PPRI
Pharmaceutical Pricing and Reimbursement Information

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI/PHIS Pharma Profile

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PPRI/PHIS Representatives
Gesundheit Österreich GmbH: Sabine Vogler, Claudia Habl, Christine Leopold, Nina Zimmermann
Main Association of Austrian Social Security Institutions (Hauptverband der österreichischen Sozialversicherungsträger): Anna Bucsics, Jutta Piessnegger
Austrian Federal Ministry of Health (Bundesministerium für Gesundheit, BMG): Gernot Spanninger, Daniela Huber

Authors
Gesundheit Österreich GmbH: Nina Zimmermann, Sabine Vogler

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AAHP	Arbeitsgemeinschaft Österreichischer Krankenhausapotheker / Austrian Association of Hospital Pharmacists
AGES	Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH / Austrian Agency for Health and Food Safety
AIFA	Agenzia Italiana del Farmaco / Italian Medicines Agency
AKH	Allgemeines Krankenhaus (e.g. in Vienna) / General Hospital
AMG	Arzneimittelgesetz / Medicines Act
Art.	Article
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
BGBl.	Bundesgesetzblatt / Federal Law Gazette
BMF	Bundesministerium für Finanzen / Federal Ministry of Finance
BMG	Bundesministerium für Gesundheit / Austrian Ministry of Health
BMGF	Bundesministerium für Gesundheit und Frauen
BMGFJ	Bundesministerium für Gesundheit, Familie und Jugend / Federal Ministry of Health, Family and Youth
BMLF	Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft / Federal Ministry for Agriculture, Forestry, Environment and Water Management
BMUKK	Bundesministerium für Unterricht, Kunst und Kultur / Federal Ministry for Education, Arts and Culture
BMWFJ	Bundesministerium für Wirtschaft, Familie und Jugend / Federal Ministry of Economy, Family and Youth
BVerG	Bundesvergabegesetz / Austrian Federal Act on Public Tenders
DDD	Defined Daily Doses
DG SANCO	Health and Consumer Protection Directorate-General

DRG	Diagnosis related group
EAHC	Executive Agency for Health and Consumers
EAHP	European Association of Hospital Pharmacists
EC	European Commission
EEA	European Economic Area
EJHP	European Journal of Hospital Pharmacy Practice
EKO	Erstattungskodex / National Reimbursement Code in the out-patient sector
ELGA	Elektronische Gesundheitsakte / Electronic Health File
EU	European Union
GDP	Gross domestic product
GGP	Österreichischer Großgeräteplan / Austrian Major Equipment Plan
GmbH	Gesellschaft mit beschränkter Haftung / Public limited liability company
GÖG/ÖBIG	Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute
GP	General practitioner
HTA	Health technology assessment
HE	Health expenditure
HEK	Heilmittel-Evaluierungskommission / Pharmaceutical Evaluation Board
HiT	Health systems in transition
HOM	Hospital-only medicine
HPF	Hospital pharmaceutical formularies
HVB	Hauptverband der österreichischen Sozialversicherungsträger / Main Association of Austrian Social Security Institutions (MASSI)
i.d.F.	in der Folge / consequently
IHHII	International Healthcare and Health Insurance Institute
INN	International Non-Proprietary Name
ISO	International Standard Organisation
KAKuG	Krankenanstalten- und Kuranstaltengesetz / Federal Hospitals Act
KAV	Wiener Krankenanstaltenverbund / Vienna Hospital Association

KH	Krankenhaus / hospital
KDOK	Program for the documentation in hospitals
LDF	Leistungs- und diagnoseorientierte Fallgruppen / Diagnosis-Related Case Groups
LKF	Leistungsorientierte Krankenanstaltenfinanzierung / DRG based funding of hospitals
LKH	Landeskrankenhaus / publicly funded province hospital
MASSI	Hauptverband der österreichischen Sozialversicherungsträger / Main Association of Austrian Social Security Institutions
MEDSAFE	Project on Patient Safety
MEL	Medizinische Einzelleistungen / single medical procedures / services
No.	Number / Nummer
Mio.	Million
n.a.	not available
n.appl.	not applicable
NCU	National currency unit
NMEs	New molecular entities
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
OPD	Out-patient departments
OPP	Out-of-pocket payment
ÖSG	Österreichischer Strukturplan Gesundheit / Austrian Health Care Structural Plan
OTC	Over-the-counter medicine
PE	Pharmaceutical expenditure
PHARMIG	Verband der pharmazeutischen Industrie Österreichs / Austrian Association of Pharmaceutical Companies
PHIS	Pharmaceutical Health Information System
PK	Preiskommission / Pricing Committee

POM	Prescription-only medicine
PPP	Pharmacy Purchasing Price
PPPa	Purchasing power parities
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRIKRAF	Privatkrankenanstalten-Finanzierungsfonds / Private Hospital Fund
PRP	Pharmacy retail price
QALY	Quality adjusted life year
R&D	Research & Development
RöV	Richtlinien über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen / Guidelines on the economic prescription of medicines and therapeutic aids
SHA	System of Health Accounts
SHI	Social health insurance
SUKL	Štátny ústav pre kontrolu liečiv / State Institute for Drug Control
SOGETI	SOGETI Luxembourg SA
THE	Total health expenditure
TPE	Total pharmaceutical expenditure
UHK	Unabhängige Heilmittelkommission / Independent Pharmaceutical Commission
VAAOE	Verband Angestellter Apotheker Österreichs / Union of Employed Pharmacists
VAT	Value added tax
VHI	Voluntary health insurance
VO-EKO	Verfahrensordnung Erstattungskodex / Procedural Rules for publication of the Reimbursement Code
WHO	World Health Organisation
WKÖ	Wirtschaftskammer / Federal Chamber of Commerce
WP	Work package
WVZ	Warenverzeichnis / Medicines Price Register

Introduction

The Pharmaceutical Health Information System (PHIS) project was a research project commissioned by the Executive Agency for Health and Consumers (EAHC) and co-funded by the Austrian Ministry of Health (BMG).

The PHIS project management was a consortium of the project leader Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG) a research institute situated in Vienna, Austria, and four associated partners: the Italian Medicines Agency (AIFA), Italy, the International Healthcare and Health Insurance Institute - (IHHII), Bulgaria, SOGETI Luxembourg SA., Luxembourg and the State Institute for Drug Control (SUKL), Slovakia. Further key stakeholders of the PHIS project management were the PHIS advisory board covering EU Commission services and agencies and international organisations, and the PHIS network, which comprises national representatives from competent authorities and further relevant institutions from the EU Member States and associated countries.

The PHIS project aimed at increasing the level of knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the European Union. This was achieved by surveying and monitoring pharmaceutical health system information in the in-patient and out-patient sector from a public health perspective, and by developing key pharmaceutical health indicators which may be included in a European Health Information System.

The PHIS project ran from September 2008 to April 2011 (32 months). Further information and all deliverables are made available at the PHIS project website http://phis.goeg.at, today integrated in the website of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies: http://whocc.goeg.at.

PHIS Monitoring

The aim of the work package “Monitoring” was to provide up-to-date country-specific information on out-patient and in-patient pharmaceutical systems in the EU Member States and beyond.

The country-specific information was compiled in different sets and for different purposes based on different templates taking into consideration a common terminology (PHIS Glossary) and a set of indicators (PHIS Indicators): e.g.

- Country reports covering information on the pharmaceutical system in the in- and out-patient sectors written by country representatives of the PHIS network (PHIS Pharma Profiles)
- Integrated flowchart of the pharmaceutical system in the in- and out-patient sectors (also part of the PHIS Pharma Profile)

- Country reports with a focus on the pharmaceutical system in the in-patient sector (national PHIS Hospital Pharma Report) and a compilation of the information in a benchmarking report (PHIS Hospital Pharma Report)

All documents together represent the PHIS Library, which has to be understood as an on-line documentation system containing up-to-date information on the pharmaceutical in- and out-patient sectors. The PHIS Library is accessible at the website of the PHIS project (http://phis.goeg.at), today integrated in the website of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies: http://whocc.goeg.at.

PHIS Pharma Profile

The production of the country-specific PHIS Pharma Profiles was based on three steps:

1. Development of a uniform PHIS Pharma Report Template

The PHIS Pharma Profile offers a homogenous, very detailed structure for describing the pharmaceutical pricing and reimbursement system in the in- and out-patient sector of a country. The Template provides detailed guidelines and specific questions, definitions and examples needed to compile the PHIS Pharma Profile. It consists of six chapters, referring to the regulatory situation in 2010 or 2011. Three of the chapters (chapter 1 Health care system, chapter 2 Pharmaceutical system and chapter 5 Interface management and developments) are covering integrated information on the in- and out-patient sectors. Chapters 3 and 4 are dedicated entirely to the pricing, reimbursement and volume control in out-patient sector and respectively to the in-patient sector.

The methodology for developing the PHIS Pharma Profile Template was based on the review of existing surveys – country profiles developed in the PPRI project (Pharmaceutical Pricing and Reimbursement Information) and the PHIS Hospital Pharma report – and by using the common terminology (glossary) developed in Work Package 4 (Terminology) and the pharmaceutical indicators (PHIS indicators) developed in Work Package 6 (Indicators) of the PHIS project. The PHIS Pharma Profile Template was developed by the leader of work package Monitoring Ms. Gergana Andre (IHHII, Bulgaria[1]) in collaboration with the PHIS main partner (GÖG/ÖBIG). The Template was kindly reviewed by the PHIS Advisory Board

[1] IHHII BG is a 10 years old Bulgarian think tank, independent non-governmental organisation, which provides information and analysis in health policy, healthcare management and organisation in Bulgaria. Through its network of consultants and independent research work it provides reports, early warning statements, organises debates, engages non-governmental stakeholders in health to perform proper government monitoring and enforce civic participation in the development and implementation of health policy. A significant part of the research work of IHHII is dedicated to the pharmaceutical system and market in Bulgaria. Through its reports and analyses the Institute is a reliable partner to many professional organisations in health and the public institutions. IHHII maintains the largest and the oldest health web portal in the country – www.zdrave.net – which is an online arena of information exchange and debates in health reaching at daily average 5,000 people acting in health and pharmaceutical system.

members. Members of the PHIS network received the draft Template for feed-back, and had the opportunity to discuss and provide personal feed-back during a meeting.

2. Collecting information and data and drafting the PHIS Pharma Profiles

The country-specific PHIS Pharma Profiles were written by members of the PHIS network. In order to get the needed information and data, experts of the in- and out-patient sectors were contacted and involved in several countries. They provided information and data in written form and during telephone conversation and personal talks. In several countries, the preparatory work for drafting the PHIS Pharma Profiles also included study visits of the authors e.g. to hospital pharmacies. Information on persons and institutions involved can be found in the "Acknowledgements" at the beginning of this PHIS Pharma Profiles. For some countries (out-dated) information on the pharmaceutical system in the in- and out-patient sectors was already available but in form of separated reports (e.g. for the out-patient sector: PPRI report; for the in-patient sector: PHIS Hospital Pharma Report). It was a challenge to integrate the two separated reports into one updated integrated description of the pharmaceutical system. The main partner (GÖG/ÖBIG) of the PHIS project offered PHIS network members to pre-fill the template with already existing information and delivered pre-filled templates for 13 countries.

3. Editorial process

The drafts of PHIS Pharma Profiles were submitted to the project management for review, which was undertaken by IHHI, Bulgaria (Work Package leader of "Monitoring") in coordination with GÖG/ÖBIG (PHIS project leader). The review focused on checking clarity and consistency in general and with regard to the outline of the Template, terminology (PHIS Glossary) and data provision for filling PHIS Indicators (to be filled in the PHIS database). In the course of the editorial process, the reviewers contacted the authors for providing feed-back on language and content, offering suggestions for re-phrasing and change and clarified open and/or misunderstanding points.

1 Health care system

This chapter provides an overview of Austria health care system[2].

1.1 Demography

Austria has 8.4 mio. (2011) inhabitants and a land surface area of 83,878.99 km^2, which correlates to about 100 inhabitants per km². The population of the capital, Vienna, exceeds 1.69 mio. people (2 mio. inhabitants suburbs) representing about a quarter of the country's population. The second largest city, Graz, is home to 257,300 people, followed by Linz with 189,300, Salzburg with 147,600, and Innsbruck with 119,200 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 declined 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 and still requires reforms.

An Austrian born in 2010 can expect to live over 80 years on average: 83.16 (2010) years if female and 77.70 (2010) years if male. Since the late 1990s, Austrians have gained about 3 years in life expectancy, with men showing a greater increase than women.

