Pharmaceutical Pricing and Reimbursement Information

AUSTRIA

September 2008

PPRI

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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 Main Association of Austrian Social Security 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 2006, total spending for health care was around 10.1% 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, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ) is the main policy-maker in health care at federal level. Further key actors in this field are the HVB and the Austrian Federal Agency for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen, BASG) acting as the Austrian Medicines Agency.

In 2007, a total of 40,798 medical doctors provided inpatient and outpatient care for the Austrian population. General practitioners (GPs) offer primary care and act as gatekeepers. In general they have contracts with one or more 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 pharmaceuticals, and the reimbursement of pharmaceuticals is regulated in the ASVG.

The main actors in the pharmaceutical system in Austria are: the BMGFJ assisted by the Pricing Committee (Preiskommission, PK), and the HVB taking decisions on the reimburse-

ment of pharmaceuticals on the basis of the recommendations of the Pharmaceutical Evaluation Board (Heilmittel-Evaluierungskommission, HEK). Another body dealing with pharmaceuticals is the BASG, being responsible for granting market authorisation and for the classification of pharmaceuticals according to prescription status.

Total pharmaceutical expenditure (TPE) amounted to € 2,913 million (Mio.) in 2005 (2004: € 2,967 Mio.). The proportion of public pharmaceutical expenditure as a share of total health care expenditure rose from 5.4% in 1995 to 8.5% in 2005, whereas the share of private pharmaceutical expenditure has been kept relatively stable (3.2% in 2005). In 2006, pharmaceutical sales at ex-factory level amounted to € 2,544 Mio. The share of generics is relatively low in Austria. In terms of value, generics made up 14.5% of total pharmaceutical sales in 2007.

There are approximately 220 pharmaceutical companies based in Austria, most of them are sales representatives. The manufacturers deliver their pharmaceuticals to about 35 wholesalers, of which 8 provide a full assortment of pharmaceuticals on the market. Pharmaceutical wholesale is organised as a multi-channel system. In Austria pharmaceuticals are mainly sold through pharmacies or branch pharmacies, which practise under the supervision of a community pharmacy. In 2008, there were 1,217 community pharmacies and 5 hospital pharmacies allowed to dispense pharmaceuticals to outpatients. Furthermore, Austria has quite a high number of self-dispensing doctors (hausapothekenführende Ärzte/Ärztinnen, SD-doctors), totalling 962 in 2008. 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 BMGFJ advised by the 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 BMGFJ, advised by the PK, sets the European Union (EU) average price. Prices for pharmaceuticals included in the Reimbursement Code (Erstattungskodex, EKO) may be further negotiated with the 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 EU average price, the holder of the market authorisation applying for the inclusion of the pharmaceutical into the 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 manufacturer price and wholesale price of the pharmaceutical in each of these countries (external price referencing). The Austrian Health Institute (GÖG/ÖBIG) is responsible for checking the price submitted by the industry; the average price is then calculated by the PK.

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

Since 1997 the sale of pharmaceuticals bears the standardrate Austrian 20% value added tax (VAT). A reduction of the VAT on pharmaceuticals to 10% is planned in 2009.

In Austria different pricing-related cost-containment measures have been taken. Among these, different mark up 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 HVB. The HVB, consulted by the 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 EKO.

In Austria, there is a positive list of pharmaceuticals, the EKO. All pharmaceuticals included in the EKO qualify for general reimbursement; however, there are different conditions regarding the prescription. The 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 replaced 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 EKO is only relevant for outpatient 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 inpatient 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 € 4.80 in 2008 (€ 4.70 in 2007). Since January 2008 the prescription fee has been capped statutorily,

meaning that all beneficiaries pay at maximum 2% of their annual income for pharmaceuticals. In total, Austrian patients pay about 17% of expenses for prescriptions privately.

In Austria, there is no reference price system. In spring 2008 discussions started on a possiblel introduction of a reference price system. Due to parliamentary election in September 2008 the reforms were postponed.

The most recent change in the reimbursement list occurred in 2005, when the EKO and the system of different boxes were introduced. The pharmaceuticals that were 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 Medicinal Products” (Richtlinien über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen, RöV). These guidelines were published in 2004 by the HVB on the basis of the 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 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 outpatient market was 14.5% in terms of value and 25% 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 the Government announced that the annual growth rate of pharmaceutical reimbursement expenditure should be limited to 3-4 percent. Though this was achieved in the beginning through a reform of the reimbursement system by introducing the EKO with the

“box-model” (cf. section 4.2), the year 2007 showed a growth rate of 7.7% in public pharmaceutical expenditure and e.g. an 11% growth in January 2008 compared to January 2007.

Because of the pharmaceutical situation and other occurrences the sickness funds were confronted with growing deficits that lead into several proposed legal changes of e.g. social insurance law and by-laws.

One proposed draft foresees to introduce a reference price system including obligatory generic substitution and the possibility to prescribe by international non-proprietary name (INN, which both was not allowed until now) in Austria by 2010/2011. However, after the parliamentary election in September 2008 and due to the current coalition negotiations reforms were postponed.

In addition, there were plans to cut both, the wholesale and the pharmacy mark ups which are regulated via enactments. But after some discussion it is more likely that all stakeholders – manufacturers/marketing authorisation holders and wholesalers / distributors and retailers (pharmacists and self-dispensing doctors) - will contribute “voluntarily” about € 200 million in savings during the next couple of years, e.g. via discounts.

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List of abbreviations

AEG	Apothekeneinkaufsgremium / Pharmacy Purchasing Comittee
AGES	Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH / Austrian Agency for Health and Food Safety
APG	Allgemeines Pensionsgesetz / General Retirement Income Act
ARGE Pharmazeutika	Association of Austrian Pharmaceutical Wholesalers
ASVG	Allgemeines Sozialversicherungsgesetz / Austrian Social Insurance Law
ATC	Anatomic Therapeutic Chemical classification
BAK	Bundesarbeiterkammer / Federal Chamber of Labour
BASG	Bundesamt für Sicherheit im Gesundheitswesen / Austrian Federal Agency for Safety in Health Care
BIfA	Bundesinstitut für Arzneimittel / National Institute of Pharmaceuticals
BMBWK	Bundesministerium für Bildung, Wissenschaft und Kultur / Federal Ministry for Education, Science and Culture
BMF	Bundesministerium für Finanzen / Federal Ministry of Finance
BMGF	Bundesministerium für Gesundheit und Frauen
BMGFJ	Bundesministerium für Gesundheit, Familie und Jugend / Federal Ministry of Health, Family and Youth
BMI	Bundesministerium für Inneres / Ministry of the Interior
BMLF	Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft / Federal Ministry for Agriculture, Forestry, Environment and Water Management
BMSGK	Bundesministerium für Soziale Sicherheit, Generationen und Konsumentenschutz / Federal Ministry of Social Security, Generations and Consumer Protection
BMWA	Bundesministerium für Wirtschaft und Arbeit / Federal Ministry for Economy and Labour
DG SANCO	Health and Consumer Protection Directorate General of the European Commission
DRG	Diagnosis related group
EKO	Erstattungskodex / Reimbursement Code
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
GÖG/ÖBIG	Gesundheit Österreich GmbH / Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
GP	General Practitioner
HE	Health Expenditure
HEK	Heilmittel-Evaluierungskommission / Pharmaceutical Evaluation Board
HOM	Hospital-Only Medicine
HVB	Hauptverband der österreichischen Sozialversicherungsträger / Main Association of Austrian Social Security Institutions
IMS	Institut für Medizinische Statistik / Institute for Medical Statistics
INN	International Nonproprietary Name
IPF	Institut für Pharmaökonomische Forschung / Institute for Pharmacoeconomic Research
KAKuG	Krankenanstalten- und Kursanstaltengesetz / Hospitals' Law
LDF	Leistungs- und Diagnoseorientierte Fallgruppen / Hospitals' lump-sum remuneration
LKF	Leistungsorientierten Krankenhausfinanzierung / DRG system
Mio.	Million
n.a.	not available
n.appl.	not applicable
NCU	National Currency Unit
ÖAK	Österreichische Apothekerkammer / Chamber of Pharmacists
ÖÄK	Österreichische Ärztekammer / Chamber of Medical Doctors
OECD	Organisation for Economic Co-operation and Development
OEGV	Österreichischer Generikaverband / Austrian Generics Association
ÖKAP	Österreichischer Krankenanstaltenplan / Austrian Hospitals Plan
OPP	Out-of pocket payment
ÖSG	Österreichischer Strukturplan Gesundheit / Austrian Health Care Structural Plan
OTC	Over-The-Counter pharmaceuticals
ÖVP	Österreichische Volkspartei / Austrian People`s Party
PE	Pharmaceutical Expenditure

PHARMIG	Verband der pharmazeutischen Industrie Österreichs / Austrian Association of Pharmaceutical Companies
PK	Preiskommission / Pricing Committee
POM	Prescription-Only-Medicines
PPPa	Purchasing Power Parity
PPP	Pharmacy Purchase Price
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
R&D	Research & Development
RöV	Richtlinien über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen / Guidelines on Economic Prescribing of Pharmaceuticals and Medicinal Products
SD-doctor	Hausapothekenführender Arzt / Self-dispensing doctor
SHI	Social Health Insurance
SPC	Supplementary Protection Certificate
SPÖ	Sozialdemokratische Partei Österreichs / Austrian Social Democratic Party
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
UHK	Unabhängige Heilmittelkommission / Independent Pharmaceutical Commission
VAT	Value Added Tax
VHI	Voluntary Health Insurance
VO-EKO	Verfahrensordnung Erstattungskodex / Procedural Rules for publication of the Reimbursement Code
WHO	World Health Organization
WKÖ	Wirtschaftskammer / Federal Chamber of Commerce
WVZ	Warenverzeichnis / Medicines Price Register

PPRI Pharma Profile Update 2008

Rationale

In the beginning, the Pharmaceutical Pricing and Reimbursement Information (PPRI) project was 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 more than 50 participating institutions (competent authorities and other relevant organisations) in the field of pharmaceuticals (for the list of PPRI members see the PPRI website http://ppri.oebig.at → Network)

Within the course of the PPRI project, country reports on pharmaceutical pricing and reimbursement systems, the called "PPRI Pharma Profiles", were produced (see http://ppri.oebig.at → Publications → Country Information). These PPRI Pharma Profiles refer, in general, to the year 2006/2007. The work was mainly done under the responsibility of the WHO Regional Office for Europe assisted by the team of the GÖG/ÖBIG.

Despite of the official end of the research project in 2007, the PPRI network participants agreed to continue the network and up-date the PPRI Pharma Profiles.

