patients of pharmaceutical treatments of certain diseases via patient leaflets (Initiative "Arznei & Vernunft"), which are provided in practices and pharmacies.⁷⁶

⁷⁵ Austrian Medicines Act 2005 [Arzneimittelgesetz 2005; i.d.F. BGBl. 153/2005 of 28.12.2005]

⁷⁶ http://www.hauptverband.at/esvapps/page/page.jsp?p_pageid=219&p_menuid=58369&p_id=5

Over-the-counter (OTC) advertising is allowed in all media. Public advertising is, however, prohibited for non-prescription pharmaceuticals, the brand name of which is the same as that of its prescription-only form, as well as for reimbursable over-the-counter (OTC) products. Distance selling of pharmaceuticals through the Internet is not allowed in Austria.

5.4 Pharmacoeconomics

Although there are no explicit pharmacoeconomic guidelines enacted in Austria, some rules and criteria are in place for so-called health-economic evaluation in the “Procedural Rules for publication of the Reimbursement Code (VO-EKO)”.⁷⁷ These rules, which were published in January 2005, state for example that only studies published in peer-review journals qualify to prove cost-effectiveness, unless the study is approved by an independent scientific or public institution. Furthermore it is defined from which perspective (third-party payer) cost-effectiveness analyses should be carried out in the case of reimbursement decisions.

In the course of the application for inclusion in the Reimbursement Code (EKO) pharmaceutical companies have to prove cost-effectiveness for selected patient groups by means of pharmacoeconomic studies. The Pharmaceutical Evaluation Board (HEK) is responsible for deciding on reimbursement (cf. 4.1). The annexes of the aforementioned VO-EKO specify in detail, which health-economic data have to be included in reimbursement applications (cf. 4.2.1).^{78, 79}

Finally, an expert group under the lead of the Institute for Pharmacoeconomic Research (Institut für Pharmaökonomische Forschung, IPF) developed consensual health-economic evaluation guidelines which were completed by April 2006.⁸⁰

The expert group consisted of high-ranking representatives from

- the Austrian Federal Ministry of Health (BMGF),
- the Federation of Austrian Social Insurance Institutions (HVB),
- the Austrian Association of Pharmaceutical Companies (Pharmig),
- the Austrian Chamber of Doctors (ÖÄK),
- selected sickness funds,
- the Austrian Academia of Science,
- the Austrian Pharmaceutical Wholesalers,
- the Medicines Agency (PharmMed) and

⁷⁷ Art.22 and Art. 25 VO-EKO as well as Annex 4 of the new Reimbursement Code (VO-EKO)

⁷⁸ Art. 25 Procedural Rules for publication of the Reimbursement Code according to Art. 351g ASVG [Art. 25 Verfahrensordnung zur Herausgabe des Erstattungskodex nach § 351g ASVG (VO-EKO)], www.avsv.at

⁷⁹ Wieninger, P., Führlinger, S. 2005; <http://www.hauptverband.at/mediaDB/93784.PDF>

⁸⁰ IPF 2006: Guidelines zur gesundheitsökonomischen Evaluation - Konsenspapier / Guidelines for health-economic evaluation; http://www.ipf-ac.at/pdf/aktuell/Konsens_Guidelines.pdf

- selected pharmaceutical companies

However, these guidelines are not mandatory but offer guidance.

5.5 Generics

The share of generic pharmaceuticals in Austria has been rather low for a long time. The share of generics in terms of value was 4.5 percent on the total out-patient pharmaceutical market in the year 2000; in 2006 the corresponding figure was 10.7 %. In terms of volume, counted by packs, the generics market share amounted to approximately 18.6 % in 2006.⁸¹

In terms of the off-patent market, the market share in volume was about 40 percent. Figure 5.1 and Table 5.1 give an overview of the development of the market share of generics in volume and value.

Table 5.1: Austria – Development of the generic market share in the out-patient sector, 2000-2006

Generic market share	2000	2001	2002	2003	2004	2005	2006
Volume (%) in packages sold	7.4	8.2	9.1	10.8	12.3	14.4	18.6
Value (%)	4.5	4.8	5.3	6.6	7.8	9.4	10.7

n.a. = not available

¹ reimbursement market

Source: OEGV 2005, OEGV 2007, HVB 2006b

If only looking at the reimbursement market the share is slightly higher, the Federation of Austrian Social Insurance Institutions (HVB) stated that the generics 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 the near future. Furthermore, there are no financial incentives for the patient to ask the doctor to prescribe a generic pharmaceutical, but information campaigns are promoted by the Austrian Generics Association (OEGV) in cooperation with the Federation of Austrian Social Insurance Institutions (HVB) and by individual sickness funds.

According to the Guidelines on Economic Prescribing (RöV) medical doctors are requested to prescribe the most economically efficient treatment alternative. Thus, the prescription of generics is encouraged.