Table 1.1: Austria – Demographic indicators 2000, 2005–2011

Demography	2000	2005	2006	2007	2008	2009	2010	2011
Total population	8,020,946	8,254,298	8,282,984	8,318,592	8,355,260	8,375,290	8,404,252	8,443,018
0-14 years	1,359,180	1,312,597	1,295,308	1,277,511	1,261,588	1,244,870.	1,234,761	1,224,361
15-64 years	5,423,750	5,584,114	5,589,077	5,616,042	5,642,785	5,654,499	5,689,364	5,719,753
> 64 years	1,238,016	1,357,587	1,398,599	1,425,039	1,450,887	1,475,921	1,480,127	1,498,904
Life expectancy at birth	78.3	79.5	80.1	80.4	80.6	80.5	80.8	81.2
Life expectancy at age 65	18.1	18.9	19.2	19.4	19.6	19.6	19.8	20.1

Data as of 31 December

Source: Eurostat 2010a, 2011a, 2011b (population data 2010), 2013a, 2013b; Statistics Austria 2010a, 2010b

1.2 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. Unemployment insurance is also included in the social in-

[2] Data refer to the year 2012 if not indicated otherwise.

surance model in a broader sense. In general it is a compulsory insurance system. The Main Association of Austrian Social Security Institutions (Hauptverband der Österreichischen Sozialversicherungsträger, 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 the four divisions mentioned above.

About 98.8% 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. Social insurance contributions are regulated by legislation.

The Austrian Social Insurance Law (Allgemeines Sozialversicherungsgesetz, 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 to get, e.g., better accommodation (single rooms) in hospitals, coverage of the costs of treatment by a doctor of choice, or the payment of daily benefits in case of illness.

The responsibilities in the Austrian health system are divided among several players: The Government of Austria, represented by the Federal Ministry of Health (Bundesministerium für Gesundheit, BMG), is responsible for assuring health care at central level. In addition, there are other relevant public bodies like the Federal Ministry for Education, Arts and Culture (Bundesministerium für Unterricht, Kunst und Kultur, BMUKK), the Regions (Bundesländer) and local communities, the HVB, professional bodies (Doctors' Association, Pharmacists' Association), statutory associations and hospital associations, concerned with ensuring the effective running of the Austrian health care system. The basis for the split of responsibilities is laid down in Art. 12 of the Federal Constitution Act[3] stating that the Federal State is only responsible for enacting basic principles and laws, whereas the legislation on implementation and the execution and enforcement thereof is the responsibility of the Regions. Due to the split of responsibilities, the variety of payers and the mixture of means of financing (social insurance contributions and tax revenues), a significant amount of coordination and negotiations among the various decision-making bodies and financing institutions is required. Agreements in line with Art. 15a[4] of the Federal Constitution Act are one of the instruments

[3] Art. 12 of the Federal Constitution Act [Bundes-Verfassungsgesetz BGBl. No. 1/1930 i.d.F. BGBl. I No. 65/2012]

[4] Art. 15a of the Federal Constitution Act [Bundes-Verfassungsgesetz BGBl. No. 1/1930 i.d.F. BGBl. I No. 65/2012]

used for this purpose, e.g. for the comprehensive allocation of rights and duties, e.g., hospital care is the responsibility of the Regions.

1.3 Funding

This section gives an overview of the health care expenditure and the sources of funding health care in Austria.

1.3.1 Health expenditure

In 2010, total spending for health care was at around € 31,44 million which equals to 11% of the Gross Domestic Product, GDP. Public health expenditure accounted for more than three quarter of the total health expenditure (THE) (76.2% in 2010) and private health expenditure (co-payments, private health insurance fees and other out-of pocket expenditures) amounted to almost one quarter of THE (23.8% in 2010).

Table 1.2: Austria – Health expenditure 2000, 2005–2010

Health expenditure in Euro	**2000**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**
GDP in mio. €	208,473.6	245,243.4	259,034.5	274,019.8	282,746.0	276.151	286,396.9
THE in mio. €	20,898.1	25,551.2	26,467.3	28,119.0	29,658.8	30,765.7	31,438.4
- thereof public HE	15,806.7	19,243.9	20,024.3	21,317.6	22,634.6	23,503.4	23,956.7
- thereof private HE	5,091.4	6,307.3	6,443.0	6,801.4	7,024.2	7,262.3	7,481.7
Current HE in mio. €	19,680.1	24,197.9	25,219.2	26,699.2	28,124.2	29,055.4	29,773.5
Investments in the health care sector	1,218.0	1,353.3	1,248.1	1,419.8	1,534.6	1,710.3	1,664.9
HE in the out-patient sector[1,2] in mio. €	n.a.	12,944	13,453	14,378	14,930	15,239	15,585
- thereof public	n.a.	8,823	9,232	9,878	10,366	10,523	10,691
- thereof private	n.a.	4,122	4,222	4,500	4,564	10,691	4,895
HE in the in-patient sector[1,3] in mio. €	n.a.	11,254	11,766	12,321	13,194	13,816	14,188
- thereof public	n.a.	9,567	10,061	10,567	11,385	11,937	12,273
- thereof private	n.a.	1,686	1,704	1,755	1,809	1,879	1,915

€ = Euro, GDP = gross domestic product, HE = health expenditure, n.a. = not available, SHA = System of Health Accounts, THE = total health expenditure, OECD = Organisation for Economic Co-operation and Development

1 The distinction between out-patient services and in-patient services refers to the location where the service is delivered and excludes investments: in-patient = within an in-patient facility (hospitals and nursing and residential care facilities), out-patient = outside of an in-patient facility (providers of ambulatory health care and retail sale and other providers of medical goods)

2 positions HP.3-9 according to OECD SHA classification (providers of ambulatory health care and retail sale and other providers of medical goods, provision and administration of public health programmes, general health administration and insurance); only current expenditure on health

3 positions HP.1-2 according to OECD SHA classification (hospitals and nursing and residential care facilities); only current expenditure on health; includes long-term nursing care

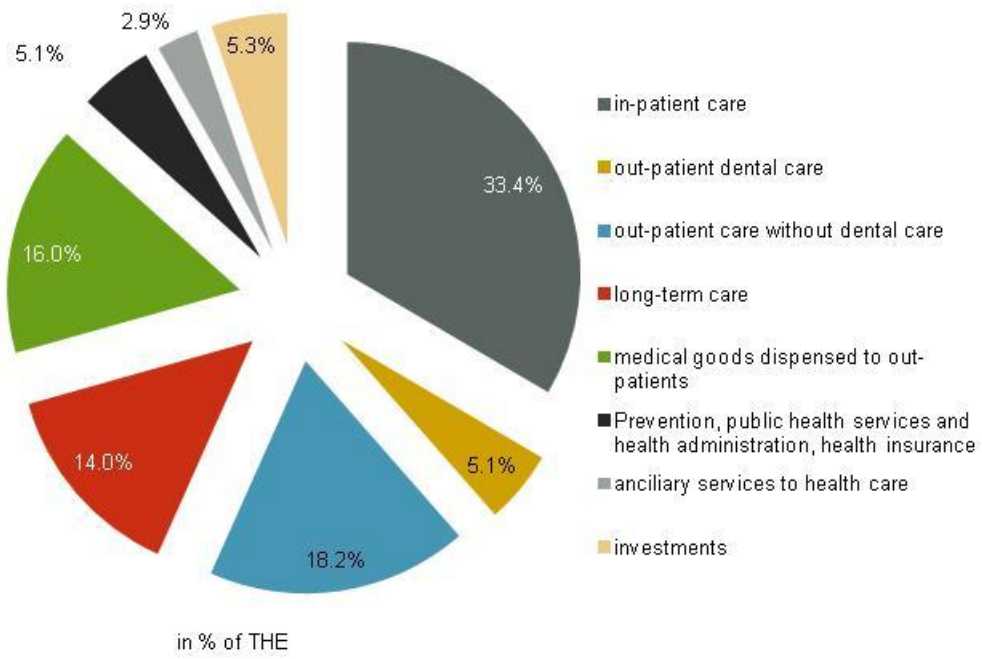
Source: OECD Statistics 2012 (in- and out-patient data), Statistics Austria 2012 (all other data)

From 1990 to 2010, total health expenditure increased steadily from € 11,481 mio. to € 31,438 mio. which corresponds to an increase of 174% (whereas the Gross Domestic Product rose by 110% between 1990 and 2010). The average annual growth rate of total health expenditure from 2000 to 2010 was 4.9%.

More than 47% of current health expenditure was spent on the in-patient sector in 2010, this proportion stayed rather stable in the last years.

The figure below shows the distribution of total health expenditure across its individual service areas in 2010.

Figure 1.2: Austria – Total expenditure on health by function, 2010



Source: OECD 2012

1.3.2 Sources of funds

Health expenditure is financed through a mix of health insurance contributions (about 47%), personal contributions (about 20%; in the form of out-of pocket payments (OPPs) and private health insurance), tax contribution provided by the general government pooled from federal, provincial and municipal budgets (about 32%) and other contributions (about 1%; non-profit institutions etc.). As already explained (cf. section 1.2), the key legal basis is the Austrian Social Insurance Law ASVG.

The amount of social security contributions depends on the income and the employment status of the insured person. In addition, the insurance funds have their own individual regulations. Generally, the contributions for people that are not self-employed (i.e. employees) are raised equally between employees and employers. Contributions to health insurance in 2011 are 7.65% for civil servants (4.10% for employees, 3.55% for employers) and also 7.65% for blue-collar workers ("Arbeiter", 3.95% for employees, 3.70% for employers) and white-collar workers ("Angestellte", 3.82% for employees, 3.83% for employers). In 2011, the maximum limit was € 4,200. The percentage for the self-employed is 7.65% (retired people 5.10%) and 7.65% for farmers (retired people 5.10%), with a ceiling of € 4,900.

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.

There is no information on the role of informal payments in the health care sector. However it is estimated that informal payments only play a minor or no role.

1.3.3 Out-patient care

The basis for payment of public out-patient doctors is contracts with one or more social health insurers (sickness funds). These contracts between doctors and sickness funds are based on framework agreements between the Main Association of Austrian Social Insurance Institutions (HVB) and the Chamber of Medical Doctors. 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.

In January 2006 the health insurance vouchers 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.

As the Social Health Insurance (SHI) does not cover all out-patient health care services, out-of-pocket payments (OPP) are required for, e.g., various dental services, services carried out by non-contract doctors, as well as the annual fee for the E-Card (€ 10.-) and the prescription fee for medicines prescribed by a doctor (€ 5.10 in 2011). Exemptions can apply on social grounds.

1.3.4 In-patient care

The Austrian hospitals are financed through a variety of stakeholders. In 2008 the current health expenditure in hospitals was € 10,921 mio. (excl. nursing and residential care facilities). The in-patient sector was financed by sickness funds with 44.7% and by the Federal

State, provincial and local governments with 46.1%. The remaining 9.2% were financed privately (private insurance institutions, private household out-of-pocket-payments).[5]

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.

Within the Austrian in-patient sector three main types of funding that mainly depend on the ownership of the hospital can be distinguished:

- **DRG based funding (Leistungsorientierte Krankenanstaltenfinanzierung, LKF) by provincial health funds** (Landesgesundheitsfonds) applies to hospitals with public law status and private general hospitals for public benefit (running on a non-profit basis). The provincial health funds get funds from the Federal Government, the provinces, local authorities and the social insurance system. The funds generated from the different bodies are then split according to defined portions to the nine provincial health funds which transfer the money to eligible hospitals. In 2011 128 (48%) hospitals of 376n-patient institutions in Austria are so-called “Fund hospitals” and are eligible to receive public funds. The LKF system consists of a core component of nationally uniform diagnosis related case groups (LDFs) and a fund control area which takes the special characteristics of hospitals into account and differs according to the province in question. However, the financial resources of the provincial health funds do not cover all expenditure incurred in hospitals. Further funds coming from the provinces which are the final responsible financing bodies and the hospital owners (e.g. the province itself, communities, fraternities, etc.) are necessary.
- **DRG based funding by the private hospitals fund** (Privatkrankenanstalten-Finanzierungsfonds, PRIKRAF) applies to private hospitals that run for profit. This body receives resources of the social insurance system to pay for services carried out in these hospitals. Patients contribute to the reimbursement of services rendered in private hospitals by private health insurance fees.
- **Non DRG based funding from other sources** applies to various specialised care institutions, especially rehabilitation centres and long term care institutions. Some of those hospitals are funded by sickness funds.

In Austria the financing of the in-patient and the out-patient sectors is separated which is considered as the key cause for difficulties and discrepancies at the interface (cf. section 5). Although several initiatives at different levels have been taken to bridge the gap, the existing dual financing system would be required to be addressed to bring major change.

[5] Statistics Austria 2011, http://www.statistik.at/web_de/statistiken/gesundheit/gesundheitsausgaben/index.html (accessed on Dec. 02 2011)

Hospitalised patients in standard class accommodation pay a fee of around € 10 to 17 per day for a maximum of 28 days per year.[6] The fee is linked to the Austrian Consumer Price Index and may be increased or decreased accordingly.

1.4 Access to health care

1.4.1 Health care professions

A total of 43,693 medical doctors provide in-patient and out-patient health care for the Austrian population at the end of 2011. Due to the fact that there are a significant number of doctors who work in a hospital and also have their own practice, the sum of in-patient and out-patient doctors does not match with the total number of physicians. In 2011, about 5 doctors were available per 1,000 inhabitants. In 2011 there were 5,700 pharmacists.