Outline

The PPRI Pharma Profile consists of six chapters, referring to the situation in 2008:

- Chapter 1 (Background) gives a brief overview of the demographic, economic and political situation and a brief introduction to the health care system.
- Chapter 2 (Pharmaceutical system) provides a description of the pharmaceutical system; the regulatory framework, the pharmaceutical market, the market players and the funding of pharmaceuticals and the methods of evaluating the system.
- Chapter 3 (Pricing) covers a description of the organisation of the pricing system, the pricing policies, the pricing procedures, exceptions to these procedures, as well as a section on margins and taxes and pricing related cost-containing measures.
- Chapter 4 (Reimbursement) covers a description of the organisation of the reimbursement system, the reimbursement scheme including the eligibility criteria, the reimbursement categories and rates and the reimbursement lists. Also described in this chapter is the reference price system, the private pharmaceutical expenditure, the reimbursement in the hospital sector and the reimbursement related cost-containing measures.
- Chapter 5 (Rational Use of Pharmaceuticals) is a description of the methods used to improve rational use of pharmaceuticals including the impact of pharmaceutical budget, prescription guidelines, patient information, pharmaco-economics, generics and consumption.

- Chapter 6 (Latest changes and future developments) is a concluding chapter on the latest changes, current challenges and future plans for developments in the pharmaceutical sector.

Further deliverables

Besides the PPRI Pharma Profiles and the PPRI network, the PPRI project produced further deliverables, among those:

- The **PPRI Glossary**, which is a unique glossary of pharmaceutical terms to establish a common “Pharma” terminology within the EU. See http://ppri.oebig.at → Glossary
- The **PPRI Conference**, held in Vienna in June 2007. See http://ppri.oebig.at → Conferences → PPRI Conference
- The **Set of Core PPRI Indicators** to compare information of different pharmaceutical system. See http://ppri.oebig.at → Publications → Indicators
- A comparative analysis, based on the developed indicators, filled with real data from 27 PPRI countries. The PPRI comparative analysis is included in the **PPRI Report** and summed up in the concise report **“PPRI at a Glance”**. See http://ppri.oebig.at → Publications → PPRI Report and http://ppri.oebig.at → Publications → Concise Information

Contact

The PPRI Secretariat is located at GÖG/ÖBIG which featured as the main partner of the PPRI research project.

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1 Background

1.1 Demography

Austria has 8.3 Mio. (2007) inhabitants and a land surface area of 83,871 km^2, which correlates to 98.9 inhabitants per km^2. 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 244,600 people, followed by Linz with 188,360 Salzburg with 148,470, 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 2006 can expect to live over 79 years on average: 82.68 (2006) years if female and 77.13 (2006) 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, 2000–2006/07

Variable	2000	2001	2002	2003	2004	2005	2006	2007
Total population	8,011,566	8,043,046	8,083,797	8,112,754	8,174,733	8,233,306	8,265,925	8,298,923
Population density per km^2	95.52	95.90	96.38	96.79	97.47	98.17	98.5	98.9
Population aged 0-14 (as a % of total)	17.0	16.8	16.6	16.4	16.2	16.0	15.0	n.a.
Population aged 15-64 (as a % of total	67.5	67.7	67.9	68.1	68.0	67.7	62.3[1]	n.a.
Population aged >64 (as a % of total)	15.4	15.5	15.5	15.5	15.7	16.3	21.9[2]	n.a.
Life expectancy at birth, total	78.12	78.61	78.77	78.76	79.29	79.45	79.50	n.a.
Life expectancy at birth, females	81.12	81.60	81.71	81.57	82.14	82.24	82.68	n.a.
Life expectancy at birth, males	75.11	75.61	75.82	75.94	76.43	76.65	77.13	n.a.

n.a. = not available

[1] population aged 15-60

[2] population aged >60

Source: Statistics Austria 2008

1.2 Economic background

In 2007, Austria had a gross domestic product (GDP) of € 272,800 Mio., i.e. a GDP per capita of € 32,800 (2006: GDP per capita 31,139). As shown in Table 1.2, the GDP has constantly increased in the last decade. The annual economic growth rate was 5.8% in 2007.

The Austrian Government spent € 118,616 Mio. in General Government Expenditure (GGE) or 50% of the GDP on public spending.[1] The health care sector is affected by a general tendency towards privatisation as well as the formation of holding companies.

[1] OECD Health Data 2006

Table 1.2: Austria – Macroeconomic indicators, 2000–2007

Variable	2000	2001	2002	2003	2004	2005	2006	2007
GDP in NCU (Mio. €)	210,392	215,878	220,841	226,243	235,819	245,103	257,897	272,800[1]
GDP / capita in NCU (€)	25,942	26,547	27,318	27,869	28,846	29,771	31,139	32,800
GDP / capita in PPPa (US $)	28,375	28,919	29,963	31,739	33,234	34,394	n.a.	n.a.
Annual economic growth rate in %[2]	5.2	2.6	2.2	2.8	4.4	3.9	5.1	5.8
GGE (Mio. €)	108,174	109,728	111,971	115,526	118,649	122,367	126,148	n.a.
GGE as a % of GDP	51.4	50.8	50.7	51.1	50.3	49,9	49,2	n.a.
Exchange rate (NCU per €), annual rate	13.7603	13.7603	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.

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

[1] preliminary data

[2] variance to previous year in %

Source: OECD Health Data 2008, Statistics Austria 2008, Austrian National Bank 2008

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 28 September 2008 with a voter participation of 78.8%. The Austrian Social Democratic Party (Sozialdemokratische Partei Österreichs, SPÖ) obtained the majority of votes (first place, 29.3%) and the Austrian People's Party (Österreichische Volkspartei, ÖVP) took second place (26%). Coalition negotiations to form a government are in progress.

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 Main Association of Austrian Social Security 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 more than eight million 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 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 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 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, Family and Youth (BMGFJ), 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 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.

In 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 explained (cf. section 1.4.1), the principal legal basis is the 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 ise 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. 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 2005, total spending for health care was around € 25,08 million or 10.2% of the GDP. Public health expenditure accounted for more than two thirds of the total health expenditure (THE) (75.7% in 2005) and private health expenditure (co-payments, private health insurance fees and other out-of pocket expenditures) amounted to one third of THE (24.3% in 2005). Table 1.3 gives an overview of the development of the health expenditure since 2000.

Table 1.3: Austria – Health expenditure, 2000–2007

Health expenditure	2000	2001	2002	2003	2004	2005	2006	2007
THE in NCU (in Mio. €)	20,948	21,634	22,241	23,068	24,251	25,079	n.a	n.a
THE as a % of GDP	10.0	10.0	10.1	10.2	10.3	10.2	10.1	n.a.
THE per capita in NCU (€)	2,615	2,690	2,751	2,844	2,966	3,046	n.a.	n.a.
Public HE as a % of THE	75.9	75.7	75.4	75.3	75.6	75.7	n.a.	n.a.
Private HE as a % of THE	24.1	24.3	24.6	24.7	24.4	24.3	n.a.	n.a.

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

Source: OECD Health Data 2008

1.4.3 Access to health care

A total of 39,519 medical doctors (c.f. Table 1.4) provide inpatient and outpatient 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 inpatient and outpatient 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 Outpatient care

In 2007, outpatient medical care is provided by 20,361 medical doctors, of which 6,947 are general practitioners (GPs), 9,313 specialists and 4,101 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, outpatient clinics and outpatient departments in hospitals play a major role in the provision of outpatient health care for the Austrian population. Since the mid-1990s, the number of outpatient medical doctors has grown considerably. Between 2000 and 2007 the ratio of outpatient doctors to population has increased from 2.2 to 2.5 doctors per 1,000 inhabitants.

Mostly, physical therapy institutes, medical laboratories, radiological facilities and sports-related medical institutions are managed as outpatient clinics (“ambulatories“). However, outpatient clinics do not traditionally treat any particular type of patient as there are also the outpatient departments in hospitals, which specialise in acute medical care of the respective medical speciality. Outpatient 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 outpatient doctors quarterly.

Public docotors are not free to open a surgery without permission. The basis for payment of public outpatient 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, GPs provide primary medical care and act as gatekeepers, referring patients to specialists, outpatient clinics or inpatient care providers. However, it is possible for patients to consult specialists without referral.

As SHI does not cover all outpatient health care services, under all health insurance schemes 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 pharmaceuticals prescribed by a doctor (€ 4.70 per prescription in 2007 and € 4.80 in 2008). The OOP amount varies depending on the health insurance fund. Exemptions can apply, on social grounds.

Table 1.4: Austria – Outpatient care, 2000–2007

Variable	2000	2001	2002	2003	2004	2005	2006	2007
Total number of doctors	33,944	32,082	35,630	37,316	38,457	39,519	40,492	40,798
No. of doctors per 1,000 inhabitants	4.2	4.0	4.4	4.6	4.7	4.9	4.9	4.9
Total no. of outpatient doctors[1]	17,383	17,643	18,278	19,161	19,775	20,080	20,159	20,361
of which GPs	*6,351*	*6,403*	*6,593*	*6,805*	*6,976*	*6,999*	*6,921*	*6,947*
of which dentists	*3,369*	*3,429*	*3,508*	*3,644*	*3,733*	*3,811*	*4,098*	*4,101*
No. of outpatient doctors per 1,000 inhabitants	2.2	2.2	2.3	2.4	2.4	2.5	2.4	2.5
No. of outpatient clinics (“ambulatories”)	n.a.	n.a.	n.a.	n.a.	114	n.a.	n.a.	n.a.

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

[1] there are medical doctors who work as both inpatient and outpatient doctors

Source: Austrian Medical Chamber 2008 (Austrian list of medical doctors)

1.4.3.2 Inpatient care

Inpatient care is provided through 264 hospitals with around 52,393 acute care beds (2006) which results in a ratio of 6.3 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 2007, there were 3.2 inpatient 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.[2]

To provide outpatient 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 inpatient 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. Inpatient 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 VAT is assigned to inpatient care funding. Table 1.5 gives an overview of the inpatient care sector in the last few years.

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

Table 1.5: Austria – Inpatient care, 2000–2007

Variable	2000	2001	2002	2003	2004	2005	2006	2007
No. of inpatient doctors[1]	21,703	19,066	22,862	23,503	24,202	25,075	26,082	26,286
Number of inpatient doctors per 1,000 inhabitants	2.7	2.4	2.8	2.9	3.0	3.1	3.2	3.2
Number of hospitals[2]	315	315	280	276	275	265	264	n.a.
No. of acute care beds	54,024	53,662	53,383	52,791	52,631	52,625	52,393	n.a.
of which in private sector	*2,529*	*2,656*	*2,651*	*2,651*	*2,679*	*2,679*	*2,643*	*n.a.*
Acute care beds per 1,000 inhabitants	6.7	6.7	6.6	6.5	6.5	6.5	6.3	n.a.
Average length of stay in hospital[3] (days)	6.8	6.5	6.2	6.2	6.2	5.9	5.8	n.a.