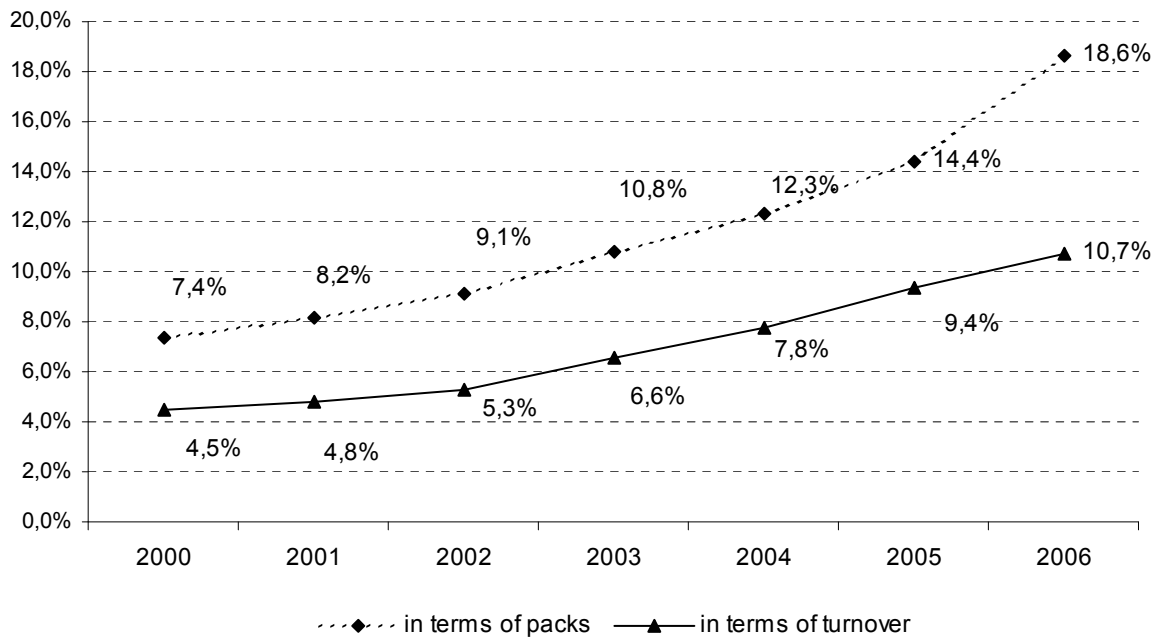
Still, there is room for the medical doctor to play a role in this decision – also borne out by the fact that not only one generic pharmaceutical but in most cases a range of pharmaceuticals

⁸¹ IMS data provided by the Austrian Association of Generic Trade (OEGV)

is listed in the green box of the positive list. At the moment generics do not play an important role in the in-patient sector.

The pricing procedure for generics was explained in more detail earlier (cf. 3.4.2).

Figure 5.1: Austria - Generics Market Shares (%) in the out-patient pharmacy market according to value and packages sold, 2000-2006



Source: OEGV 2005

5.5.1 Generic substitution

In Austria generic substitution by the pharmacist is not allowed and also doctors are not permitted to prescribe by International Nonproprietary Name (INN) (the active ingredient name) but always have to use the brand name or the generic product name.

As mentioned earlier (cf. 5.5), patients do not have financial incentives to ask the doctor to prescribe generics.

5.5.2 Generic prescription

As already mentioned, doctors are not permitted to prescribe by International Nonproprietary Name (INN) – they always have to use the brand name or the generic product name.

5.5.3 Generic promotion

Promotion of generics in Austria is only in its early stages. Therefore, only a few sickness funds have started to promote the prescription of generics. They invest into activities such as

regular information about generics in doctors' magazines, publishing extra information about generics ("Helfen auch Sie sparen") and organising information conferences on generics. Furthermore the generics industry, represented through the Austrian Generics Association (OEGV), is also trying to promote the use of generics.

The Federation of Austria Social Insurance Institutions (HVB) also agrees that the promotion of generics is an important issue and it is looking to introduce more schemes designed to increase their use in the future.

5.6 Consumption

The consumption of pharmaceuticals is not monitored on a regular basis; there are only a few regional initiatives with this purpose accomplished by the different regional sickness funds.

6 Current challenges and future developments

6.1 Current challenges

One of the main challenges facing the Austrian pharmaceutical system is, as in many other countries, the rising pharmaceutical expenditure (PE). The major reasons for the growing costs are an ageing population and the uptake of new, more expensive pharmaceuticals (e.g. in oncology treatment).

In 2004, therefore, the Government announced that the annual growth rate of pharmaceutical reimbursement expenditure was to be limited to approximately 3-4%. This is to be achieved through a reform of the reimbursement system by introducing the so-called "box-model" and the new Reimbursement Code (VO-EKO) (cf. 4.2 for details).