Table 1.3: Austria – Doctors and pharmacists development 2000, 2005–2011

Health professionals	2000	2005	2006	2007	2008	2009	2010	2011
Total no. of doctors[1]	33,939	38,618	40,014	40,771	41,327	42,242	43,156	43,693
- of which GPs[2]	10,655	11,618	12,018	12,219	12,223	12,478	12,694	12,857
- of which work in the out-patient sector[3]	16,098	17,851	18,188	18,430	18,779	19,003	19,259	19,449
- of which work in the in-patient sector[4]	21,705	25009	26,011	26,605	26,900	27,586	28,286	28,762
No. of pharmacists[7]	4,531	5,076	5,192	5,263	5,326	5,452	5,579	5,700
- of which work in community pharmacies	4,311	4,815	4,929[5]	4,991[5]	5,046[5]	5,160[5]	5,275[5]	5.385[5]
- of which work in hospital pharmacies	220[6]	261[6]	263[6]	272[6]	280[6]	292[6]	304[6]	315[6]

GP = general practitioner, n.a. = not available
Data as of 31 December

1 all practicing physicians; due to multiple specialisations some overlap exists between groups of physicians. Employed physicians may also work on a self-employed basis in their own practice.

2 without multiple qualifications

3 including dentists

4 employed in hospitals, ambulatory clinics, schools and other institutions

5 covering self-employed and employed pharmacists and including "Aspiranten" (= trainees) after having completed the university studies of pharmacy, graduates have to attend one year of practical training in a pharmacy followed by a final examination in order to be allowed to work as pharmacists.

6 exclusive of the pharmacists employed in five pharmacies which also operate as community pharmacy

7 sum of community pharmacists and hospital pharmacists

Source:Statistik Austria,
http://www.statistik.at/web_de/statistiken/gesundheit/gesundheitsversorgung/personal_im_gesundheitswesen/index.html; Lists of doctors of the Austrian Medical Chamber and Chamber of Dentists; Die Österreichische Apotheke in Zahlen 2002, 2007, 2008, 2009, 2010: Chapter II, 2011, 2012, 2013: Chapter IV, BMG 2010; additional data gathering by GÖG

6 According to Art. 27a of the Federal Hospital Act [§27a Krankenanstalten- und Kuranstaltengesetz (KAKuG 1957) i.d.F. BGBI. I No. 108/2012]

1.4.2 Out-patient care

43,693 practicing physicians were available for the medical treatment of the Austrian population on 31 December 2011. About 10,400 doctors had a contractual relationship with one or more sickness funds (about 4,100 general practitioners, about 3,700 specialists and about 2,600 dentists).

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. Since August 2010 it is possible to found "group practices" in form of a limited liability company, however not many physicians have used this opportunity so far. Furthermore, out-patient clinics and out-patient departments in hospitals play a major role in the provision of out-patient health care for the Austrian population.

In general, physical therapy institutes, medical laboratories, radiological facilities and sports-related medical institutions are managed as out-patient clinics ("ambulatories").

Doctors can either practise privately or publicly but there are differences in the establishment of their practices and funding arrangements. Due to the principle of freedom of choice of care provider, patients have the right to freely choose and change their public and/or private out-patient doctors quarterly. Public doctors are not free to open a surgery without permission.

1.4.3 In-patient care

Traditionally, in-patient care has been playing a very important role in Austria. The in-patient medical care of the Austrian population is provided by 273 hospitals with 64,417 available beds (as of 31 December 2011)[7].

The hospital system in Austria is quite diverse and shaped by the following dimensions: type of hospital, type of care, legal status, financing and funding, ownership and responsible bodies and the hospital size. Each of the dimensions characterises the structure, organisation and processes within a hospital or specific hospital associations. For details see the PHIS Hospital Pharma Report Austria, 2009 (report accessible at the WHO CC Website: http://whocc.goeg.at).

The Austrian Federal Hospitals Act (Krankenanstalten- und Kuranstaltengesetz, KAKuG) defines hospitals (both curing and nursing institutions) as institutions, which are dedicated to:

- determination and monitoring of the health status by medical examinations/diagnostics;
- realisation of surgical operations;
- prevention, improvement and curing of diseases by treatments;

[7] Including general hospitals, special hospitals, hospitals for convalescent patients, hospitals for chronically ill patients, sanatoria and independent out-patient health clinics (for definition see PHIS Hospital Pharma Report Austria 2009, Table 1.1. available at: http://whocc.goeg.at/Literaturliste/Dokumente/CountryInformationReports/PHIS_Hospital_Pharma_AT_Report_Final_version_090630.pdf).

- birth;
- medical measures for reproduction or
- medical care and special nursing of chronically ill patients.[8]

The building and the operating of hospitals need to be authorised by the provincial government.[9] By and large the Austrian definition of a hospital is in line with the OECD definition.[10]

The difference between public and private hospitals can be answered with reference either to the legal status of a hospital (public law status) or to the responsible body involved. Within this framework, hospitals with public law status in private ownership exist as well as hospitals without public law status, owned and/or run by provincial or municipal hospital companies or sickness funds (cf. Table 1.4).

Table 1.4: Austria – Hospitals according to public law status and public / private ownership, 2011

	Public ownership / responsibility[1]	**Private ownership / responsibility[2]**	**Total**
Hospitals **with public law status**	100	25	**125**
Hospitals **without public law status**	21	127	**148**
Total	**121**	**152**	**273**

[1] Federal Government, provincial and municipal hospital associations, sickness funds

[2] Religious orders and congregations, private individuals and societies, associations and foundations

Source: BMG 2011a; data gathering by GÖG 2011 as of 31 December 2011

More than 72% of the actual hospital beds are in hospitals with public law status. Table 1.5 provides an overview of Austrian in-patient statistics.

[8] Art. 1 of the Federal Hospitals Act [§1 Krankenanstalten- und Kuranstaltengesetz (KAKuG 1957) i.d.F. BGBI. I No. 65/2012]

[9] Art. 3 of the Federal Hospitals Act [§3 Krankenanstalten- und Kuranstaltengesetz (KAKuG 1957) i.d.F. BGBI. I No. 65/2012]

[10] OECD definition of a hospital- http://www.oecd.org/health/health-systems/1841456.pdf). Nursing homes, which primarily provide long term care services particularly for the elderly, would not normally be considered as “hospital” of the purpose of this PHIS Hospital Pharma Report.

Table 1.5: Austria – In-patient care 2000, 2005–2011

In-patient care	2000	2005	2006	2007	2008	2009	2010	2011
No. of hospitals	269	264	264	270	267	267	268	273
– thereof general hospitals*	109	106	103	103	102	102	101	100
Average length of stay (acute care) in days[5]	6.3	5.8	5.7	5.6	5.6	5.5	5.4	*n.a.*
No. of hospital pharmacies	49	49	49	46	46	46	46	46

Data as of 31 December

No. = number

1 according to the OECD definition and its subtypes.

* without sanatoria

5 In-patient stays between 1 and 28 days (excluding day cases and long-term stays) in acute care hospitals

Source: BMG 2011b (No. of hospitals); Statistics Austria 2011b (average length of stay); ÖAK 2000, 2005, 2006, 2007, 2008, 2009, 2010, 2011 (No. of hospital pharmacies);

Since the beginning of the 1980's the number of hospital beds has been decreasing.[11] Furthermore, the average length of stay has been on the decline for many years.

The Austrian in-patient sector is characterised by a large number of small hospitals, which often cooperate at different levels and in different ways. They are organised within hospital ownership organisations, whereas the management of public hospitals has been largely "privatised" on a formal basis. In most cases, the province is the majority owner.

Within the in-patient sector, the Austrian Federal Ministry of Health mainly uses health care planning as an instrument of controlling health care provisions and services. It is supported by Gesundheit Österreich GmbH (GÖG) in fulfilling this task.

Since 2006, the Austrian Health Care Structural Plan (Österreichischer Strukturplan Gesundheit, ÖSG) has regulated the geographic locations and specialisation structures of the out- and in-patient health care sectors as well as acute and long term care and rehabilitation including the establishment of upper limits for total bed numbers in hospitals and provinces.

11 Statistics Austria 2009b

2 Pharmaceutical system

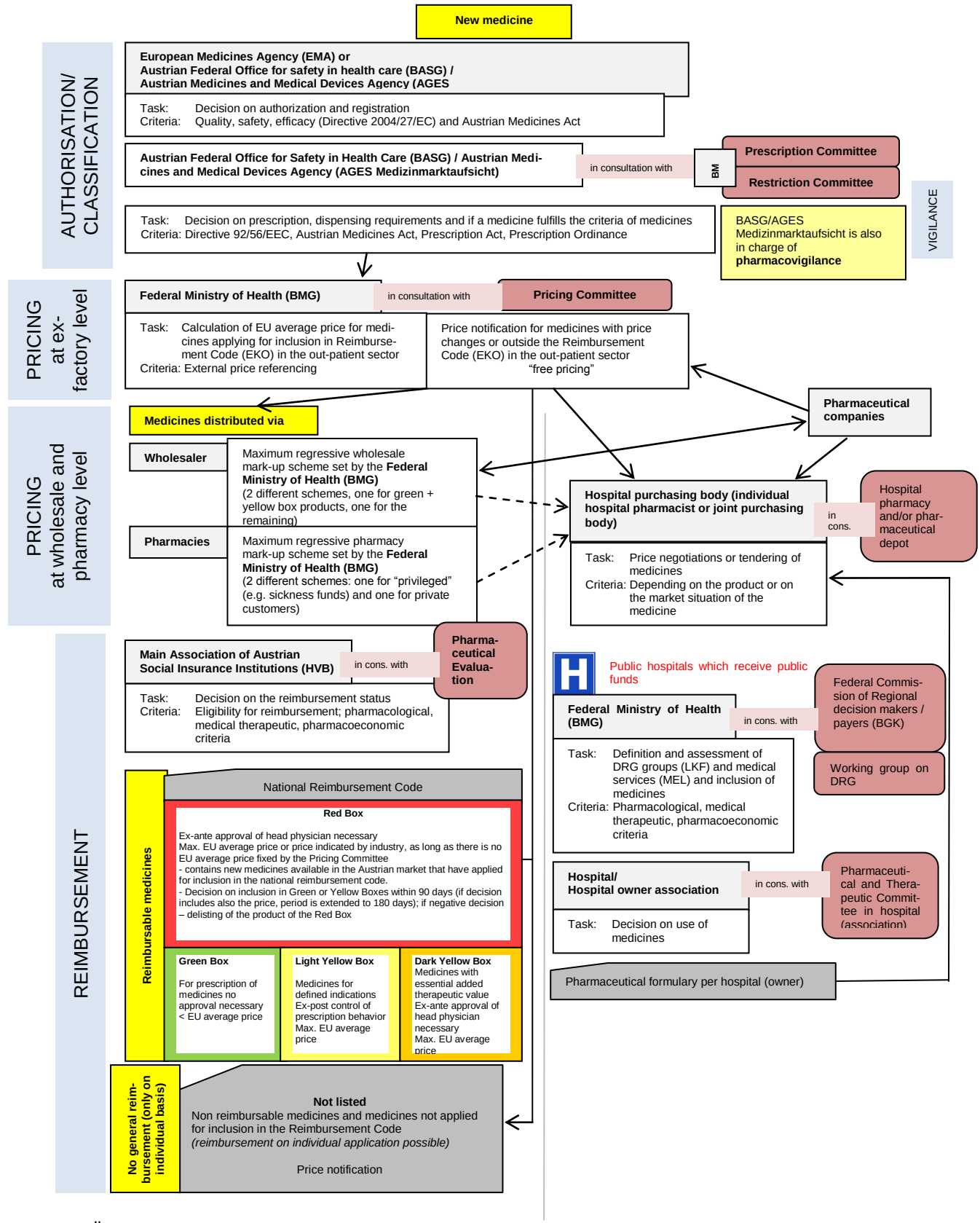
This chapter gives an introduction to the Austrian pharmaceutical system, including organisation, key statistic data, market players, and funding.[12]

2.1 Organisation

Figure 2.1 provides a comprehensive overview of the Austrian pharmaceutical system covering both the out- and in-patient sector.

[12] Data refer to the year 2011 if not indicated otherwise. Description of the pharmaceutical system refers to the situation in 2012.

Figure 2.1: Austria – Flowchart of the pharmaceutical system, 2012



Source: GÖG

2.2 Regulatory framework

This subsection includes a description of the legal framework for pharmaceutical policy, the authorities and the most important players and their roles within this framework.