[1] there are medical doctors who work as both inpatient and outpatient doctors

[2] acute care hospitals and non-acute care hospitals

[3] in acute care hospitals

n.a. = not available

Source: Austrian Medical Chamber 2008 (Austrian list of medical doctors), BMGF 2008 (Statistics of hospitals, Register of hospitals, Documentation of diagnosis and performances)

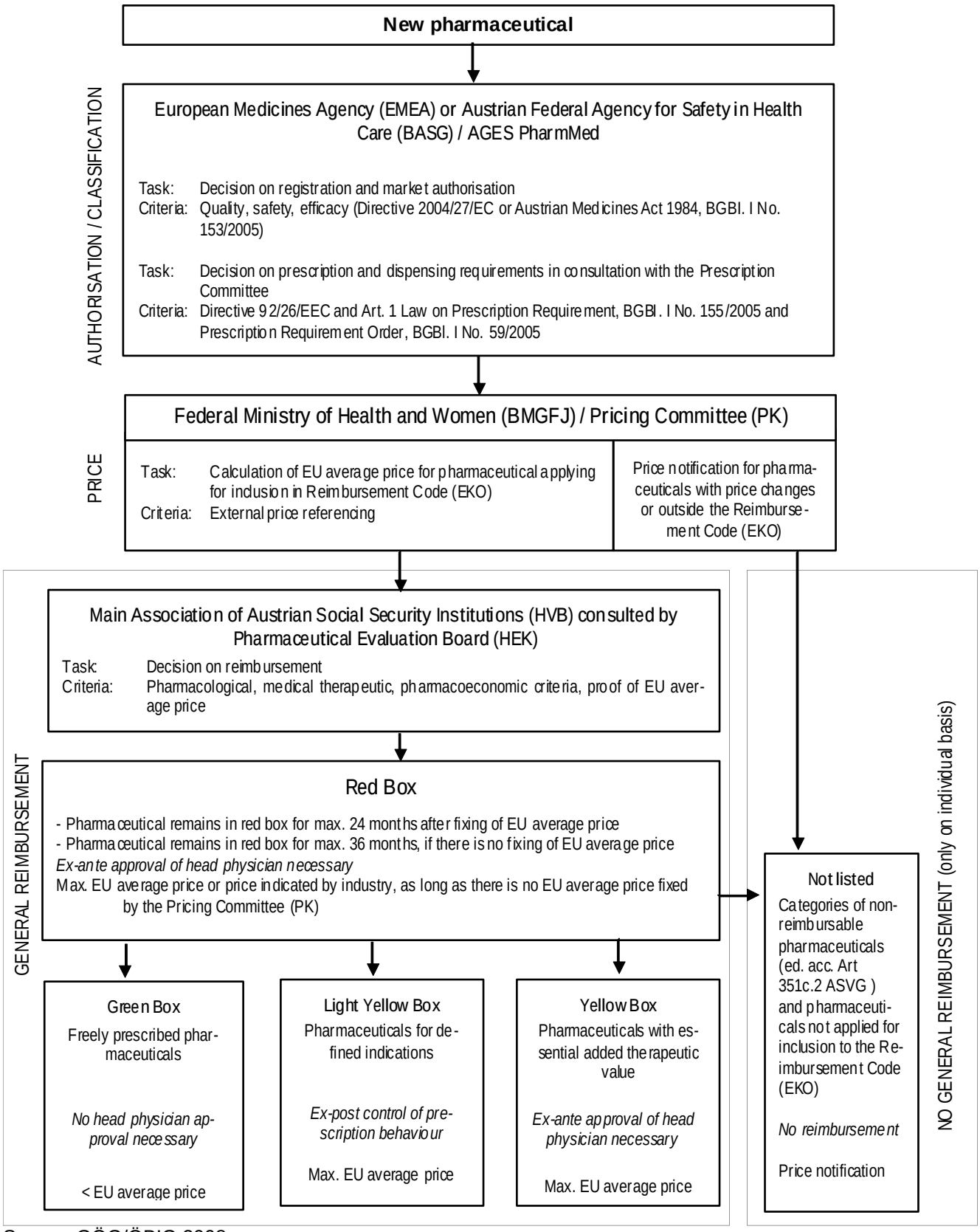
2 Pharmaceutical system

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, 2008



Source: GÖG/ÖBIG 2008

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, Family and Youth (BMGFJ), 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 2006, the BMGFJ is the legal successor of the former Federal Ministry of Health and Women (Bundesministerium für Gesundheit und Frauen, BMGF). The last parliamentary elections for the Nationalrat were held on 28 September 2008.

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)[3]. The 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 EU legislation on the new market authorisation system.

The classification of pharmaceuticals into prescription-only or non-prescription medicines follows the Prescription Act (Rezeptpflichtgesetz)[4]. The Pharmacy Act (Apothekengesetz)[5] regulates the competition among pharmacies and comprises provisions for the licensing of community and hospital pharmacies.

The Price Act (Preisgesetz)[6] 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 EU average price is calculated according to the Regulation on Procedural Rules for Calculation of the EU average price[7] (cf. section 3.2.1). Wholesalers and pharmacists are remunerated via statutory regressive mark up schemes, which are laid down in enactments.[8,9]

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[3] 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]

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

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

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

The reimbursement of pharmaceuticals is regulated through the ASVG[10]. According to the 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.[11]

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, Family and Youth (BMGFJ). The 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 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 comprehensive 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 BMGFJ assisted by the Pricing Committee (PK), especially in terms of the EU average pricing system introduced in 2004. The Austrian Health

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7 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.bmgfj.gv.at/cms/site/standard.html?channel=CH0723&doc=CMS10789318811119]

8 Enactment of the BMGF on the maximum mark ups in pharmaceutical wholesale 2004 [Verordnung des BMGF über Höchstaufschläge im Arzneimittelgroßhandel 2004], http://www.bmgfj.gv.at/cms/site/attachments/0/3/3/CH0723/CMS1071504141891/vo_hoechstaufschlaege_am.pdf

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

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

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

Institute (GÖG/ÖBIG) is responsible for checking prices of pharmaceuticals in the other EU Member States (cf. section 3.2.1).

The PK consists of one representative of each of the following institutions:

- the BMGFJ – 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, Lebensministerium, 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 BMGFJ – assisted by the 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 BMGFJ, 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 EU average price. The PK collects price notifications from companies and assesses them, as well as working out the actual calculation of the EU average price (cf. section 3.2.1).

Decisions on reimbursement status are made by the HVB on the basis of recommendations of the HEK, a body consisting of 20 experts nominated by several Austrian public bodies, 10 of which are 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 GPs and specialists, as these providers are obliged to ensure that their prescribing behaviour complies with the HVB Guidelines on Economic Prescribing (RöV).[12]

An important public body is the Independent Pharmaceutical Commission (Unabhängige Heilmittelkommission, UHK), which functions as an appeal court to whom manufacturers may

[12] Guidelines on Economic Prescribing of Pharmaceuticals and Medicinal Products [Richtlinien über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005)], www.avsv.at

turn in case their reimbursement application is refused. All members of the UHK are independent experts nominated by several public bodies in Austria, such as the WKÖ, 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, 2008

Name in local language (Abbreviation)	Name in English	Description	Responsibility
Bundesministerium für Gesundheit, Familie und Jugend (BMGFJ)	Federal Ministry of Health, Family and Youth	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)	Main Association of Austrian Social Security 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 2008

Further bodies dealing with pharmaceuticals at federal level are the Restriction Committee (Abgrenzungsbeirat), Prescription Committee (Rezeptpflichtkommission) and the Restriction Commission (Abgrenzungskommission). The Prescription Committee meets on an annual basis and makes general suggestions for changes in prescription status. The Restriction Commission is an advisory body to the BMGFJ and is responsible for decisions whether pharmaceuticals may also be dispensed by dispensaries other than pharmacies (e.g. drugstores). However, the role of the Restriction Committee – which is also an advisory body to the BMGFJ – is the decision, whether the pharmaceutical fulfills the definition of a pharmaceutical.

The former National Institute of Pharmaceuticals (Bundesinstitut für Arzneimittel, BIfA), including the official Medicines Control Laboratory, which used to support the work of the BMGFJ 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 15,530 pharmaceuticals were authorised in Austria (counting different pharmaceutical forms and dosages and including homeopathics, but excluding different pack sizes). Of these, 7,952 pharmaceuticals are subject to the Prescription Act,[13] 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 BASG is the authority responsible for the classification of pharmaceuticals into prescription-only and non-prescription.

Table 2.2: Austria – Number of pharmaceuticals, 2000–2008[1]

Pharmaceuticals[2]	2000	2001	2002	2003	2004	2005	2006	2007	2008
Authorised	12,394	12,633	12,443	15,339	15,144	14,347	15,530	n.a.	n.a.
On the market	n.a.	n.a.	n.a.	n.a.	~ 60%	6,155[3]	n.a.	n.a.	n.a.
POM	8,062	7,904	8,320[4]	8,693[4]	8,758[4]	8,733[4]	7,952	n.a.	n.a.
Reimbursable	2,979[5]	2,965[5]	3,013[5]	3,049[5]	3,109[5]	3,926[5]	4,122[5]	n.a.	n.a.
Generics	n.a.	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.	n.a.
HOM	n.a.	n.a.	n.a.	n.a.	n.a.	~ 20%	n.a.	n.a.	n.a.

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

[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 homoepathics

[5] as of 1 July

Source: HVB 2007b, PHARMIG 2007, data gathering by GÖG/ÖBIG 2008

The number of reimbursable pharmaceuticals has increased substantially since 1 January 2005 when the new reimbursement scheme for pharmaceuticals ("Erstattungkodex", EKO) was introduced (cf. section 4.2). However, most of the pharmaceuticals that have been added to the list of reimbursable pharmaceuticals can only be prescribed under very specific

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

circumstances (for example only by a specialist, rather than a general practitioner. Decisions on reimbursement status are made by the HVB and based on certain criteria, described later (cf. section 4.2.1). In January 2008 about 1,000 substances or substance combinations, counted by ATC-5 code were included in the EKO.

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 OTC pharmaceuticals.

2.1.2.2 Consumption

In 2007 the annual number of prescriptions was 107,690,576 and in value € 2,180 Mio. In 2006 the annual consumption in packs was 108.5 million. In 2007 on average there were 17.5 prescriptions per insured person. Table 2.3 gives an overview on the annual prescriptions and consumption.

In Austria, there is no limitation on how many items (packs) a prescription may include.