The fast uptake of new pharmaceuticals is a threat to the rational use of medicines, including good prescribing practice by doctors and patient adherence to the treatment. The new pharmaceuticals are replacing older, less expensive pharmaceuticals with the same indication. Therefore we observe a clear need for priority setting.

Still, it is the intention of the Austrian Government and the Austrian Social Health Insurance to keep the burden on patients as low as possible, e.g. through out-of-pocket payments (OPPs). This is reflected in the Governmental Declaration of the new Government that was established in January 2007.⁸²

A current major discussion point in Austria is the interface-management between pharmaceutical therapy in the in-patient and the out-patient health care sector. As there is a split responsibility for the funding of pharmaceuticals in these both markets, a trend of shifting "expensive" treatment between the two sectors is sometimes observed.

6.2 Future developments

The above mentioned Governmental Declaration states that an annual co-payment maximum shall be introduced by 1 January 2008. This maximum co-payment is planned to be about 2 percent of the annual income of a patient and shall be administrated via the existing E-Card. Every insured patient has such an e-card, which is necessary to access (out-patient) health care services.

Besides, these plans no major reforms are planed for the years 2007 and early 2008.

⁸² Bundeskanzleramt Österreich 2007

7 Appendixes

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7.2 Further reading

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7.3 Web links

Information on Austrian Laws and Enactments may be accessed at:
<http://www.ris.bka.gv.at/auswahl/>

Gesundheit Österreich GmbH: www.goeg.at

Ministry of Health, Family and Youth (BMGFJ): www.bmgfj.gv.at

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PHARMIG (Verband der pharmazeutischen Industrie Österreichs / Austrian Association of Pharmaceutical Companies): www.pharmig.at

7.4 Country authors and Editorial Board

7.4.1 Authors

Ms. Danielle Arts is a doctor in Medical Information Sciences and an author of a number of international publications in this field. She has been working at Gesundheit Österreich GmbH (GÖG) since May 2005 and has since then been involved in several research projects on pharmaceutical systems and pharmacy systems in the European Union (EU) Member States, among which the Pharmaceutical Pricing and Reimbursement Information (PPRI) project.

Ms. Claudia Habl is senior health economist at the Austrian Health Institute (GÖG/ÖBIG), involved in a great number of international pharmaceutical projects like the Austrian Pharmaceutical Price Information Service and works as a consultant for, e.g., the European Union and World Bank. She is author of a number of international publications in the field of pharmaceuticals and other topics like gender-health and Health Technology Assessment. In addition she heads the Austrian Medical Devices Register and is Member of the Austrian Independent Pharmaceutical Commission (UHK).

Ms. Christine Leopold has extensive experience in international, national and regional research of health care systems (in particular pharmaceutical systems in all 25 European Union (EU) Member States) and in health economics and pharma economics. She graduated from the University of Applied Science, Austria where she studied International Business Relations with a focus on Central & Eastern European Countries (1998-2002). Ms. Leopold also has a Master's degree in International Health Care Management, Economics and Policy from Bocconi University, Italy (2003-2004). At present Ms. Leopold is working at Gesundheit Österreich GmbH (GÖG), Department of Health Economics where she is a member of the Pharmaceutical Pricing and Reimbursement Information (PPRI) team dealing with price information and price comparison of pharmaceuticals in the European Union (EU).

Ms. Friederike Windisch graduated with honours from the University of Applied Management Sciences Krems, Austria, where she studied Health Management with focus on Pharmaceutical Management, Hospital Management and Insurance Management (2002-2006). She also has a degree in Nutrition Science and worked for a Viennese hospital for four years (1998-2002). Since 2004, Ms. Windisch has been working for Gesundheit Österreich GmbH (GÖG), Department of Health Economics where she is concerned with price information and price comparison of pharmaceuticals in the European Union (EU).

7.4.2 Editors

The first draft of the Austrian Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Profile was reviewed in September 2006 by Health Economist Ms. Katja Antony of the Austrian Health Institute (GÖG/ÖBIG) and by the head of the Health Economics Department of GÖG/ÖBIG, Ms. Ingrid Rosian-Schikuta, who have both been dealing with the Austrian pharmaceutical system for years. Ms. Rosian-Schikuta, in addition, is an ordinary Member of the Independent Austrian Pharmaceutical Commission (UHK).

Additional Feedback was given by the Federation of Austrian Social Insurance Institutions (HVB), represented by the Head of the Pharmaceutical Department Mr. Peter Wieninger, and the Austrian Federal Chamber of Labour (BAK), represented by Ms. Vera Lacina and Ms. Daniela Huber. The second draft of the Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Profile was reviewed again in March 2007 by Ms. Katja Antony and Ms. Ingrid Rosian-Schikuta. Afterwards it was proof-read by Ms. Nicole Satterly of WHO Europe.