Health care in Austria is characterised by the cooperation of a large number of actors. This also applies to the pharmaceutical system. The main competent authority at federal level is the Federal Ministry of Health (BMG), which submits bills – legislative proposals – on changes in the pharmaceutical system, which are then debated and voted upon in the National Council ("Nationalrat") and the Federal Council ("Bundesrat"). Another important entity in the pharmaceutical system is the Austrian Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen, BASG). The Office has the responsibility for granting market authorisation and for the vigilance of human and veterinary medicines as well as of medical devices. The BASG is responsible for carrying out public services undertakings and is directly subordinate to the Federal Ministry of Health (BMG). The BASG acts as a Medicines Agency. A limited liability company owned by the Republic of Austria - the Austrian Agency for Health and Food Safety (Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH, AGES) supports the BASG in its work. A subdivision of this Agency, the AGES Medizinmarktaufsicht (Austrian Medicines and Medical Devices Agency, until Feb. 2012 it was named "AGES PharmMed"), takes care of the pharmaceutical agenda. AGES Medizinmarktaufsicht is represented by two members in the Federal Office and provides services, staff and facilities for the Office.

Pricing activities are in the hands of the Federal Ministry of Health assisted by the Pricing Committee (PK), especially in terms of the EU average pricing system introduced in 2004 for reimbursed medicines (cf. section 3.1) in the out-patient sector. Wholesalers and pharmacists are remunerated via statutory regressive mark-up schemes.

Decisions on reimbursement status in the out-patient sector (i.e. inclusion into the positive list) are taken by the Main Association of Austrian Social Security Institutions (HVB) on the basis of the recommendations of the Pharmaceutical Evaluation Board (Heilmittel-Evaluierungskommission, HEK, cf. section 3.2). An important public body is the Independent Pharmaceutical Commission (Unabhängige Heilmittelkommission, UHK), which functions as an appeal court to whom manufacturers may turn in case their reimbursement application is refused. Further bodies dealing with medicines at federal level are the Restriction Committee (Abgrenzungsbeirat), Prescription Committee (Rezeptpflichtkommission) and the Restriction Commission (Abgrenzungskommission), for their tasks see Table 2.1.

In addition to the Agreement according to the Federal Constitution Article 15a on the organisation and financing of the health care system 2008-2013 (see section 1.2), the Austrian Federal Hospitals Act (Krankenanstalten- und Kuranstaltengesetz, KAKuG) and nine provincial Acts (Landesgesetze) are the most relevant laws for the in-patient sector and the organization of the in-patient pharmaceutical system.

Table 2.1 provides an overview of the relevant laws and regulations in place and shows key players in the Austrian pharmaceutical system.

Table 2.1: Austria – Legal basis and actors (authorities, payers and market players) of the pharmaceutical system, 2011/2012

Fields	Legal basis	Scope (in-patient, out-patient sector)	Key authorities and payers, in English (local name, local abbreviation)[1]	Activity / responsibility in the pharmaceutical system	Market players and interest associations, in English (local name, local abbreviation)[2]
Marketing authorisation	Austrian Medicines Act (Arzneimittelgesetz)	In- and out-patient sector	Federal Office for Safety in Health Care and Austrian Medicines and Medical Devices Agency (Bundesamt für Sicherheit im Gesundheitswesen (BASG) / AGES Medizinmarkaufsicht (previously called „PharmMed“)	Responsible for marketing authorisation of medicines in Austria and assessment of medicines and medical devices which are already on the market regarding efficacy, adverse reactions, production, shipment and storage.	Pharmaceutical companies – “market authorisation holders” Interest associations: Pharmig – pharmaceutical industry association, FOPI (Forum der forschenden phamazeutischen Industrie) – association of research oriented manufacturers, Österreichischer Generikaverband (ÖGV) - generics industry association
	Austrian Medicines Act (§ 49a)	In- and out-patient sector	Restriction Committee (Abgrenzungsbeirat) as advisory body to the Federal Ministry of Health	Body of currently 15 experts coming from different expert institutions: • Representatives of the Federal Ministry of Health • Representatives of the Austrian Agency for Health and Food Safety and the Austrian Medicines Agency • One representative of the Austrian Chamber of Pharmacists • One representative of the Austrian Federal Chamber of Commerce • One representative of the Austrian Federal Chamber of Labour • One representative of the Main Association of Austrian Social Security Institutions Decision whether a medicine fulfils the definition of a medicine	- Market authorisation holders and respective interest organisations Authorities, payers

Fields	Legal basis	Scope (in-patient, out-patient sector)	Key authorities and payers, in English (local name, local abbreviation)[1]	Activity / responsibility in the pharmaceutical system	Market players and interest associations, in English (local name, local abbreviation)[2]
Pricing / Purchasing	Price Act (Preisgesetz) Regulation on Procedural Rules for Calculation of the EU average price (by external price referencing)	Basically out-patient sector	Federal Ministry of Health (Bundesministerium für Gesundheit, BMG) assisted by the Pricing Commitee (Preiskommission, PK)	According to the Price Act the BMG – assisted by the PK – is basically entitled to set an economically justified price for medicines. *For reimbursed medicines (ex-factory price):* Regulation on Procedural Rules for Calculation of the EU average price (by external price referencing) *For all other medicines (with price changes or outside the national out-patient reimbursement list – Erstattungskodex EKO; ex-factory price):* Price notification to the BMG	Market authorisation holders and respective interest organisations Authorities, payers
	Enactment of the BMGF on the maximum mark-ups in pharmaceutical wholesale (Verordnung des BMGF über Höchstaufschläge im Arzneimittelgroßhandel)	In- and out-patient sector	Federal Ministry of Health (Bundesministerium für Gesundheit) Sickness funds (as payers)	It regulates the remuneration system for wholesalers on the basis of statutory maximum regressive mark- up schemes.	Wholesalers Working group of the pharmaceutical wholesalers (Arbeitsgemeinschaft des Pharmazeutischen Großhandels, ARGE Pharmazeutika)
	"Austrian Pharmaceutical Tax Enactment" (Österreichische Arzneitaxe – Pharma mark-up regulation)	Out-patient sector	Federal Ministry of Health (Bundesministerium für Gesundheit) Sickness funds (as payers)	It regulates the remuneration system for pharmacies on the basis of statutory regressive mark-up schemes. For in-patient pharmacies specific conditions apply.	Pharmacies Austrian Chamber of Pharmacists (Österreichische Apothekerkammer, ÖAK)
	Austrian Federal Act on public tenders (Bundesvergabegesetz) and nine Provincial State Acts	Public sector - mainly in-patient sector	Hospital owners (associations) For public functions: Federal Procurement Agency (Bundesbeschaffung GmbH)	Tendering of medicines in the in-patient sector: Only in selected cases e.g. for medical gases or radio contrast media For public functions: e.g. military service or federal pandemic plans, vaccines etc.	Market authorisation holders and respective interest organisations Wholesalers Working group of the pharmaceutical wholesalers (Arbeitsgemeinschaft des Pharmazeutischen Großhandels, ARGE Pharmazeutika)

Fields	Legal basis	Scope (in-patient, out-patient sector)	Key authorities and payers, in English (local name, local abbreviation)[1]	Activity / responsibility in the pharmaceutical system	Market players and interest associations, in English (local name, local abbreviation)[2]
Reimbursement	Austrian Social Insurance Law (Allgemeines Sozialversicherungsgesetz)	Mainly out-patient sector but also relevant for in-patient sector	Main Association of Austrian Social Security Institutions (Hauptverband der österreichischen Sozialversicherungsträger, HVB) supported by the Pharmaceutical Evaluation Board (Heilmittel-Evaluierungskommission, HEK) Several Austrian sickness funds	- Decision on the reimbursement of medicines - Responsible for the national reimbursement list - Reimbursement Code (Erstattungskodex, EKO) 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 medicines to patients is the responsibility of the 19 sickness funds. In the area of in-patient care provision the sickness funds make payments on the basis of agreements between the provinces and the Federal Government. These are annually adjusted according to the extent of the increase in contributions revenue.	Market authorisation holders Pharmacies Prescribers Patients and their interest associations
			Independent Pharmaceutical Commission (Unabhängige Heilmittelkommission, UHK),	Function as appeal court for pharmaceutical manufacturers in case of rejection of reimbursement application.	Market authorisation holders and respective interest organisations
	Agreement according to the Federal Constitution Article 15a on the organisation and financing of the health care system 2008-2013	In-patient sector	Federal Ministry of Health (Bundesministerium für Gesundheit) and all 9 regional governments (Landesregierungen)	Establishment of Regional Health Funds (Landesgesundheitsfonds) which are the basis for the financing of most public and private non-profit hospitals using a performance DRG based funding system (Leistungsorientierte Krankenanstaltenfinanzierung, LKF) of in-patient services	In-patient institutions (basically hospitals)

Fields	Legal basis	Scope (in-patient, out-patient sector)	Key authorities and payers, in English (local name, local abbreviation)[1]	Activity / responsibility in the pharmaceutical system	Market players and interest associations, in English (local name, local abbreviation)[2]
	9 Regional laws on Regional Health Funds	In-patient sector	9 regional governments (Landesregierungen)	Organisation, tasks, responsibilities and management of the Regional Health Funds: - Allocate hospital budget on the basis of guidelines of national budget - Responsible for measuring quality in hospitals - Transformation of the Austrian Health Care Structural Plan (ÖSG [13] – Österreichischer Strukturplan Gesundheit) to a Regional Health Care Structural Plan Health (RSG – Regionaler Strukturplan Gesundheit)	In-patient institutions (basically hospitals)
	Federal Hospitals Act (Krankenanstalten- und Kuranstaltengesetz) 9 Regional Hospital Acts	In-patient sector	Hospital owners (e.g. provinces) Pharmaceutical and therapeutic committee (Arzneimittelkommission).	Hospital owners are responsible for setting up regulations of a public institution (e.g. legal form, appoint management team, type of hospital, administration). A hospital is managed by a cooperative leadership consisting of head of doctors, head of care and head of commercial. Hospitals are financed by national budgets (cf. section 1.3.4). Pharmaceutical and therapeutic committee decides on the inclusion of a medicine in the hospital pharmaceutical formulary (cf. section 4.2.2) which is the basis for the application of the medicine in the hospital.	Hospital pharmacists – ARGE Krankenhausapotheker
Promotion	Austrian Medicines Act	In- and out-patient sector	Austrian Medicines and Medical Devices Agency (Bundesamt für Sicherheit im Gesundheitswesen (BASG) / AGES Medizinmarktaufsicht)	Advertising of medicines and industry behaviour towards health professionals	Market authorisation holders and respective interest organisations
Prescription	Austrian Medicines Act Guidelines on the economic prescription of medicines and therapeutic aids (RöV)	Mainly out-patient sector	Main Association of Austrian Social Security Institutions (Hauptverband der österreichischen Sozialversicherungsträger, HVB)	The guidelines on the economic prescription of medicines and therapeutic aids have to be followed by all prescribers.	Prescribers

[13] Article 4 Agreement pursuant to the Federal Constitution Article 15a on the organisation and financing of the health care system [Artikel 4 Vereinbarung gemäß Art. 15a B-VG über die Organisation und Finanzierung des Gesundheitswesens BGBl. I Nr. 105/2008]

Fields	Legal basis	Scope (in-patient, out-patient sector)	Key authorities and payers, in English (local name, local abbreviation)[1]	Activity / responsibility in the pharmaceutical system	Market players and interest associations, in English (local name, local abbreviation)[2]
	Prescription Act (Rezeptpflichtgesetz) and Prescription Ordinance (Rezeptpflichtverordnung)	In- and out-patient sector	Prescription Committee	Classification of medicines into prescription-only medicines or non-prescription medicines. According to the Prescription Act medicines 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 prescription committee consists of the following experts: • head of one Austrian University Institute of pharmacology • representative of the Austrian Chamber of Pharmacists • representative of the Austrian Chamber of Medical Doctors • representative of the Austrian Chamber of Veterinarian Doctors • representative of the Main Association of Austrian Social Security Institutions • representative of the Austrian Agency for Health and Food Safety • expert of manufacturer of pharmaceutical products	Market authorisation holders and respective interest organisations

Fields	Legal basis	Scope (in-patient, out-patient sector)	Key authorities and payers, in English (local name, local abbreviation)[1]	Activity / responsibility in the pharmaceutical system	Market players and interest associations, in English (local name, local abbreviation)[2]
Distribution	Austrian Medicines Act (§ 60)	In- and out-patient sector	Restriction Commission (Abgrenzungskommission) as an advisory body to the Federal Ministry of Health	Body of 10 experts coming from 9 institutions: • Head of one Austrian University Institute of pharmacology • Head of the Austrian University Department of pharmacognosy • Two representatives of the Austrian Federal Chamber of Commerce • One representative of the Austrian Chamber of Pharmacists • One representative of the Austrian Chamber of Medical Doctors • One representative of the Austrian Chamber of Veterinarian Doctors • One representative of the Austrian Federal Chamber of Labour • One representative of the Main Association of Austrian Social Security Institutions • One expert of the Austrian Agency for Health and Food Safety Decision whether medicines may also dispensed by dispensaries other than pharmacies: Prescription-only medicines (POM) may only be distributed via community pharmacies and dispensing doctors. Few OTC products may also be distributed by drugstores.	Pharmacies Other pharmaceutical dispensaries, such as dispensing doctors and drugstores (for few OTC products)
	Pharmacy Act	In- and out-patient sector	Federal Ministry of Health (Bundesministerium für Gesundheit)	The Pharmacy Price Act regulates the competition among pharmacies and comprises provisions for the licensing of community and hospital pharmacies. It determines the personal and physical prerequisites for the operation of pharmacies and the establishment of new pharmacies, their organisation in the legal form of a partnership under specific conditions, the management of a pharmacy, operating hours, the employment of skilled staff etc. It also contains rules on the establishment and operation of hospital pharmacies as well as on dispensing doctors.	Pharmacies and respective interest organisations Dispensing doctors and respective interest associations