Table 2.3: Austria – Annual prescriptions and consumption, 2000–2007[1]

Consumption	2000	2001	2002	2003	2004	2005	2006	2007
No. of prescriptions per year (in volume in thousand)	94,512	101,432	98,454	99,130	102,028	104,130	103,614	107,691
No. of annual prescriptions in value (in Mio. €)	1,147	1,644	1,722	1,836	1,950	2,028	2,060	2,180
No. of annual consumption in packs (in thousand)	166,372	167,448	171,476	175,985	179,404	189,056	n.a.	n.a.
No. of annual consumption in DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

DDD = Defined Daily Doses, n.a. = not available

[1] as of 1 January

Source: HVB 2008, PHARMIG 2008

2.1.2.3 Market data

Table 2.4 presents pharmaceutical market data for Austria. In 2006 the total pharmaceutical sales at consumer price level amounted to € 3,743,6 Mio. Between 2005 and 2006 total pharmaceutical sales rose by 4.3%, whereas between 2001 and 2002 total pharmaceutical sales increased by 10.4%. Pharmaceutical sales at ex-factory level amounted to € 2,543.5 Mio. in 2006, an increase of 5.5% compared to 2005.

Table 2.4: Austria – Market data, 2000–2007

In Mio. €	2000	2001	2002	2003	2004	2005	2006	2007
Pharmaceutical sales								
Sales at ex-factory price level[1]	n.a.	1,726.5	1,885.3	2,149.7	2,311.8	2,410.6	2,543.5	n.a.
Sales at wholesale price level	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales at PRP level[2,3]	n.a.	2,833	3,127.6	3,347.0	3,449.4	3,588.17	3,743.57	n.a.
Sales in hospitals[1,5]	n.a.	n.a.	458.9	634.9	690.7	719.3	790.8	n.a.
Sales of generics[4,6]	55.5	63.7	76.3	100.2	126.2	171.0	n.a.	
Sales of parallel traded pharmaceuticals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Exports and imports								
Total pharm. exports	1,982	n.a.	3,042	3,003	2,875	3,606	4,234	n.a.
Total pharm. imports	2,141	n.a.	3,092	2,947	2,996	3,366	3,905	n.a.

n.a. = not available, pharm. = pharmaceutical, PRP = pharmacy retail price
[1] source: PHARMIG 2008
[2] source: AESGP 2007
[3] including SD-doctors, excluding hospital sales
[4] source: OEGV 2006, PHARMIG 2008
[5] at ex-factory price level
[6] sold in pharmacies
Source: EFPIA 1998-2006, HVB 2007b, data gathering by GÖG/ÖBIG

The share of generics sales is relatively low in Austria. In terms of value, generics sales made up 14.5% of the total sales of pharmaceuticals in terms of manufacturer prices in 2007 (cf. section 5.5).

In 2006, the total pharmaceutical export amounted to € 4,234 Mio. Table 2.5 lists the top 10 best-selling reimbursable pharmaceuticals by active ingredient, based on their turnover in 2007.

Table 2.5: Austria – Top 10 best-selling reimbursable pharmaceuticals (highest turnover), by active ingredient, 2007

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 2008

2.1.2.4 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 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. section 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.[14] This number includes 24 manufacturing companies[15] 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, Biochemeie 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 relatively low with about 14.5% (2007) of the market in terms of turnover at pharmacy level.

Pharmaceutical production in Austria amounted to € 1,799 Mio. in 2005, a significant rise compared to the year 2003 when production was € 1,344 Mio.[16] The total pharmaceutical sales at ex-factory level have continued to rise over the years and amounted to € 2,543.5 Mio. in 2006. In recent years, the total values of pharmaceutical imports and exports were almost balanced (cf. Table 2.4). 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 the vast majorities of deliveries to pharmacies, direct supply by pharmaceutical manufacturers is allowed (provided that the manufacturer has obtained a wholesale licence from the federal authorities). The approximate share of direct deliveries is

[14] PHARMIG Facts & Figures 2003

[15] Statistik Austria, personal communication, 2005

[16] EFPIA 2007, 2005

reported to be three percent. SD-doctors may only procure pharmaceuticals from pharmacies, but this provision is evaded in practice by wholesalers holding a pharmacy concession.

The Austrian pharmaceutical industry employed 10,000 people in 2005[17], which is significantly lower than in other EU countries that have a stronger industry presence.

Table 2.6: Austria – Key data on the pharmaceutical industry, 2000–2007[1]

Pharmaceutical industry	2000	2001	2002	2003	2004	2005	2006	2007
Total no. of companies	103[2]	n.a.	160	160	~ 220	~ 220	222.	n.a.
- research-oriented	n.a.	n.a.	n.a.	24	n.a.	n.a.	n.a.	n.a.
- generic producers	n.a.	n.a.	n.a.	~ 9	n.a.	n.a.	n.a.	n.a.
- biotech	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Number of persons employed[3]	n.a.	n.a.	n.a.	9,523	n.a.	10,002	n.a.	n.a.

n.a. = not available, ~ = estimate

[1] as of 1 January

[2] 1999

[3] counted per head

Source: PHARMIG Facts & Figures 1998-2007, EFPIA 2007

2.1.3.2 Wholesalers

The manufacturers deliver their pharmaceuticals to about 35 distributors including shortliners and pre-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 HEK and the PK through the WKÖ).

Pharmaceutical wholesale is organised as a multi-channel system. 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 maxium 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.

[17] EFPIA 2007

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 2.7: Austria – Key data on pharmaceutical wholesale, 2000–2007[1]

Wholesalers	2000	2001	2002	2003	2004	2005	2006	2007
Total number of wholesale companies	10	n.a.	n.a.	n.a.	10	10	9	9
Total number of full-line wholesale companies	5	n.a.	n.a.	n.a.	8	8	8	8
Total number of outlets	27	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available

[1] as of 1 January

Source: GIRP 2008

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 GP has his/her practice, and the distance to the nearest pharmacy is more than six kilometers, both prescription-only-medicines (POM) and OTC pharmaceuticals may be dispensed through self-dispensing doctors. Drugstores are only allowed to sell a very restricted range of non-pharmacy OTC pharmaceuticals, in particular dietary supplements.

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;
- 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 GP has his/her practice within the same municipality.

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

Another criterion for the establishment of a new pharmacy is the space available in the premises. The Regulation of the Opeation of Pharmacies[19] defines a minimum size of 120 m^2 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 2008, there were 1,217 community pharmacies in Austria (of which 19 were branch pharmacies) and 5 hospital pharmacies acting as community pharmacies. This corresponds to about 1 POM dispensary per 3,816 inhabitants or 0.26 POM dispensaries per 1,000 inhabitants (data from 2008) (cf. Table 2.8).[20]

Table 2.8: Austria – Retailers of pharmaceuticals, 2000–2008[1]

Retailers	2000	2001	2002	2003	2004	2005	2006	2007	2008
Number of community pharmacies[2]	1,106	1,133	1,147	1,160	1,182	1,191	1,184	1,200	1,217
No. of private pharmacies	1,106	1,133	1,147	1,160	1,182	1,191	1,184	1,200	1,217
No. of public pharmacies	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Number of hospital pharmacies for outpatients	5	5	5	5	5	5	5	5	5
Number of other POM dispensaries: SD-doctors	987	998	982	993	989	992	992	978	962
Total number of POM dispensaries[1]	2,098	2,136	2,134	2,158	2,176	2,188	2,176	2,183	2,184
No. of internet pharmacies	n.app.	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.	n.a.

n.a. = not available, n.app. = not applicable, no. = number; OTC = Over-The-Counter, POM = prescription-only-medicines, SD-doctors = self-dispensing doctors

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

[1] as of 1 January

[2] incl. branch pharmacies

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

Source: ÖAK 2008s

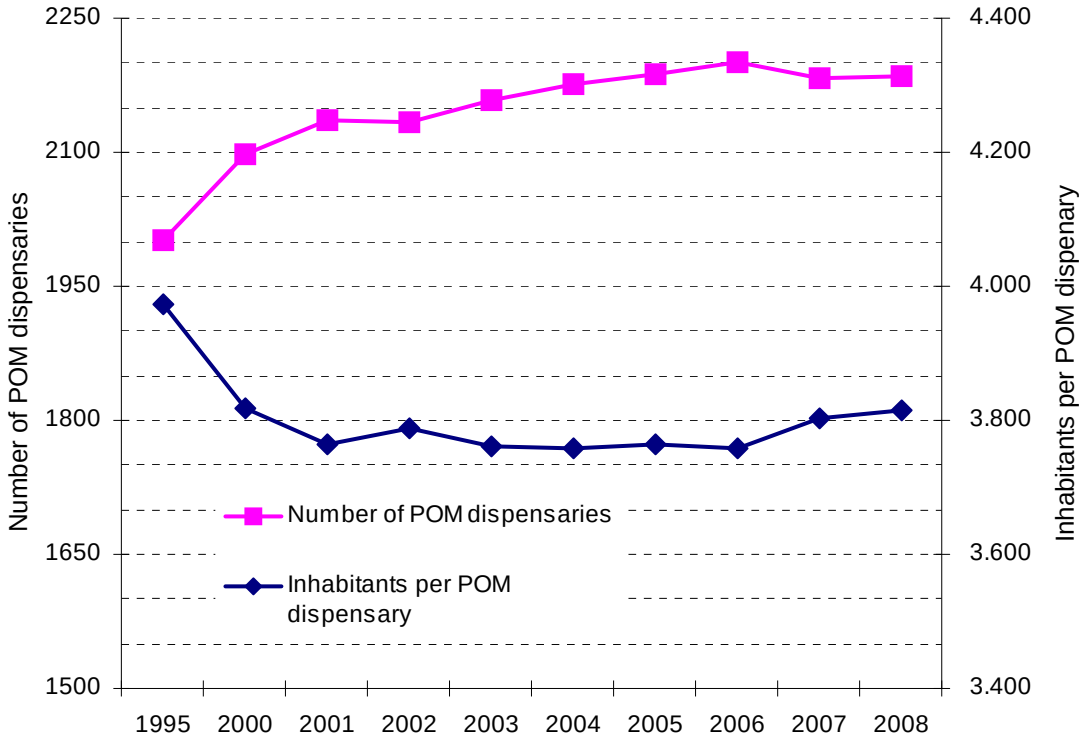
Every community pharmacy is allowed to open a maximum of one branch pharmacy, provided that the distance to the nearest pharmacy is more than 4 km. This branch pharmacy is under the supervision of the (main) pharmacy. Apart from running a maximum of one branch

[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)

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 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, 1995 and 2000–2008



POM = prescription-only-medicines; all POM dispensaries = including branch pharmacies, self-dispensing doctors, and other university pharmacies, policlinic pharmacies and hospital pharmacies acting as community pharmacies

Source: Data gathering by GÖG/ÖBIG 2008

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 Pharma-

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

cists (ÖAK). Through the ÖAK pharmacists are also represented in the HEK and the Prescription Committee (Rezeptpflichtkommission).

In general, hospitals are not allowed to run pharmacies for outpatients. 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, POM and OTC pharmaceuticals, cf. section 3.5.2). Rebates (in cash) from wholesalers to pharmacies are quite common in Austria, whereas rebates from manufacturers to pharmacies are not.

Looking at the distribution of pharmaceuticals in Austria, in 2008 64% of pharmaceutical prescriptions were sold through pharmacies and SD-doctors, 14% through hospital pharmacies and the remaining 2% were sold thorugh other distribution channels, such as supermarket.

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 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, SD-doctors play an important role, as they constitute nearly half of all POM dispensaries (cf. Table 2.8).

In a municipality without a pharmacy a GP (“Arzt für Allgemeinmedizin”) who has a contract with a social insurance company according to the ASVG[23] is entitled to apply for a licence for the dispensing of pharmaceuticals, if no pharmacy is established within the community in which the 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 Enactment [Österreichische Arzneitaxe, 1962 i.d.F. BGBl. II No. 433/2005]

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

In January 2008, the Austrian pharmaceutical distribution system included 962 SD-doctors. The 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)[24] SD-doctors are remunerated via the same statutorily fixed mark up as pharmacies (cf. section 3.5.2). Also according to the Austrian Pharmaceutical Tax Enactment,[25] self-dispensing doctors have to pay the Main Association of Austrian Social Security 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. section 3.6.1).

Discounts in kind ("natural rebates") granted by the pharmaceutical industry to SD-doctors are prohibited[26] in order to counteract the possibility of influencing the prescribing decisions of 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 2008 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 outpatients. According to the Hospitals Law (Krankenanstalten- und Kursanstaltengesetz, KAKuG)[27] 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

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

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

[26] 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]

[27] Austrian Hospitals Law [Krankenanstalten- und Kuranstaltengesetz (KAKuG 1957) i.d.F. BGBI. II No. 65/2002]

advantageous or equivalent pharmaceuticals are available on the market, the cheapest one 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 LKF system ("Leistungsorientierten Krankenhausfinanzierung"), comparable to the 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 outpatient sector for patients who have been released from hospital.

2.1.3.5 Doctors

Doctors are represented in committees such as the HEK by the ÖÄK.

The prescription volume or prescribing habits of doctors are monitored by the individual sickness funds with regard to their compliance with the HVB Guidelines on Economic Prescribing (RöV)[28], 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. section 5.2).

All pharmaceuticals listed in the 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 POM, the patient receives limited information on the price and the product. All POM are fully paid for by the sickness funds, independent of the type of POM, the pack size, and dispensing pharmacy (cf. section 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 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 EKO be-

[28] Guidelines on Economic Prescribing of Pharmaceuticals and Medicinal Products [Richtlinien über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005)], www.avsv.at

sides the brand-name originator Zocord®, which also may be freely prescribed at the expense of the sickness funds.

According to the RöV,[29] 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 EKO (Positive list) (cf. section 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 € 2,913 Mio. in 2005. 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 8.5 % in 2005, whereas the share of private pharmaceutical expenditure has been kept relatively stable (3.2% in 2005).

Pharmaceutical expenditure of the health insurance institutions amounted to € 2,605.510 in 2006.

[29] Art. 10.2 Guidelines on Economic Prescribing of Pharmaceuticals and Medicinal Products [Richtlinien 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 2.9: Austria – Total pharmaceutical expenditure, 2000–2007

Pharmeceutical Expenditure	2000	2001	2002	2003	2004	2005	2006	2007
TPE in € (Mio.)	2,482	2,517	2,714	2,907	2,955	2,913	n.a.	n.a.
TPE as a % of THE	11.8	11.6	12.2	12.6	12.2	11.6	n.a.	n.a.
TPE per capita in €	306	310	336	358	361	354	n.a.	n.a.
Public PE as a % of THE	8.1	8.1	8.5	8.7	8.6	8.5	n.a.	n.a.
Private PE as a % of THE	3.7	3.5	3.7	3.9	3.6	3.2	n.a.	n.a.

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

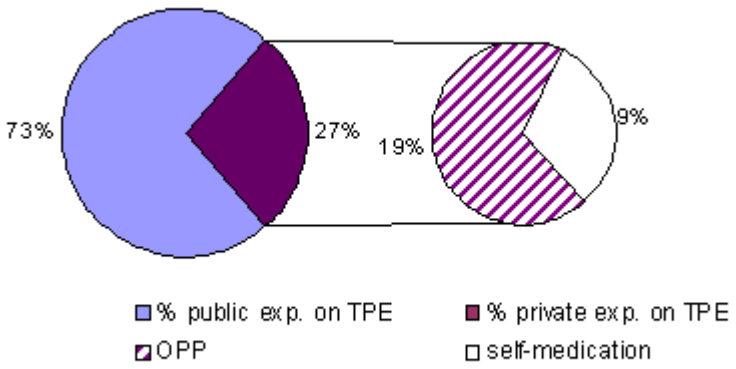
Source: OECD Health Data 2008

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 OPPs and private health insurance) and taxes (20%) (cf. section 1.4.2).

Private pharmaceutical expenditure makes up 27.2% of the TPE in 2005, which can be further subdivided into expenses for self-medication (18.6%) and OPPs (8.6%). 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 72.8% in 2005.

Figure 2.3: Austria – Share of private and public pharmaceutical expenditure, 2007



TPE = total pharmaceutical expenditure

Source: OECD Health Data 2008

2.3 Evaluation

At the moment pharmaceutical policies are not regularly monitored. According to the new governmental programme (2007) it is planed to evaluate the EKO, the EU average price system and the price notification system (cf. section 6.2).

One of the last major changes in the pharmaceutical system, the establishment of the Independent Pharmaceutical Committee (cf. section 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 EKO in 2004 (cf. section 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 (Preisgesetz[30]) 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, Family and Youth (BMGFJ) but the BMGFJ needs 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 BMGFJ. 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 BMGFJ, which is assisted by the Pricing Committee (PK) that meets once a month. The PK consists of representatives of each of the following institutions besides the BMGFJ itself, which also acts as chair of the Committee:

- the 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.

Since 1 September 1999, in addition to the Price Act, a price notification agreement between the BAK and WKÖ has been in place. Manufacturers have to notify the BMGFJ of the ex-factory price for new products or of price changes. This pricing procedure is applied to all pharmaceuticals (on- and off-patent, POM or OTC products).

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 EKO. Pharmaceuticals included in the EKO have to be priced either according to the EU av-

[30] 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]

erage price, as established by the PK, or below this price. Decisions on the reimbursement status are made by the Main Association of Austrian Social Security Institutions (HVB) on the basis of recommendations of the Pharmaceutical Evaluation Board (HEK) (cf. section 4.1).

The HVB decides in accordance with the Transparency Directive[31] within 90 days (180 days in the case of an application to have a product's status changed) from the date it receives the recommendation of HEK. Further information on price reviews is given later (cf. section 3.6.4).

Besides the EU average price which applies for pharmaceuticals that are included in the EKO, there is the possibility of further price negotiations with the HVB (cf. section 3.2.2) and in addition there are special pricing regulations for, e.g., generics (cf. section 3.4.2).

3.2 Pricing policies

As mentioned earlier (cf. section 3.1), according to the Price Act of 1992[32], the BMGFJ is entitled and obliged to calculate a "national price justified in terms of the national economy". The BMGFJ advised by the PK therefore calculates the EU average price for all pharmaceuticals applying for reimbursement. When doing so the PK may ask the GÖG/ÖBIG to check the price information delivered by the pharmaceutical companies.

However, in practice the price notification system under the agreement between the BAK and the WKÖ is the most common pricing procedure in Austria.

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

[31] Council Directive 89/105/EEC

[32] 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, 2008

	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 customers" i.e. SHI)	
Institution in charge of pricing	- BMGFJ advised by PK - price negotiation between industry and HVB, advised by HEK		
Legal Basis	- 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; - BMGFJ 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 = Bundesminsterium für Gesundheit und Frauen (Federal Ministry of Health and Women), BMGFJ = Bundesministerium für Gesundheit, Familie und Jugend (Federal Minitstry of Health, Family and Youth), EKO = Erstattungskodex (Austrian Reimbursement Code), EU = European Union, HEK = Heilmittel-Evaluierungskommission (Pharmaceutical Evaluation Board), HVB = Hauptverband der österreichischen Sozialversicheurngsträger (Main Association of Austrian Social Security Institutions), n.app. = not applicable, OTC = over-the-counter pharmaceuticals, PK = Preiskommission (Pricing Committee), POM = prescription-only-medicines, SHI = social health insurance

Source: GÖG/ÖBIG 2006

In order to find a justified reimbursement price, external referencing pricing was 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 EU average price[33] (cf. sections 3.2.1 and 3.3.1 for further explanations).

[33] 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.bmgfj.gv.at/cms/site/standard.html?channel=CH0723&doc=CMS1078931881119]

There are different pricing rules (cf. section 3.4.2) for the inclusion of generics in the 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. section 3.4.4).

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

3.2.1 Statutory pricing

In general, prices are either calculated by the BMGFJ advised by the 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. section 3.5).

According to the Price Act, if such a notified price is deemed too high from the perspective of th Austrian economy, the BMGFJ has the opportunity to start an official price-fixing process (cf. section 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. section 3.6.4).

The EU average price is only set for pharmaceuticals applying for inclusion into the EKO. The regulations of the EKO and its system of coloured boxes are explained in more detail later (cf. section 4.2.2). According to the procedure on the calculation of the EU average price[34], 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. section 3.3.1). The GÖG/ÖBIG is responsible for checking the prices submitted by the industry on a random basis.

The 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 on-patent pharmaceutical is marketed in at least half of the European Union Member States and generics 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 EKO. The EKO is divided into different boxes (cf.

[34] 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.bmgfj.gv.at/cms/site/standard.html?channel=CH0723&doc=CMS1078931881119

Table 4.1). The EU average price is also the maximum limit for pharmaceuticals in the yellow box of the EKO and green box products must always be priced below the EU average price.

Furthermore, the HVB may negotiate ex-factory prices with pharmaceutical companies (cf. section 3.2.2).

3.2.2 Negotiations

In Austria, price negotiations are a tool used in addition to the common method of setting the EU average price. Therefore, the EU average price at manufacturer level for pharmaceuticals of the EKO can be further negotiated with the HVB. The legal framework of the price negotiations is contained in the Procedural Rules for the publication of the EKO[35]. The procedure for the price negotiations is based on price referencing (cf. section 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 UHK.

3.2.3 Free pricing

Free pricing at ex-factory price level is applied for non-reimbursable pharmaceuticals, which are mostly 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 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. section 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.

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.

[35] 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: Austria – Pricing procedures, 2008

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 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 EU average price system in 2004 the comparison method and the relevant country basket – which consists of all EU Member States – were fixed according to the BMGFJ Regulation on Procedural Rules for Calculation of the EU average price, published on 1 October 2005[36]. 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 EKO has to provide information, including whether the product is on the market in other 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).[37] GÖG/ÖBIG may be 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.