Fields	Legal basis	Scope (in-patient, out-patient sector)	Key authorities and payers, in English (local name, local abbreviation)[1]	Activity / responsibility in the pharmaceutical system	Market players and interest associations, in English (local name, local abbreviation)[2]
	Ordinance on the Operation of Pharmacies (Apothekenbetriebsordnung)	In- and out-patient sector	Federal Ministry of Health (Bundesministerium für Gesundheit)	It regulates among other things the organisation and management of pharmacies (community and hospital pharmacies)	Pharmacies Interest association: Chamber of Pharmacists (Österreichische Apothekerkammer, ÖAK) Austrian Association of Hospital Pharmacists (Arbeitsgemeinschaft Österreichischer Krankenhausapotheker, AAHP)
Vigilance / Safety	Pharmacovigilance Ordinance (Phamakovigilanzverordnung)	In- and out-patient sector	Austrian Medicines and Medical Devices Agency (Bundesamt für Sicherheit im Gesundheitswesen (BASG) / AGES Medizinmarktaufsicht)	Adverse effects of medicines have to be reported to the Austrian Medicines and Medical Devices Agency. The institute also undertakes site inspections.	Responsible persons for pharmacovigilance and reporting persons (doctors, pharmacists, midwives, manufacturers of medicines, etc.) Pharmaceutical companies and respective interest associations
	Austrian Medicines Act (§ 49)	In- and out-patient sector	Pharmaceutical Committee (Arzneimittelbeirat) as advisory body at the Federal Ministry of Health (Bundesministerium für Gesundheit)	The Pharmaceutical Committee deals with general questions regarding the Austrian pharmaceutical system and pharmaceutical safety, regarding new therapies (e.g. gene therapy) and clinical trials. 2 working groups: - Scientific working group of the Pharmaceutical Committee - Working group of the Pharmaceutical Committee on the rational use of medicines Members are nominated experts from different Austrian institutions.	-

[1] Competent Authorities which provide the regulatory framework, take policy decisions, etc. and payers.

[2] Market actors and their interest organisations which operate in this field.

Source: Data gathering by GÖG

2.3 Statistics

This section gives an overview on the number of medicines as well as on market figures and consumption.

2.3.1 Availability of medicines

2.3.1.1 Marketing authorisation

By beginning of 2011 a total of about 10,100 medicines were authorised in Austria (counting different pharmaceutical forms and dosages and including homeopathics, but excluding different pack sizes). Of these, 8,100 medicines (~80% of all authorised medicines) are subject to the Prescription Act[14], which means that a doctor's prescription is required for dispensing these medicines to patients.

The number of reimbursable medicines has increased substantially since 1 January 2005 when the new reimbursement scheme for medicines ("Erstattungkodex", EKO) was introduced (cf. section 3.2). Most of the medicines that have been added to the list of reimbursable medicines can only be prescribed under very specific circumstances (for example only by a specialist, rather than a general practitioner, cf. section 3.2).

In Austria, about 50-60% of the authorised medicines are available on the market. Possible reasons for this situation are[15]:

1. Partly due to the fact that pharmaceutical companies apply for a decentralised marketing authorisation without having the intention to actually bring the product onto the market in Austria

2. Consultancy businesses frequently submit multiple (even as many as seven) applications for the same product. After receiving the marketing authorisations, the consultancy firms sell these to generics companies.

3. A third reason could be the cancellation of an authorisation, e.g. when a company chose to take a medicine from the market, this takes some time or is simply not submitted to the responsible authority at all.

[14] Prescription Act [Rezeptpflichtgesetz 1972, i.d.F. BGBl. I No. 50/2012]

[15] cf. GÖG/ÖBIG 2008 – PPRI Pharma Profile

Table 2.2: Austria – Number of medicines 2000, 2005–2011

Medicines	2000	2005	2006	2007	2008	2009	2010	2011	Method of counting
Authorised[1]	12,394[7]	14,347	15,527	14,456	13,186	11,985	9.827	10.104	Counted including different pharmaceutical forms and dosages, excluding different pack sizes, and including homeopathic products
On the market[2]	n.a.	6,155	7,846	7,573	6,956	7.106	7.091	n.a.	According to the database of administering the national Reimbursement Code at the HVB (Basisdatenbank EKO HVB)
POM	n.a.	9,535[4]	10,628[4]	9,787[4]	8,617[3]	7,720[3]	7,773[3]	8,100[3]	See authorised medicines
Reimbursable	2,979[2]	3,926[2]	4,122[6]	4,226[6]	4,054[6]	4,222[5]	4,218[5]	n.a.	No. of medicines in the national Reimbursement Code at a specific date
Generics	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	3,341	4,254	n.a.
Parallel traded[2]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	~370	~350	Authorised parallel traded products according to the Austrian Medicines Act – counted by products (incl. same strengths) imported from different countries and incl. veterinary products
Hospital-only[8]	~ 20%								n.a.

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

1 In contrast to other tables, in Table 2.2 data are asked for as of 1 January, as this refers to administrative data; medicines only for human use

2 as of 1 July

3 as of 2 or 3 January

4 as of 31 December of the previous year

5 as of 1 January 2010 or 2011

6 as of 31 December

7 excl. homeopathics

8 In Austria there is no legal classification of medicines, which have to be used only in hospitals. The figure presented is an estimation of medicines which are usually only used in hospitals. In such cases the marketing authorization holder does not apply for reimbursement in the out-patient sector but directly addresses the hospitals.

Source: HVB 2005, 2006a + b, 2007a + b, 2008b + c, 2009a + b, 2010a + b, 2011a + b (referring to data of AGES PharmMed); PHARMIG 2004, AGES PharmMed 2010a + b; AGES PharmMed 2011a + b; data gathering by GÖG

It is estimated that around 20% of the medicines are only used in the hospital setting (cf. Table 2.2). There is no legal classification of medicines which have to be used only in hospitals and therefore the term “hospital-only medicines” does not exist in Austria. The medicines used in hospitals can be found on the individual hospital pharmaceutical formularies. In such cases the marketing authorization holder does not apply for reimbursement in the out-patient sector (for which specific pricing procedure applies, cf. Section 3.1.3.1) but directly addresses the hospitals.

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 – medicines 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.

More than one third of authorised medicines are generics. Parallel traded medicines are of minor importance in Austria.

2.3.1.2 Access to medicines

No data on e.g. average time between marketing authorisation and patient accessibility (defined as the medicines actually being available on the market) or on the number of new molecular entities (NMEs) launched in recent years could be provided by the addressed stakeholders or the Austrian industry association.

2.3.2 Prescriptions

In 2010 the total number of prescriptions in the out-patient sector at expense of the sickness funds was ~118,000,000 and in value € 2,595 mio. On average there were about 14 prescriptions per insured person. In Austria, there is no limitation on how many items (different medicines) a prescription may include.

Table 2.3: Austria – Annual prescriptions 2000, 2005–2011

Prescriptions	2000	2005	2006	2007	2008	2009	2010	2011
No. of prescriptions (in volume in thousands)	101,433	103,614	107,691	112,453	117,628	117,081	118,022	120,349
Prescriptions in value (= mio. €)	1,644	2,060	2,180	2,357	2,533	2,575	2,595	2,654

Prescription in volume = number of items prescribed.
Prescription in value = public expenditure of prescribed medicines.

Source: HVB 2005, HVB 2011a, HVB 2012

On average the number of prescriptions has increased by 3 - 4% in recent years, however between the years 2008 and 2010 the number of prescriptions remained rather stable. In comparison the rise in expenditure for prescriptions was higher (6 – 8 % in comparison to the previous year). Possible reasons for this development can be found in the introduction of more costly medicines in the National Reimbursement Code EKO in recent years. Between the years 2008 and 2010 also expenditure levelled. Austrian sickness funds spent on average 21.99 Euro per prescription.

2.3.3 Sales

Table 2.4 presents pharmaceutical market data for Austria. Pharmaceutical sales at ex-factory level amounted to € 3,096 mio. in 2011, an increase of 2.4% compared to 2010. Sales in hospitals represent almost a third of total pharmaceutical sales. Sales of parallel traded medicines are not known.

Table 2.4: Austria – Pharmaceutical sales 2000, 2005 –2011

Sales	2000	2005	2006	2007	2008	2009	2010	2011
Sales at ex-factory price level	1,764.0	2,410.6	2,543.5	2,735.5	2,920.6	2,995.9	3,022.4	3,095.6
– Sales in out-patient sector	1,245.7	1,691.3	1,752.7	1,885.9	2,011.8	2,072.7	2,086.3	2,124.6
– Sales at hospitals	518.3	719.3	790.8	849.6	908.8	923.2	936.1	971

Source: PHARMIG 2011, PHARMIG 2013, AESGP 2010

In 2011, the total pharmaceutical export amounted to € 6,573 mio. and import to € 6,008 mio. In recent years, the total values of pharmaceutical imports and exports were almost balanced, whereas the pharmaceutical industry in Austria is among the exporting countries.

2.3.4 Consumption

Medicine consumption has been steadily growing for years. Usually the pharmaceutical consumption in Austria is measured in packs, only antibiotics are reported in DDD. In the year 2011, 233.6 Mio. packages of medicines were sold, thereof about 10% were sold to hospital pharmacies and 90% were sold to pharmacies in the out-patient sector (cf. Table 2.5).

Table 2.5: Austria – Annual pharmaceutical consumption 2000, 2005–2011

Consumption	2000	2005	2006	2007	2008	2009	2010	2011
Total pharmaceutical consumption								
In packs (in thousands)	186,539	211,635	210,170	219,121	227,558	232,704	232,102	233,607
In DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Pharmaceutical consumption in the in-patient sector								
In packs (in thousands)	20,167	22,579	23,166	23,782	24,665	24,048	23,415	23,308
In DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Pharmaceutical consumption in the out-patient sector								
In packs (in thousands)	166,372	189,056	178,004	195,339	202,893	208,656	208,687	210,299
In DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

DDD = defined daily doses

Source: PHARMIG 2011, PHARMIG 2013

2.3.5 Generics

Generic uptake 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 out-patient 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.[16]

In terms of the off-patent market, the market share in volume was about 46 percent in 2010. Table 2.6 gives an overview of the development of the market share of generics in volume and value.

Table 2.6: Austria – Development of the generic shares 2000, 2005, 2007, 2010

Generic share	Volume[1]			Value[2]		
	2005	2007	2010	2005	2007	2010
Shares in % of total market (in-patient/ out-patient)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Shares in % of total out-patient market[4]	14.4%	25%	n.a.	9.4%	14.5%	n.a.
Shares in % of out-patient reimbursement market	20.1% (2006)	21.1%	26.4%	10.8% (2006)	11.1%	12.6%
Shares in % of out-patient off-patent market[3]	39.1% (2006)	40.2%	46.1%	32.6% (2006)	34.1%	40.4%
Shares in % of the in-patient market	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

1 Expressed in number of prescriptions

2 Expressed in expenditure

3 only reimbursement market

4 data of 2005 covering an unknown period of 2004 and 2005 but in total one year ; data of 2007 covering the period 11/2006-10/2007

Source: OEGV 2008, HVB 2008a, HVB 2011c

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 26.4% in 2010. Main drivers for this development were generic promotion campaigns (e.g. by the sickness funds, HVB, the Austrian Medicines Agency and the Ministry of Health etc.), the patent expiry of several blockbusters (Clopidogrel, Pantoprazol) and the introduction of an information tool accompanying the reimbursement EKO in 2010.

Despite of the increase in recent years, generic market shares remain relatively low. One of the reasons is that neither voluntary nor obligatory generic substitution by pharmacists nor prescribing by International Non-Proprietary Name (INN) are allowed. 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 medicine. In the in-patient sector

16 IMS data provided by the Austrian Generics Association (OEGV), more up-to-date data was requested from the Austrian Generics Association, but was not provided.

the use of generics is mainly dependant on the position of the Pharmaceutical and Therapeutic Committee and the chief pharmacist within hospitals (cf. section 4.1.2).

Further information on generic policies can be found in section 3.3.2.

From the regulatory side certain mechanisms regarding generics are in place:

- As far as marketing authorisation of generics is concerned, a fast track procedure for generic applications is possible under certain conditions laid down in the Medicines Act (authorisation by reference).
- For the out-patient sector, there are different pricing rules for the inclusion of generics in the national reimbursement code EKO (cf. section 3.1.3.5).