[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.bmgfj.gv.at/cms/site/standard.html?channel=CH0723&doc=CMS1078931881119]

[37] Price notification form according to Regulation on Procedural Rules for Calculation of the EU average price, http://www.bmgfj.gv.at/cms/site/standard.html?channel=CH0723&doc=CMS1078931881119

3.3.2 Internal price referencing

Internal price referencing is applied in the course of the application for inclusion in the 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. section 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 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 green[38] and in the yellow[39] 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. section 3.4.2) becomes available, the HVB re-initiates price negotiations over the price of the original product (cf. section 3.1). Companies are obliged to notify the HVB of patent expiries. If no generic is launched in Austria in the wake of a patent expiry, the HVB still may – on recommendation of the 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 the social security system” (Finanzierungs-Sicherungs-Beitrag)[40], 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

[38] Art. 25.2 VO-EKO

[39] Art. 25.5 VO-EKO

[40] 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]

20% 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 EU average price system in the following way: in the event that the EU average price, established by the 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 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 medicines (HOM), generics, OTC products and parallel traded pharmaceuticals are explored in more detail.

3.4.1 Hospital-only medicines

As mentioned earlier, prices for HOM are set in a different way. Pharmaceutical companies submit their price application at the BMGFJ. The BMGFJ 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 HOM via tendering processes and invidual negotiations.

3.4.2 Generics

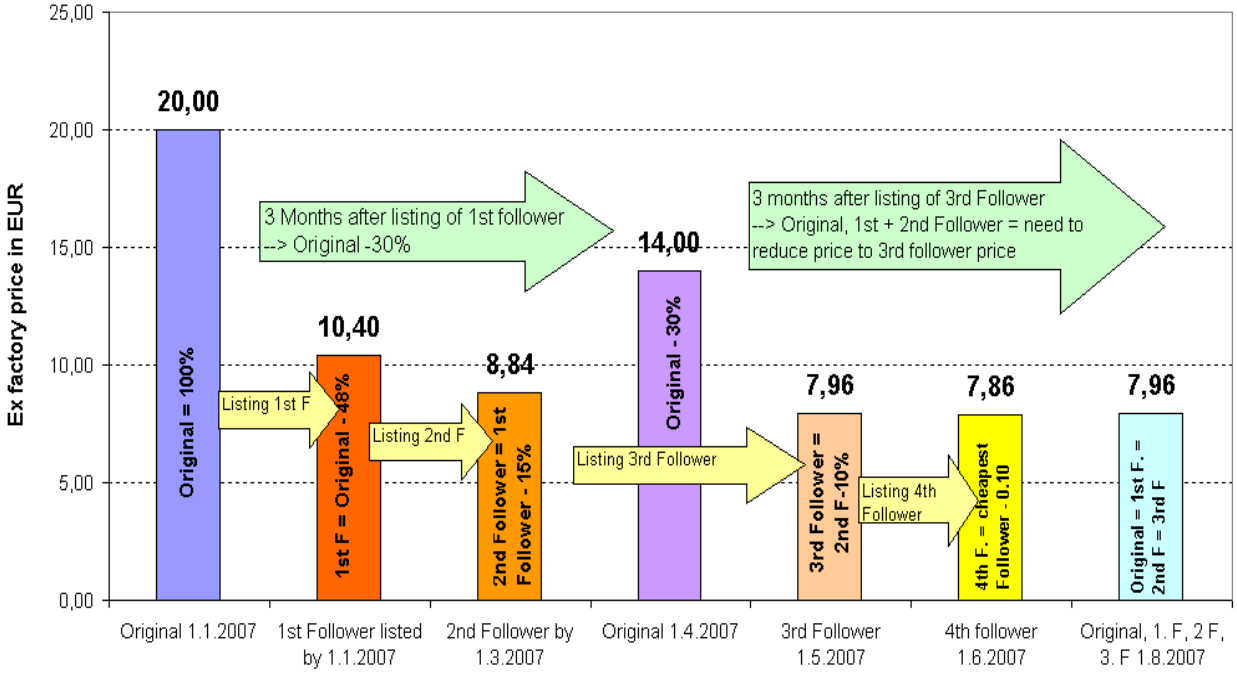
For generics (defined as products containing bio-equivalent substances of off-patent original brand) different pricing rules for inclusion in the EKO apply. Generics are usually included in the green box, however, prior to the formal decision of the Pharmaceutical Evaluation Board (HEK) they are initially included in the red box.

The ASVG[41] and the Procedural Rules for publication of the EKO[42] state that in this case economic efficiency of the first generic product is established if the price is at least 48% below the price of the now off-patent original brand. Economic efficiency is assumed if the second and each subsequent generic “follower” offer a pre-determined price difference to the previous included generic (e.g. second follower needs to reduce it's price by 15% compared to the first follower, cf. Figure 3.1). 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.

[41] Art. 351c.10 ASVG

[42] 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

Figure 3.1: Austria – Price modification of original brand and followers at the inclusion of followers in the Green Box of the Austrian Reimbursement List (EKO), 2007



Source: HVB 2007

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 EKO at the latest three months after the inclusion of the third generic product with the same active ingredient into the EKO.

3.4.3 Over-The-Counter pharmaceuticals

In Austria most OTC products are non-reimbursable pharmaceuticals. Non-reimbursable pharmaceuticals are not listed in the red, yellow or green boxes of the EKO, and patients therefore have to pay the full amount out-of pocket (cf. section 4.4.1). Since most OTC products are not included in the EKO the price notification procedure is applied (cf. section 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. section 3.2), parallel importers do not need to file a seperate 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 EKO (e.g. because of its different pack size) they have to negotiate the price with the 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, 2008

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 2008

3.5.1 Wholesale remuneration

In Austria, wholesalers are remunerated via a statutory regressive mark up scheme applicable to all pharmaceuticals[43]. From 1 January 2004, there are different mark up schemes for pharmaceuticals included in the yellow or green boxes of the EKO and for all other pharmaceuticals. Before this, there was one single mark up scheme for all pharmaceuticals.

[43] Enactment of the BMGF on the maximum mark ups in pharmaceutical wholesale 2004 [Verordnung des BMGF über Höchstaufschläge im Arzneimittelgroßhandel 2004] , http://www.bmgfj.gv.at/cms/site/attachments/0/3/3/CH0723/CMS1071504141891/vo_hoechstaufschlaege_am.pdf

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 9.0% for the reimbursement market.

Table 3.4: Austria – Wholesale mark up scheme for products included in the yellow and green boxes of the Reimbursement Code, 2008

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 (BMGF) on the maximum mark ups in pharmaceutical wholesale 2004

Table 3.5: Austria – Wholesale mark up scheme for products not included in the green and yellow boxes of the Reimbursement Code, 2008

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 (BMGF) on the maximum mark ups in pharmaceutical wholesale 2004

3.5.2 Pharmacy remuneration

According to the Austrian Pharmaceutical Tax Enactment (Österreichische Arzneitaxe)[44] pharmacies are remunerated via a statutorially fixed mark up scheme applicable to all pharmaceuticals (on- and off-patent, POM and 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 hospitals[45] (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,[46] valid since 1 February 1997.

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

[45] 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]

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

Table 3.6: Austria – Pharmacy mark up scheme for privileged customers, 2008

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

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 OTC products).

The Austrian Pharmaceutical Tax Enactment 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. section 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, 2008

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, SD-doctors supply pharmaceuticals to patients. SD-doctors have to procure the pharmaceuticals through a pharmacy. In practice some wholesalers also have a pharmacy licence, thus supplying pharmaceuticals to SD-doctors.

3.5.3 Remuneration of other dispensaries

The reumuneration 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, POM and OTC products).[47] These fees are only applicable for pharmaceuticals, not for medical devices. SD-doctors have to grant a 3.6% discount (2006) to "privileged customers" (cf. section 3.6.1).

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

In Austria pharmaceuticals are also dispensed in hospital pharmacies (cf. section 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% VAT rate, the second highest rate in the EU after Denmark. 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 PRP. The Federal Ministry of Finance (BMF) refunds part of the VAT on reimbursed products to the sickness funds. It is planned to reduce the VAT on pharmaceuticals to 10% in the year 2009.

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 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.

Growing pharmaceutical expenditure (PE) led to another agreement between the 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.[48] This has resulted in different mark ups for “privileged customers” (i.e. sickness funds) and private customers. Similar regulations apply to SD-doctors.

As mentioned earlier there are 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).[49] It is a sort of

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

[49] 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]

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% 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 SD-doctors in summer 2005. Following the public discussion these kinds of rebates were explicitly prohibited in an amendment to the Austrian Medicines Act[50] 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. sections 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 further margin cut by offering a sort of pay-back ("Solidarity Contribution") to the Austrian sickness funds executed by the 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 EU average price system together with the new 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 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%.

[50] 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]

3.6.4 Price reviews

Considering the price consultation of the 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 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 HVB, which was explained in more detail earlier (cf. section 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.[51]

In Austria, reimbursement of pharmaceuticals is characterised by reimbursement in kind. On a very general level all duly registered pharmaceuticals are reimbursable by SHI for certain diseases if there is no treatment alternative.[52] 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.[53]

All pharmaceuticals listed in the Reimbursement Code (EKO)[54] 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. section 3.1), the pricing and reimbursement system are very closely linked, since there are special pricing rules for pharmaceuticals applying for inclusion in the EKO.

In Austria, there are 19 sickness funds, being represented by their umbrella organisation the Main Association of Austrian Social Security Institutions (HVB). The HVB consulted by the Pharmaceutical Evaluation Board (HEK) is responsible for deciding whether a pharmaceutical should be reimbursed or not. The 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 UHK functions as an appeal court to whom manufacturers may turn in case of reimbursement applications being turned down, etc.

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 EKO to the HVB. Since 1 September 2005 the application can be submitted electronically. The application needs to include

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

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

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

[54] Art. 31.3(12), on the publication of the Reimbursment Code EKO (Art. 31.3(12) latest amended by BGBl. I No. 131/2006

information, including whether the pharmaceutical is on the market in 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. To do this, the companies have to complete a form, which was developed by the Pricing Committee (PK).[55] The GÖG/ÖBIG is - on request of the PK - responsible for checking the prices submitted by the industry.

The HVB decides within 90 days from the complete application, on the recommendation of the HEK, whether the pharmaceutical qualifies for inclusion into the EKO at all.

4.1.1 Appeal procedure

In the case of a negative decision, the manufacturer may appeal to the UHK.[56] All committee members, including those of the HEK, are independent experts nominated by several public bodies in Austria such as the WKÖ, the BAK, the ÖÄK, various sickness funds, the ÖAK, the GÖG/ÖBIG, etc.

The UHK was established in the course of the 60th amendment to the ASVG in 2002 as an appellation court to assess the decision of the HVB on the inclusion of a pharmaceutical in the EKO (cf. section 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 HVB.[57] The manufacturer has the right to comment or complain against any such decision to the UHK.[58]

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. section 3.5.2). This mark up scheme is applicable to all pharmaceuticals dispensed on behalf of the sickness funds, re-

[55] Price notification form according to Regulation on Procedural Rules for Calculation of the EU average price, http://www.bmgfj.gv.at/cms/site/standard.html?channel=CH0723&doc=CMS1078931881119

[56] Details on the UHK, e.g. procedure regulations and topics may be found at http://www.bmgfj.gv.at/cms/site/standard.html?channel=CH0723&doc=CMS1096983721392

[57] Art. 35 VO-EKO

[58] Details on the UHK, e.g. procedure regulations and topics may be found at http://www.bmgfj.gv.at/cms/site/standard.html?channel=CH0723&doc=CMS1096983721392

gardless 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 ASVG published in 2003 (61st Amendment of the ASVG)[59] and the Procedural Rules for publication of the EKO are fixed by decree (Verfahrensordnung Erstattungskodex, VO-EKO).[60]

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 ASVG.

If the pharmaceutical qualifies for inclusion on the basis of these rather formal criteria the HEK will study the therapeutic benefits of the pharmaceutical in question, basing their analysis on pharmacological, medical-therapeutic, and health-economic data[61] (cf. section 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 and frequency of administration are also taken into account. The criteria / data which are evaluated can be found in the Annex of the new VO-EKO.
- As far as the health-economic aspect is concerned, according to the Procedural Rules for publication of the new VO-EKO[62] pharmacoeconomic evaluations have to be submitted by the market authorisation holder if applying for inclusion to the EKO for an innovative product, providing an substantial therapeutic benefit, or if applying for inclusion to the yellow box, if no comparable medicinal preparation is listed in this box.

After assessment of the above three categories the 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 EKO is given later (cf. section 4.2.2).

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

60 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

61 Art. 351g.2 ASVG

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

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 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. section 4.1), the HVB decides on the reimbursement status upon the recommendation of the HEK. If the application for reimbursement is denied the manufacturer may appeal to the UHK (cf. section 4.1).

4.2.2 Reimbursement categories and reimbursement rates

In Austria, there is a positive list, the EKO (cf. section 4.1). All pharmaceuticals included in the 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. section 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 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).

The pharmaceuticals in the EKO are categorised in accordance with the WHO’s ATC classification. The 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, 2008

Reimbursement category[1]	Characteristics of category
Red Box	**Scope:** • Newly launched pharmaceuticals and all pharmaceuticals (including off-patents) that have applied for inclusion into the EKO the yellow or green box **Procedure:** • Stay in box for a period of 24 to 36 months - 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; 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 HVB on inclusion into yellow or green box • HEK studies the therapeutic benefits of the product, basing their analysis on pharmacological, medical-therapeutic and health-economic data, then recommends inclusion or not into the yellow or green box **Conditions for reimbursement**: • Ex-ante approval of head physician sought by the doctor prescribing the pharmaceutical to the patient is needed for reimbursement **Price:** • Priced at the 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 HVB within 90 days of receipt of the PK recommendations
Yellow Box	**Scope:** • Pharmaceuticals with fundamental therapeutic benefits or considered important therapeutic innovation ("essential added therapeutic value") **Conditions for reimbursement:** • Pharmaceuticals are only reimbursed - 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 • Ex-ante approval of head physician sought by the doctor prescribing the pharmaceutical to the patient is needed for reimbursement **Price:** • Price must not exceed the EU average price, applications for price increments are decided upon by the HVB within 90 days

Reimbursement category[1]	Characteristics of category
Light Yellow Box	**Scope:** • Same as for other yellow box products **Conditions for reimbursement:** • Same conditions as for yellow box, but for indications as defined in the 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:** • Same as for yellow box pharmaceuticals
Green Box	**Scope:** • "Standard" pharmaceuticals (all pharmaceuticals originally listed in the old Reimbursement List (Heilmittelverzeichnis) and pharmaceuticals prepared by pharmacists (unless registered in the yellow box) • Pharmaceuticals considered medically and health-economically sound, identical or similar therapeutic effects to already available pharmaceuticals – many generics and off-patent products **Conditions for reimbursement:** • In general no conditions, pharmaceuticals may be prescribed by any contract physician • Restrictions concerning specialist prescription or age of patient are possible **Price:** • 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 HVB within 90 days

Reimbursement category[1]	Characteristics of category
Not listed pharmaceuticals	**Scope:** • Contains pharmaceuticals that are deemed unsuitable for use in outpatient medical care, e.g. because they are used in a hospital setting under constant medical supervision or used for preventive purposes[63] **Conditions for reimbursement:** • 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 **Price:** • The ex-factory price of such pharmaceuticals is freely determined by industry, whereas the respective statutory wholesaler and pharmacy mark ups ("privileged customers") are set

[1] Reimbursement Code (EKO) is divided into different boxes, which can be seen as reimbursement categories

EKO = Reimbursement Code, EU = European Union, HEK = Pharmaceutical Evaluation Board, HVB = Main Association of Austrian Social Security Institutions, PK = Pricing Committee, SHI = Social Health Insurance

Source: GÖG/ÖBIG 2008

Besides the mentioned categories there are also pharmaceuticals on the market that did not 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 did not apply for reimbursement status.

4.2.3 Reimbursement lists

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

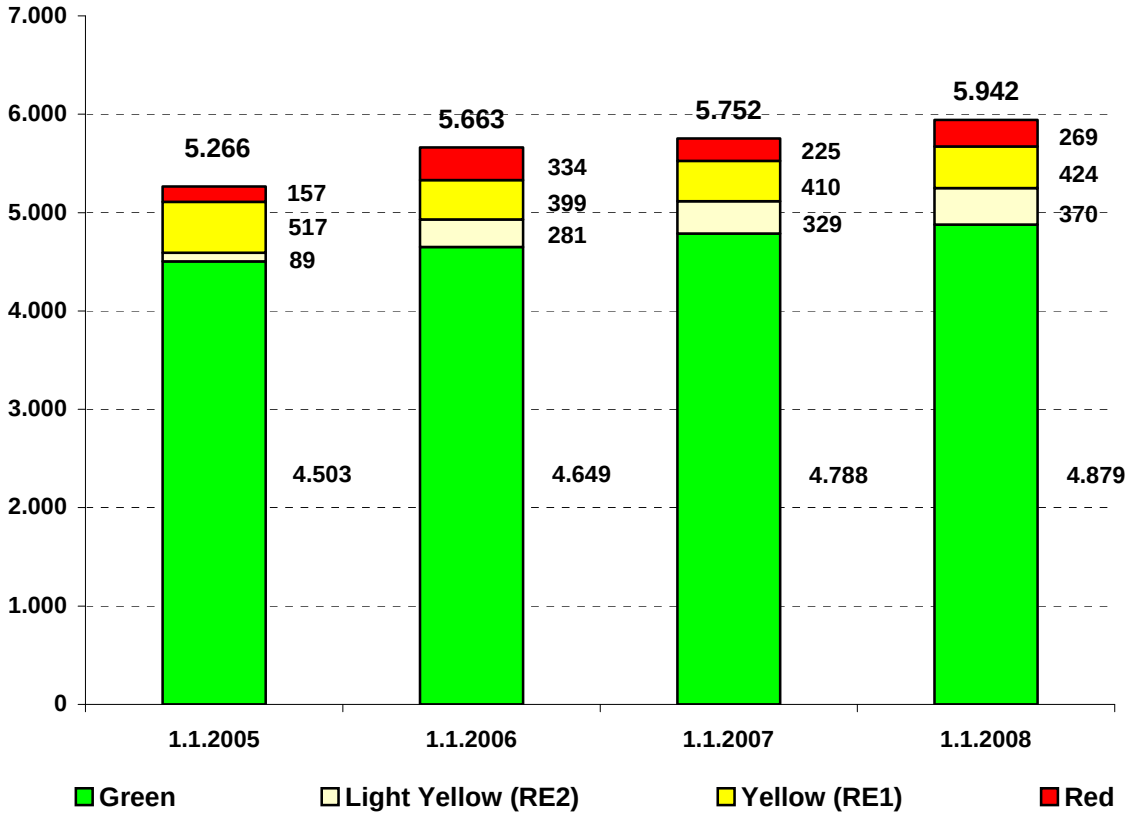
The eligibility criteria for whether a pharmaceutical can remain in the EKO or not were explained in more detail earlier (cf. section 4.2.1).

The 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 the green, yellow and light-yellow boxes of the EKO, whereas the red box is only available via the Internet as it may change daily. Besides information on the ATC classification, brand name, available pharmaceutical forms, dosage and pack size, the 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.

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

The 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 inpatient treatment.

Figure 4.1: Austria – Development of pharmaceuticals in Reimbursement Code[1], 2008



[1] number of packages

Source: HVB 2008a

As displayed in Figure 4.1 the number of pharmaceuticals included in the new 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 January 2005 5,266 pharmaceuticals (counted by packs) are included in the EKO. In 2008 the number was 5,942 packs (and approximately 1,000 substances counted by ATC-5 code).

However, most of the pharmaceuticals that have been added to the 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 individ-

ual 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.

In spring 2008 discussions started on a possible introduction of a reference price system. Due to parliamentary election reforms were postponed.

4.4 Private pharmaceutical expenses

In Austria, all pharmaceuticals that are included in the EKO are fully reimbursable. The only private expense for patients, as far as pharmaceuticals that are included in the EKO are concerned is the prescription fee. There are exemptions for socially disadvantaged patients and patients with communicable diseases (cf. section 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 price system (cf. section 4.3) nor generic substitution (cf. section 5.5.1) are relevant in Austria.

4.4.1 Direct payments

As mentioned earlier (cf. section 4.2.3), pharmaceuticals not listed in the red, yellow or green boxes of the 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 criteria[64] for the exclusion of pharmaceuticals from general reimbursement include if the pharmaceutical categories are deemed unsuitable for use in outpatient care, either because they are used in a hospital setting under constant medical supervision (cf. section 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

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

again calculated on the basis of the mark up scheme for “privileged customers” (cf. section 3.5.2). On average 45,000 prescriptions per month were approved via the individual reimbursement procedure in 2005.[65]

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 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 price system (cf. section 4.3) nor generic substitution (cf. section 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 2008, the prescription fee amounted to € 4.80 as it is annually adjusted by the inflation rate (in 2007 it was € 4.70).[66] The latest extraordinary rise happened in October 2000 when the fee was changed by 22.2% to € 4. Patients do not have to pay any other additional payments for reimbursable pharmaceuticals.

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

[66] 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]

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.[67]

4.4.2.2 Percentage co-payments

There are no percentage co-payments in Austria.

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 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 VAT is assigned to inpatient care funding.

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

In general, each public hospital has to have a pharmaceutical committee (Arzneimittelkommittee) 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)[68] (cf. section 5.2).