2.3.6 Top 10 medicines

Table 2.7 lists the top 10 active ingredients accounting for highest consumptions and expenditure in the out-patient sector, based on their turnover in 2010.

Table 2.7: Austria – Top 10 active ingredients in value and volume in the out-patient sector, 2010

Position	Top active ingredients used in the out-patient sector[1], ranked with regard to consumption		Position	Top active ingredients used in the out-patient sector[1], ranked with regard to expenditure	
1	A02BC02	Pantoprazol	1	L04AB04	Adalimumab
2	C10AA01	Simvastatin	2	B01AB05	Enoxaparin
3	C08CA01	Amlodipin	3	A02BC02	Pantoprazol
4	M01AB05	Diclofenac	4	L04AB01	Etanercept
5	C05CA53	Diosmin, combinations	5	R03AK06	Salmeterol and other drugs for obstructive airway diseases
6	C09BA03	Lisinopril & Diuretics	6	R03BB04	Tiotropiumbromid
7	C07AB07	Bisoprolol	7	C10AA01	Simvastatin
8	A02BC03	Lansoprazol	8	L03AB07	Interferon beta-1a
9	C09AA03	Lisinopril	9	B01AC04	Clopidogrel
10	J01CR02	Amoxicillin and enzyme inhibitor	10	N05AH03	Olanzapin

[1] reimbursable medicines only

Source: HVB 2011c

On top of the consumption lists in hospitals oncology medicines can be found (cf. Table 2.8).

Table 2.8: Austria – Top 10 active ingredients in value and volume in the in-patient sector, 2010

Position	Top active ingredients used in the in-patient sector, ranked with regard to consumption		Position	Top active ingredients used in the in-patient sector[1], ranked with regard to expenditure	
1	n.a.	n.a.	1	L01XC07	Bevacizumab (conc. 25MG/ML 16 ML)
2	n.a.	n.a.	2	L01XC02	Rituximab (vial 500MG)
3	n.a.	n.a.	3	L01XC03	Trastuzumab (vial 150MG)
4	n.a.	n.a.	4	L01BA04	Pemetrexed (vial 500MG)
5	n.a.	n.a.	5	L01BC	Azacitidin (vial 25MG/ML 100MG)
6	n.a.	n.a.	6	L01XC06	Cetuximab (vial 5MG/ML 100ML)
7	n.a.	n.a.	7	L03AA13	Pegfilgrastim (solution for infusion, pre-filled syringe 6MG)
8	n.a.	n.a.	8	L04AB02	Infliximab (solution for infusion 100MG)
9	n.a.	n.a.	9	L01BC	Azacitidin (ampoule 100MG)
10	n.a.	n.a.	10	J06BA02	Immunglobuline (200ML/10G)

[1] Data refer to a ranking of the top medicines (brand names and pharmaceutical form) with regard to expenditure. Data gathered by GÖG on the basis of data provided by a big hospital owner organisation in one Austrian region in 2011

n.a. = not available

Source: GÖG/ÖBIG 2011

2.4 Market players

This section describes the key players in the pharmaceutical system, not talking about the authorities introduced earlier (cf. section 2.2). It gives an overview of the key players in the production, distribution, dispensing, prescription and use of medicines and their influence on pharmaceutical policy-making.

2.4.1 Industry

Currently there are approximately 220 pharmaceutical companies based in Austria.[17] 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 consulted in committees involved in pricing and reimbursement (e.g. the Pharmaceutical Evaluation Board, HEK) and are represented in the Pricing Committee (PK) through the Federal Chamber of Commerce (WKÖ). Furthermore the research oriented international pharmaceutical companies operating

[17] PHARMIG 2010

in Austria founded a "Forum of pharmaceutical research companies" (Forum der Forschenden Pharmazeutischen Industrie, FOPI) which has 20 members (e.g. Abbott, GSK, Roche).

The local pharmaceutical industry in Austria is characterised by small- and medium-sized enterprises. Almost 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 Austrian pharmaceutical industry employed about 10,700 people in 2009[18], which is significantly lower than in other EU countries that have a stronger industry presence.

Direct supply by pharmaceutical manufacturers is allowed (provided that the manufacturer has obtained a wholesale licence from the federal authorities), but wholesalers supply the vast majorities of deliveries to pharmacies. The relative importance of direct delivery by pharmaceutical companies is different in the in- and out-patient sector. Whereas the approximate share of direct deliveries to community pharmacies is reported to be three percent, pharmacies in hospitals in many cases receive medicines directly from pharmaceutical companies. Dispensing doctors and hospitals without pharmacies may only procure medicines from pharmacies, but this provision is evaded in practice by wholesalers holding a pharmacy concession.

Table 2.9: Austria – Key data on the pharmaceutical industry 2000, 2005–2010

Pharmaceutical industry	2000	2005	2006	2007	2008	2009	2010
Total number of companies	n.a.	~220[2]	~220[2]	~220[2]	~220[2]	~220[2]	~220[2]
- research-oriented	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- generic producers[3]	n.a.	n.a.	n.a.	n.a.	n.a.	2	2
- biotech	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Number of persons employed[1]	~9,200	9,593	9,877	10,534	n.a.	10,697	n.a.

1 counted per head, data of 2009 = estimate

2 160 manufacturers and importers ("Depositeure"), as well as 60 manufacturing pharmacies

3 companies that produce in Austria

Source: EFPIA 2002, 2006, 2007, 2008, 2009, 2011; PHARMIG 2010, ÖGV

Medicine production in Austria amounted to € 2,175 mio. in 2009, a significant rise compared to the year 2003 when production was € 1,325 mio.[19] Pharmaceutical Research & Development (R&D) expenditure in Austria is considered low compared to other European countries, such as the United Kingdom or Germany.

18 EFPIA 2011

19 EFPIA 2011, 2005

2.4.2 Wholesalers

The manufacturers deliver their medicines to about 35 distributors including short-liners and pre-wholesalers, of which eight provide a full range of medicines on the market and hold a market share of 95%. The eight full-range wholesalers are members of the Association of Austrian Pharmaceutical Wholesalers (ARGE Pharmazeutika). The interests of pharmaceutical wholesalers are, such 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. Items on stock held by pharmaceutical full-line wholesalers ranged from 23,500 to 100,000, depending on the size of the market and the number of products authorized to be marketed[20].

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

Parallel trade in medicines plays a minor role in Austria, as on the one hand the overall ex-factory price level is relatively low (no incentive for parallel exports) and on the other there are no incentives for doctors, patients or pharmacists to use parallel imports. For parallel imported medicines, the same statutorily regulated wholesale and pharmacy mark-up schemes are applicable as for other medicines.

Table 2.10: Austria – Key data on pharmaceutical wholesale 2000, 2005–2012

Wholesalers	2000	2005	2006	2007	2008	2009	2010	2011	2012
Total number of wholesale companies	10	10	9	9	n.a.	n.a.	8	8	8
Total number of importers	5	8	8	8	n.a.	n.a.	n.a.	n.a.	n.a.
Total number of outlets	27	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available

Source: GIRP 2008, IPF 2013

Wholesalers only play a minor role in the in-patient sector as medicines are mostly directly delivered by pharmaceutical companies.

[20] IPF 2012

2.4.3 Retailers

Medicines in Austria are mainly dispensed in the out-patient sector through pharmacies or branch pharmacies, which practise under the supervision of a (main) community pharmacy. In addition, if no pharmacy is established within the municipality in which a general practitioner (GP) has his/her practice, and the distance to the nearest pharmacy is more than six kilometers, both prescription-only medicines (POM) and OTC medicines may be dispensed through dispensing doctors. Drugstores are only allowed to sell a very restricted range of non-pharmacy OTC medicines, in particular dietary supplements.

Within the Austrian in-patient sector, medicines are provided by hospital pharmacies or "pharmaceutical depots" (which are served by hospital pharmacies or community pharmacies), mainly for internal use (cf. Section 2.4.3.3).

2.4.3.1 Community pharmacies

The establishment of a new pharmacy in Austria requires authorisation by regional authorities, which is granted provided that the pharmacy fulfils statutory prerequisites as defined in the Austrian Pharmacy Act (Apothekengesetz)[21]. The establishment of a new pharmacy requires:

- that the minimum 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 general practitioner has his/her practice within the same municipality.

Another criterion for the establishment of a new pharmacy is the space available in the premises. The Regulation of the Operation of Pharmacies[22] 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 2012, there were 1,316 community pharmacies in Austria (of which 24 were branch pharmacies), and 5 hospital pharmacies acting as community pharmacies. This corresponds to about 1 community pharmacy per 6,389 inhabitants (cf. Table 2.11). More than half of the pharmacies are located at the countryside and in small towns.

[21] Pharmacy Act [Gesetz vom 18. Dezember 1906, betreffend die Regelung des Apothekenwesens (Apothekengesetz), i.d.F. BGBl. I No. 70/2012]

[22] 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, BGBl. II No. 65/2005, i.d.F. BGBl. II No. 474/2010)]

Table 2.11: Austria – Retailers of medicines 2000, 2005–2012

Retailers	2000	2005	2006	2007	2008	2009	2010	2011	2012
No. of community pharmacies[1]	1,106	1,191	1,203	1,217	1,235	1,251	1,275	1,299	1,316
– *Thereof: No. of private pharmacies*[2]	1,106	1,191	1,203	1,217	1,235	1,251	1,275	1,299	1,316
– *Thereof: No. of public pharmacies*	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
No. of hospital pharmacies for out-patients	5	5	5	5	5	5	5	5	5
No. of dispensing doctors	987	992	992	978	962	962	950	n.a.	n.a.
No. of other POM disp.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Total no. of POM dispensaries	2,098	2,188	2,200	2,200	2,202	2,218	2,230	n.a.	n.a.
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 disp., like drugstores	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.

Disp. = dispensaries, No. = number, OTC = over-the-counter medicines, POM = prescription-only medicines

POM dispensaries are facilities that are allowed to sell POM to out-patients.

1 Hospital pharmacies dispensing to out-patients are not included in this figure. This figure includes branch pharmacies.

2 Private pharmacies are pharmacies owned by private persons or entities; public pharmacies are in public ownership.

Data as of 1 January (Data of 31 January of the previous year for reasons of consistency)

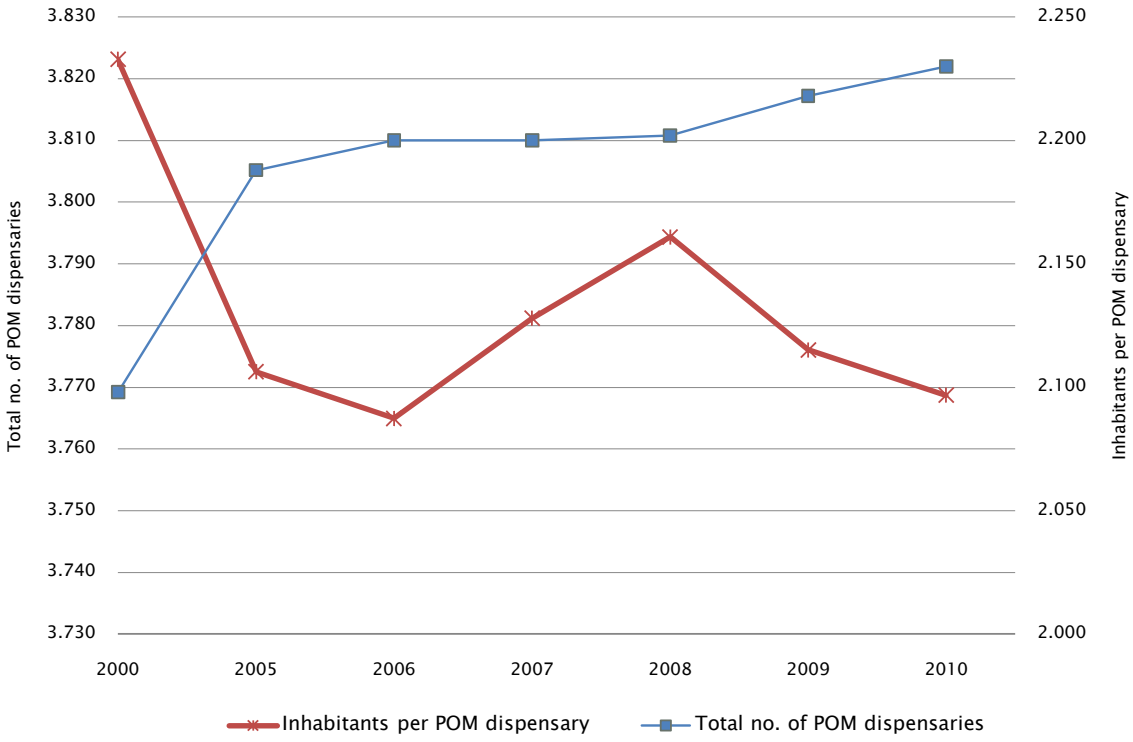
Source: ÖAK 2000, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012

Every community pharmacy is allowed to open a maximum of one branch pharmacy, provided that the distance to the nearest pharmacy is more than 4 km. This branch pharmacy is under the supervision of the (main) pharmacy. Apart from running a maximum of one branch pharmacy under the supervision of the main pharmacy, it is forbidden to fully (100%) own more than one pharmacy. The right to own a pharmacy in Austria is statutorily reserved for pharmacists with a university degree, trained according to EU Directive 2005/36/EC.[23] 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 partner-

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

ship 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 prescription-only-medicines dispensaries and number of inhabitants per prescription-only-medicines dispensary, 1995 and 2000–2010



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

Source: Data gathering by GÖG 2012

All Austrian pharmacies are in private ownership, whereby 51% of the pharmacy has to be owned by a pharmacist. All pharmacists, irrespective of whether they work in a community pharmacy or in a hospital pharmacy, are represented by the Austrian Chamber of Pharmacists (ÖAK).