[67] 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

[68] Guidelines on Economic Prescribing of Pharmaceuticals and Medicinal Products [Richtlinien über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005)], www.avsv.at

4.6.1 Major changes in reimbursement lists

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

4.6.2 Introduction / review of reference price system

In Austria, there is no reference price system. In spring 2008 discussions started on a possible introduction of a reference price system. Due to parliamentary election reforms have been postponed.

4.6.3 Introduction of new / other out-of pocket payments

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

4.6.4 Claw-backs

There are no explicit claw-backs in Austria, but the 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 ATC classification, etc.). However, if a pharmaceutical included in the EKO goes off-patent and the first followers enter the market the HVB starts a price-lowering process (cf. sections 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 GPs and specialists are monitored by the individual sickness funds with a view to their compliance with the Main Association of Austrian Social Security Institutions (HVB) Guidelines on Economic Prescribing (RöV)[69] in which doctors are encouraged to prescribe the most economic 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. section 5.2).

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

5.2 Prescription guidelines

As mentioned earlier (cf. section 5.1), the RöV[70] in use. These guidelines were published in 2004 by the HVB on the basis of the ASVG[71] 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. section 4.4.1), if treatment is necessary for therapeutic reasons and no medication for treatment of the disease is available in the EKO. The RöV also set out general criteria on approval by the head physician for pharmaceuticals in the EKO.

The sickness funds monitor to a greater or lesser extent the prescription patterns of their contracted GPs and specialists as these are obliged to comply in their prescribing practices with the 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 choose the most cost-effective one. This system is also called the “Red-Light System“(cf. section 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.

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[69] Guidelines on Economic Prescribing of Pharmaceuticals and Medicinal Products [Richtlinien über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005)], www.avsv.at

[70] Guidelines on Economic Prescribing of Pharmaceuticals and Medicinal Products [Richtlinien über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005)], www.avsv.at

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

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 inpatient sector, there is no monitoring of prescribed packages. Pharmaceuticals are prescribed according to their need and purpose.

Doctors in the inpatient 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,[72] 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 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 HVB together with the ÖÄK and the Austrian Chamber of Pharmacists (ÖAK) 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.[73]

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 OTC products. Distance selling of pharmaceuticals through the Internet is not allowed in Austria.

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

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

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 VO-EKO".[74] 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 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. section 4.1). The annexes of the abeforementioned VO-EKO specify in detail, which health-economic data have to be included in reimbursement applications (cf. section 4.2.1).[75,76]

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.[77]

The expert group consisted of high-ranking representatives from

- the BMGFJ,
- the 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
- selected pharmaceutical companies

However, these guidelines are not mandatory but offer guidance.

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

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5.5 Generics

The share of generic pharmaceuticals in Austria has been rather low for a long time. However, there has been an increase in the last few years. The share of generics in terms of value was 4.5 percent on the total outpatient pharmaceutical market in the year 2000, in 2007 the corresponding figure was 14.5%. In terms of volume, counted by packs, the generics market share amounted to approximately 25% in 2007.[78]

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 outpatient sector, 2000–2007

Generic market share	2000	2001	2002	2003	2004	2005	2006	2007
Share of number of generic prescriptions as number of total prescriptions (%)	7.4	8.2	9.1	10.8	12.3	14.4	18.6	25
Share of expenditure for generics as percentage of total pharmaceutical expenditure (%)	4.5	4.8	5.3	6.6	7.8	9.4	10.7	14.5

n.a. = not available

Source: OEGV 2008

If only looking at the reimbursement market the share is slightly higher, the HVB stated that the generics market share in terms of volume on the reimbursement market grew from 11% in 2002 to 40.2% in 2007.

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. However, information campaigns are promoted by the Austrian Generics Association (OEGV) in cooperation with the HVB and by individual sickness funds.

According to the RöV medical doctors are requested to prescribe the most economically effiecient treatment alternative. Thus, the prescription of generics is encouraged.

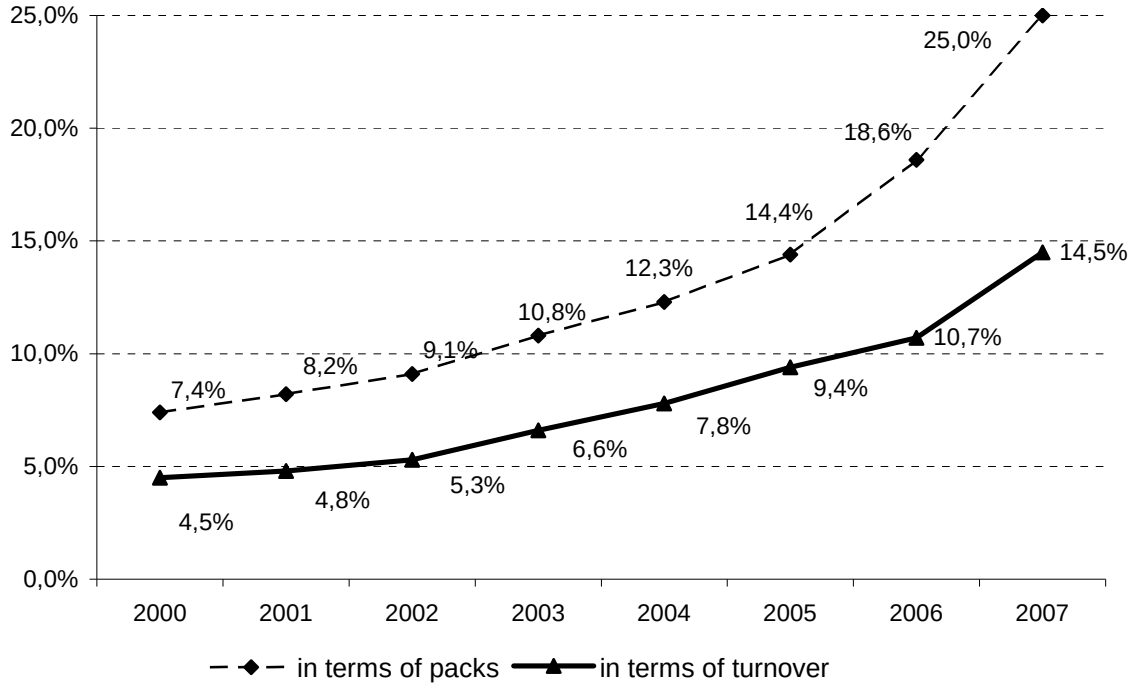
Still, there is room for the medical doctor to play a role in this decision – also borne out by the fact that not only one generic pharmaceutical but in most cases a range of pharmaceuticals

[78] 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 inpatient sector.

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

Figure 5.1: Austria – Generic market shares (%) in the outpatient pharmacy market according to value and packages sold, 2000–2007



Source: OEGV 2008

5.5.1 Generic substitution

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

As mentioned earlier (cf. section 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 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 OEGV, is also trying to promote the use of generics.

The 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 Latest changes

The most important changes regarding the pharmaceutical system since 2005 are summarised in Table 6.1.

Table 6.1: Austria – Changes in the pharmaceutical system, 2005–2008

Year	Pricing	Reimbursement	Not attributable to Pricing or Reimbursement
2005	Introduction of the EU average price	Introcution of new reimbursement code (EKO) with the different system of boxes	
		Increase of prescription fee: € 4.45	
2006		Increase of prescription fee: € 4.60	Establishment of a Medicines Agency called the Austrian Federal Agency for Safety in Health Care (BASG) with several institutes like the PharmMed that is in charge of vigilance issues.
			Introduction of e-card (replaced the health insurcane certificate)
2007		Increase of prescription fee: € 4.70	
2008		Increase of prescription fee: € 4.80. Since January 2008 the prescription fee is capped, meaning that all beneficiaries pay a maximum of 2% of their annual income	
2009	Eventually: Change of the pharmacy and wholesale mark up scheme		
	Reduction of VAT on pharmaceuticals to 10% planned in 2009		

Source: GÖG/ÖBIG 2008

6.2 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). 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.

In 2004 the Government announced that the annual growth rate of pharmaceutical reimbursement expenditure should be limited to 3-4 percent. Though this was achieved in the beginning through a reform of the reimbursement system by introducing the EKO with the "box-model" (cf. section 4.2), the year 2007 showed a growth rate of 7.7% in public pharmaceutical expenditure and e.g. an 11% growth in January 2008 compared to January 2007.

Because of the pharmaceutical situation and other occurrences the sickness funds were confronted with growing deficits that lead into several proposed legal changes of e.g. social insurance law and by-laws. The Austrian government announced to give extra funding of presumly € 450 million to the Austria sickness funds, provided they sickness funds will also generate savings.

In spring 2008, a draft law propose to introduce a reference price system including obligatory generic substitution and the possibility to prescribe by INN (which both is not allowed until now) in Austria by 2010/2011. However, due to the political situation (new parlamentary elections in September 2008) the health care reform was postponed.

In addition, there were plans to cut respectively cup both, the wholesale and the pharmacy, mark ups which are regulated via enactments. But after some discussion it is more likely that all stakeholders – manufacturers/marketing authorisation holders and wholesalers/ distributors and retailers (pharmacists and dispending doctors)" will contribute "voluntarily" about € 200 million in savings during the next couple of years, e.g. via discounts.

Another current major discussion point in Austria is the interface-management between pharmaceutical therapy in the inpatient and the outpatient 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 oberserved.

6.3 Future developments

The year 2008 is faced by a huge cost-containment debate, especially in the light of affordability and access to pharmaceuticals in Austria. Due to the current broad discussions including media and patients and the new political situation (parliamentary election in September 2008) it is almost impossible to report future developments.

Another potential change concerns the pharmacy system as the European Commission challenged the current ownership and establishment limitations (cf. section 2.1.3.3). Futhermore drugstores are claiming their right to expand the currently very limited range of OTC products they are allowed to sell.

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

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7.4 Authors and editors

7.4.1 Authors

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).

Christine Leopold has extensive experience in international, national and regional research of health care systems (in particular pharmaceutical systems in the 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 GÖG/ÖBIG, 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 EU.

7.4.2 Editors

Sabine Vogler is a senior researcher at GÖG/ÖBIG. She is a health economist with in-depth knowledge on the European countries with regard to pharmaceutical pricing/prices, reimbursement and distribution, as well as cost-containment reforms, access and affordability issues. Sabine Vogler is the project leader of the PPRI project (http://ppri.oebig.at) and the Pharmaceutical Health Information System (PHIS) project (http://phis.goeg.at), both including networks of competent authorities from the whole EU. Before joining the Austrian Health Institute in 1995, she worked as research assistant at the Vienna University of Business Administration and Economics. Sabine Vogler has regularly been invited to seminars and conferences, and she has published several reports and articles.

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Previous versions were proof-read by Ms. Nicole Satterly. Additional feedback has been given by other team members of the GÖG/ÖBIG as well as by the HVB.

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