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

According to the "Austrian Pharmaceutical Tax Enactment" (Österreichische Arzneitaxe - Pharmacy mark-up regulation)[24] pharmacies are remunerated via a statutorily fixed mark-up scheme for all medicines (on- and off-patent, POM and OTC medicines, cf. section 3.1.5.2).

[24] Austrian Pharmaceutical Tax Enactment [Österreichische Arzneitaxe, 1962 i.d.F. BGBl. II No. 21/2013]

Discounts (in cash) from wholesalers to pharmacies are quite common in Austria, whereas discounts from manufacturers to pharmacies are not.

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

Looking at the distribution of reimbursed medicines in the Austrian out-patient sector, in 2010 83% of pharmaceutical prescriptions were sold through community pharmacies and 16% through dispensing doctors. Less than 1 percent was distributed by other channels.

2.4.3.2 Dispensing doctors

In Austria, dispensing doctors play an important role, as they constitute more than 40 percent of all POM dispensaries (cf. Table 2.11).

In a municipality without a pharmacy a general practitioner (“Arzt für Allgemeinmedizin”) who has a contract with a sickness fund according to the ASVG[25] is entitled to apply for a licence for the dispensing of medicines, if no pharmacy is established within the community in which the general practitioner has his/her practice, and the distance to the nearest pharmacy is more than 6 km. In case a new community pharmacy opens, the dispensing 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.

In January 2010, the Austrian pharmaceutical distribution system included 950 dispensing doctors. The dispensing doctor must be the owner of the “in-house-pharmacy” and he/she must in all cases dispense the medicines personally.

2.4.3.3 Hospital pharmacies

Within the Austrian in-patient sector three forms of pharmaceutical provision can be distinguished:

1. Hospital pharmacy for in-patient services only

   There were 273 hospitals and 46 hospital pharmacies in Austria at the end of 2011. According to the Federal Hospital Act[26] all priority hospitals (Schwerpunktkrankenanstalten) are supposed to have a hospital pharmacy. Currently only about 17% of hospitals have their own pharmacy. The purchase and supply of medicines 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. The custom made production of medicines is of higher impor-

[25] Austrian Social Insurance Law [(§ 342 Abs. 1 Allgemeines Sozialversicherungsgesetz (ASVG 1955), i.d.F. BGBl. I No. 4/2013]

[26] Federal Hospitals Act [Krankenanstalten- und Kuranstaltengesetz (KAKuG 1957) i.d.F. BGBI. I No. 108/2012]

tance in the in-patient sector than in the out-patient sector in Austria. Hospital pharmacies produce medicines on a small scale (e.g. preparing prescriptions) and in larger batches.

2. Hospital pharmacy for in- and out-patient services

Five of the hospital pharmacies operate parallel a community pharmacy by virtue of holding long established rights and also serve the out-patient sector.

3. Pharmaceutical depots (which are served by hospital pharmacies or other community pharmacies)

Small hospitals in Austria often only have a pharmaceutical depot. Pharmaceutical depots in public hospitals are only allowed to purchase the required products from another licensed pharmacy in the European Economic Area, EEA.[27] The production of medicines is prohibited in pharmaceutical depots. Often only qualified nursing staff is in charge of such facilities. According to law they have to be consulted and supervised by a licensed pharmacist of a nearby public pharmacy or a hospital pharmacy probably within the same hospital owner organisation. Pharmaceutical depots are often served by hospital pharmacies of the same owner organisation. If this is not possible, pharmaceutical depots often collaborate with wholesalers which have the license of an affiliated community pharmacy. Private hospitals are not allowed to run a hospital pharmacy; in most cases they established a pharmaceutical depot.

2.4.3.4 Other POM dispensaries

No other players are allowed to dispense POM in Austria.

2.4.3.5 Other retailers

OTC products are usually also sold by POM dispensaries. However, a very limited number of defined OTC products (e.g. herbal preparations, teas etc.) may be sold in drugstores. In general also self-service of non-prescription medicines is not allowed. Distance selling of medicines through Internet pharmacies is not allowed for all Austrian based companies. However, private customers are allowed to order OTC medicines 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.).

2.4.4 Promotion

Advertising and industry behaviour towards health professionals is regulated by the Austrian Medicines Act,[28] 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.

[27] Art. 20 Sec. 3 of the Federal Hospitals Act [§20 (3) Krankenanstalten- und Kuranstaltengesetz (KAKuG 1957) i.d.F. BGBI. II No. 108/2012]

[28] Medicines Act [Arzneimittelgesetz AMG, Bundesgesetz vom 2. März 1983 über die Herstellung und das Inverkehrbringen von Arzneimitteln, i.d.F. BGBI. I No. 114/2012]

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. 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.[29]

OTC advertising is allowed in all media. Public advertising is, however, prohibited for non-prescription medicines, whose brand name is the same as of its prescription-only medicine, as well as for reimbursable OTC products.

2.5 Funding

This section provides an overview of the funding of medicines.

2.5.1 Pharmaceutical expenditure

The Austrian pharmaceutical sector has been characterised by substantial increases in expenditure since the beginning of the 1990s. The pharmaceutical expenditure in the out-patient sector amounted to € 3.800 Mio. in 2011. The reasons for the large increase in recent years are demographic developments and the related factor of medical progress.

The proportion of public out-patient pharmaceutical expenditure as a share of total current health care expenditure rose from 5.6% in 1995 to 8.3 % in 2011, whereas the share of private pharmaceutical expenditure has been kept relatively stable (4% in 2011).

Pharmaceutical expenditure of the health insurance institutions amounted to € 2,654 Mio in 2011. Data on in-patient pharmaceutical expenditure are not publicly available, only estimations can be made.

29

Table 2.12: Austria – Total pharmaceutical expenditure 2000, 2005–2011

Pharmaceutical expenditure	2000	2005	2006	2007	2008	2009	2010	2011
TPE = mio. Euro	n.a.	n.a.	n.a.	4,695	n.a.	n.a.	n.a.	n.a.
– thereof public	n.a.	n.a.	n.a.	3,262	n.a.	n.a.	n.a.	n.a.
– thereof private	n.a.	n.a.	n.a.	1,433	n.a.	n.a.	n.a.	n.a.
PE in the out-patient sector	2,529[1]	3,261	3,414	3,680	3,895	3,668	3,725	3,800
– thereof public	1,738	2,175	2,279	2,486	2,666	2,497	2,512	2,567
– thereof private	791	1,086	1,135	1,194	1,229	1,170	1,213	1,233
PE in the in-patient sector[2]	n.a.	n.a.	n.a.	1,015	n.a.	n.a.	n.a.	n.a.
– thereof public[3]	n.a.	n.a.	n.a.	776	n.a.	n.a.	n.a.	n.a.
– thereof private[2]	n.a.	n.a.	n.a.	239	n.a.	n.a.	n.a.	n.a.

n.a. = not available, PE = pharmaceutical expenditure, POM = prescription only medicines, TPE = total pharmaceutical expenditure

1 Pharmaceutical and other medical non-durables dispensed to out-patients (HC.5.1 according to OECD SHA classification);

2 estimation (total pharmaceutical expenditure of hospitals funded by the provincial health funds and extrapolation of the data for privately funded hospitals) includes pharmaceuticals, blood, reagents, vaccine and nutriments

3 only hospitals funded by the provincial health funds

Source: OECD 2013; BMGFJ 2008; data gathering by GÖG

2.5.2 Sources of funds

Health care expenditure is financed through a mix of health insurance contributions (47%), personal contributions (about 20%%; in the form of out-of pocket payments (OPPs) and private health insurance) and taxes (32%) (cf. section 1.3.2).

Private pharmaceutical expenditure makes up 32% of the out-patient pharmaceutical expenditure in 2011, which can be further subdivided into expenses for self-medication (20%) and OPPs (9.6%). The proportion of out-patient public pharmaceutical expenditure as a share of TPE has risen considerably over the years, from 61% in 1995 to 69% in 2000 but remained relatively stable between 67% and 68% between 2001 and 2011 (67.8% in 2011).

3 Pricing, reimbursement and volume control in the out-patient sector

This chapter gives an overview of the pricing and reimbursement system as well as volume control mechanisms in the out-patient sector as of 2012.

3.1 Pricing in the out-patient sector

3.1.1 Organisation of pricing

In Austria the reimbursement system and the pricing system are very closely linked.

The Price Act (Preisgesetz[30]) builds the overall legal framework for pricing in Austria. It is considered as a sort of back-up law, as ex-factory prices of new medicines as well as price changes to existing ones do not usually need to be approved by the Federal Ministry of Health (BMG), but the BMG needs only be notified (see details below). The authority in charge of the Price Act is the Federal Ministry of Economy, Family and Youth (BMWFJ), which has delegated the task of assigning health care topics to the BMG. As the Price Act does not only apply to medicines 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.

Thus, the pricing of medicines is in the hands of the BMG, 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 BMG itself, which also acts as chair of the Committee:

- the Federal Ministry of Economy, Family and Youth (Bundesministerium für Wirtschaft, Familie und Jugend, BMWFJ)
- 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“)
- the Federal Chamber of Commerce (WKÖ)
- the Federal Chamber of Labour (BAK)
- the Presidential Conference of the Chambers of Agriculture (Präsidentenkonferenz der Landwirtschaftskammern Österreichs).

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 BMG about the ex-

[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. 50/2012]

factory price for new medicines or of price changes. This pricing procedure is applied to all medicines (on- and off-patent, POM or OTC products).

As mentioned above, the pricing scheme is very much linked to the reimbursement system, since there are specific pricing rules for medicines which apply for inclusion in the EKO. Medicines included in the EKO have to be priced either according to the EU average price, as established by the PK, or below this price. Decisions on the reimbursement status are taken by the Main Association of Austrian Social Security Institutions (HVB) on the basis of recommendations of the Pharmaceutical Evaluation Board (HEK) (cf. section 3.2).

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.

Besides the EU average price which applies for medicines that are included in the EKO, there is the possibility of further price negotiations with the HVB (cf. section 3.1.2.2) and in addition there are special pricing regulations for, e.g. generics (cf. section 3.1.3.5).

3.1.2 Pricing policies

As mentioned earlier (cf. section 3.1.1), according to the Price Act of 1992[32], the BMG is entitled and obliged to calculate a "national price justified in terms of the national economy". The BMG advised by the PK therefore calculates the EU average price for all medicines applying for reimbursement. When doing so the PK may ask GÖG 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. 50/2012]

Table 3.1: Austria – Ways of pricing of medicines at manufacturer level, 2012

Pricing policies	(Non) prescription market		(Non) reimbursement market		Specific groups of medicines	
	POM	OTC	Reimbursable	Non-reimbursable	Generics	Parallel traded
Free pricing	Only if non-reimburs-able	Yes, if non-reimbursable	No	Yes	Yes, but only if non-reimburs-able	Yes, but only if non-reimburs-able
Statutory pricing	Yes, but only if reim-bursable	No	Yes	No	Yes, but only if reimburs-able	Yes, but only if reimburs-able
Price negotiations	Yes, but only if reim-bursable	No	Yes	No	Yes, but only if reimburs-able	Yes, but only if reimburs-able
Tendering	Yes, but only if reim-bursable	No, usually not	Yes	Usually not	Yes, but only if reimburs-able	Yes, but only if reimburs-able

POM = prescription-only medicine, OTC = over-the-counter medicines

Source: GÖG 2012

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. section 3.1.3.1).

There are different pricing rules (cf. section 3.1.3.5) for the inclusion of generics in the EKO. As long as the pack size of a parallel traded medicine is the same as the generic one, an "own price application" does not need to be filed (cf. section 3.1.3.6).

3.1.2.1 Statutory pricing

In general, prices are either calculated by the BMG advised by the PK (European Union average price) or notified by companies (price notification at manufacturer level). These prices are maximum prices and medicines may be priced below them. Furthermore, there are statutory wholesale and pharmacy mark-ups for all medicines (cf. section 3.1.5).

According to the Price Act, if such a notified price is deemed too high from the perspective of the Austrian economy, the BMG has the opportunity to start an official price-fixing process.

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

However, this has not occurred during recent years. If such a process is not started within six weeks, the proposed price will automatically be granted.

The EU average price is only set for medicines applying for inclusion into the EKO. The regulations of the EKO and its system of boxes are explained in more detail later (cf. section 3.2.4.3). According to the procedure on the calculation of the EU average price[34], the holder of the market authorisation applying for inclusion of the medicine into the EKO must provide information, including whether the medicine is on the market in the other EU Member States and if so the ex-factory and wholesale prices of the medicine in each of these countries have to be submitted. According to law (ASVG), GÖG is responsible for checking the prices submitted by the industry on a random basis.

The PK then calculates the EU average price of the medicines applying for inclusion in the reimbursement system in the following way: the EU average price can be established if the on-patent medicine is marketed in at least half of the European Union Member States and generics in at least two Member States. 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 medicine is allowed to enter into the red box of the EKO. The EKO is divided into different boxes (cf. section 3.2.4.3). The EU average price is also the maximum limit for medicines in the yellow box of the EKO and green box products must always be priced below the EU average price.

3.1.2.2 Negotiations

In Austria, price negotiations are a tool used in addition to the common method of setting the EU average price for reimbursable medicines. Therefore, the EU average price at manufacturer level for medicines 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]. As soon as an agreement is reached, negotiations end and the ex-factory price is then binding. If negotiations fail e.g. due to formal reasons, companies may appeal to the Independent Pharmaceutical Commission (Unabhängige Heilmittelkommission, UHK).

3.1.2.3 Free pricing

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

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[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://bmg.gv.at/home/Schwerpunkte/Medizin/Arzneimittel/Arzneimittelpreise/EU-Durchschnittspreise_laut_ASVG

[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

3.1.2.4 Tendering

Public procurement in form of tendering is only relevant in public hospitals (cf. section 4.1.2.1) and for medicines that are mainly used for vaccines or meant as strategic reserve (for armed forces or against pandemic influenza).

3.1.2.5 Others

There are no other pricing policies.

3.1.3 Pricing procedures

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

Table 3.2 gives an overview of the different pricing procedures in the Austrian out-patient sector and in the following subsections the procedures are explained in more detail.

Table 3.2: Austria – Pricing procedures, 2012

Pricing procedure	In use: yes / no	Price type[1]	Scope[2]
External price referencing	Yes	Ex-factory price level	Only reimbursable medicines
Internal price referencing	Yes	Ex-factory price level	Only reimbursable generic medicines (“followers”)
Cost-plus pricing	No	n.app.	n.app.
Indirect profit control	No	n.app.	n.app.
Specific procedure for reimbursable generics	Yes	Ex-factory price level	Only reimbursable generic medicines (“followers”)

1 Price type = the level (manufacturer, pharmacy purchasing, pharmacy retail) at which the price is set.

2 Scope = a pricing procedure does not always refer to all medicines: e.g. a pricing procedure could only refer to reimbursable medicines, whereas for Over-The-Counter medicines there is free pricing.

n.app. = not applicable

Source: GÖG 2012

3.1.3.1 External price referencing

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.

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;

The regulation states that the holder of a market authorisation applying for inclusion of a medicine 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 medicine 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 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.

3.1.3.2 Internal price referencing

Internal price referencing is applied for generics and other "followers" which apply for inclusion in the EKO. As soon as a generic (cf. section 3.1.3.5) becomes available, the HVB reinitiates price negotiations over the price of the original product (cf. section 3.1.2.2). 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 Pharmaceutical Evaluation Board (HEK) – reduce the price.

3.1.3.3 Cost-plus pricing

Cost-plus pricing is not applied in Austria.

3.1.3.4 (Indirect) profit control

In Austria, there are no profit controls to regulate medicines prices. However, one might argue that the contribution by pharmaceutical industry/wholesalers and by pharmacists under the respective framework agreements (c.f. section 3.3.3) impact the profits.

3.1.3.5 Specific procedure for reimbursable generics

For generics (defined as products containing bio-equivalent substances of off-patent original brand) different pricing rules for inclusion in the EKO apply.

The ASVG[38] and the Procedural Rules for publication of the EKO[39] state that in this case economic efficiency of the first generic product or follower 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

http://www.bmg.gv.at/home/Schwerpunkte/Medizin/Arzneimittel/Arzneimittelpreise/EU_Durchschnittspreise_laut_ASVG]

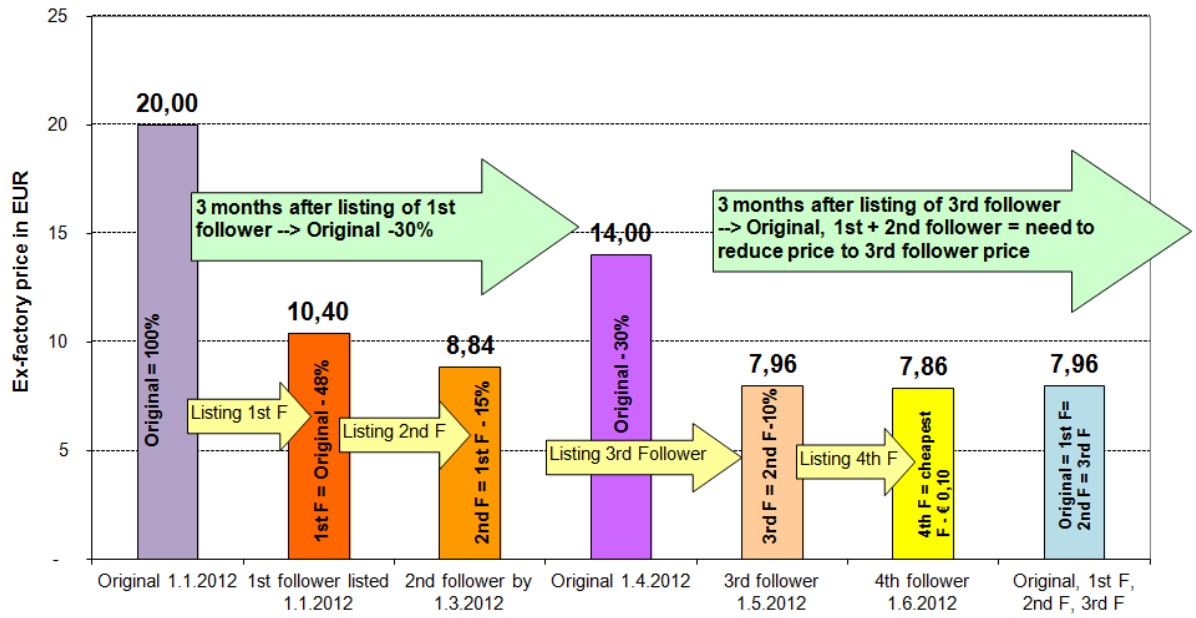
[37] Price notification form according to Regulation on Procedural Rules for Calculation of the EU average price, http://www.bmg.gv.at/cms/site/standard.html?channel=CH0723&doc=CMS1078931881119

[38] Art. 351c.10 ASVG

[39] 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

least 30% within three months of the inclusion of the first generic into the EKO, to ensure the economic efficiency of the original.

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), 2012



Source: HVB 2012

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.

3.1.3.6 OTC products and parallel trade

In Austria most OTC products are non-reimbursable medicines. Non-reimbursable medicines are not listed in the EKO, and patients therefore have to pay the full amount out-of pocket (cf. section 3.2.4.3). Since most OTC products are not included in the EKO the price notification procedure is applied (cf. section 3.1.2.3).

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.

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

However, if they want their product to 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 medicines the same wholesale and pharmacy margins are applicable as for other medicines (cf. 3.1.5).

3.1.4 Discounts / rebates

As a reaction to growing pharmaceutical expenditure, margins were cut in 2004. Additionally a further 2.5% rebate on turnover for "privileged customers" above the nationwide mean turnover was introduced payable by pharmacies. Medicines with a wholesale price above € 200 are exempt from the discount (rebate) calculation.[40] Similar regulations apply to dispensing doctors.

To further contribute to the financial stability of the sickness funds community pharmacies grant them a retrospective discount of a yearly amount of 6 Mio. Euro (incl. VAT) in the years 2012 till 2015. For this purpose, an additional agreement to the comprehensive contract of pharmacists was concluded.

The profits of pharmaceutical companies are, on basis of the Procedural Rules for publication of the Reimbursement Code (Verfahrensordnung Erstattungskodex, VO-EKO)[41] indirectly influenced by the "Pharma Framework Contract" ("Rahmen-Pharmavertrag")[42], where pharmaceutical companies and wholesalers paid about € 180 mio. (including VAT and owing contributions resulting from the former regulation, see below) between 2008 and mid 2011 to the Austrian sickness funds. This contribution was seen as an ex-post rebate granted to the Austrian social health insurance system. At the beginning of July 2011 the "Pharma Framework Contract" was prolonged for another 4.5 years. Until the end of September 2015 the pharmaceutical industry will contribute another 82 million Euro to the Austrian sickness funds.

Following extensive public discussions on rebates in kind ("natural rebates") granted by the pharmaceutical industry to dispensing doctors in 2005 these kinds of rebates were explicitly prohibited in an amendment to the Austrian Medicines Act[43] to counteract even the possibility of influencing the prescribing decisions of dispensing doctors through the existence of rebates in kind. However, cash rebates are not prohibited, especially as the pharmacy purchasing price (i.e. wholesale price) for dispensing doctors is not fixed by law.

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[40] Art. 3a Austrian Pharmaceutical Tax Enactment 1962, amended [Österreichische Arzneitaxe, 1962 i.d.F. BGBl. II No. 21/2013]

[41] 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

[42] 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]

[43] Art. 55b Medicines Act [Arzneimittelgesetz AMG, Bundesgesetz vom 2. März 1983 über die Herstellung und das Inverkehrbringen von Arzneimitteln, i.d.F. BGBI. I No. 114/2012]

3.1.5 Mark-ups and taxes

This section provides a description of the wholesale and pharmacy margins and mark-ups, dispensing fees and sales taxes applied to medicines, as of 2012. Table 3.3 gives an overview of the methods for regulating wholesale and pharmacy mark-ups. In Austria all medicines are regulated via regressive mark-up schemes for both wholesalers and pharmacies.

Table 3.3: Austria – Regulation of wholesale and pharmacy mark-ups, 2012

Wholesale mark-up			Pharmacy mark-up		
Regulation	**Content**	**Scope**	**Regulation**	**Content**	**Scope**
Yes	*Regressive mark-ups*[1]	*All medicines*	*Yes*	*Regressive mark-ups*[2]	*All medicines*

[1] *different depending on the reimbursement category*

[2] *different for privileged and private customers*

Source: GÖG

3.1.5.1 Wholesale remuneration

In Austria, wholesalers are remunerated via a statutory regressive mark-up scheme applicable to all medicines[44]. From 1 January 2004 on, there are two mark-up schemes – one for medicines included in the yellow or green boxes of the reimbursement EKO and one for all other medicines. Before, there was one single mark-up scheme for all medicines.

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

In 2010, the average wholesale mark up for the total market was 9.97% (9.07% margin) and 9.8% for the reimbursement market (8.9% margin).

[44] Enactment of the BMGF on the maximum mark-ups in pharmaceutical wholesale 2004 [Verordnung des BMGF über Höchstaufschläge im Arzneimittelgroßhandel 2004] , http://www.bmgf.gv.at/cms/home/attachments/0/2/1/CH1224/CMS1288333891695/verordnung_ueber_hoechstaufschlaege_im_arzneimittelgrosshandel.pdf

Table 3.4: Austria – Wholesale mark-up scheme for products included in the yellow and green boxes of the Reimbursement Code, 2012

Ex-Factory Price in €	Maximum Mark-Up as a % of Ex-factory Price	Pharmacy purchasing 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, 2012

Ex-factory Price in €	Maximum Mark-Up as a % of Ex-factory Price	Pharmacy Purchasing 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

3.1.5.2 Pharmacy remuneration

According to the Austrian Pharmaceutical Tax Enactment (Österreichische Arzneitaxe - Pharmacy mark-up regulation)[45] pharmacies are remunerated via a statutorily fixed mark-up scheme applicable to all medicines (on- and off-patent, POM and OTC products).

Table 3.6: Austria – Pharmacy mark-up scheme for privileged customers, 2012

Pharmacy Purchasing 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

Like wholesale mark-ups, pharmacy mark-ups are regressively staggered and are based on the pharmacy purchasing 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 Regions or communities and funds and institutions held by these, as well as non-profit-making hospitals[46] (cf. Table 3.6); and

[45] Austrian Pharmaceutical Tax Enactment 1962, amended [Österreichische Arzneitaxe, 1962 i.d.F. BGBl. II No. 21/2013]

- a basic scheme for “private customers” (cf. Table 3.7), on which an additional flat “private customer mark-up” of 15% is added,[47] valid since 1 February 1997.

In 2011, according to the Austrian Chamber of Pharmacists, the average pharmacy margin for the reimbursement market was 18.18% (2001: 21.68%). The reduction of 16% in the last ten years was due to the trend to prescribe more expensive products with lower margins. [48]

Pharmacy mark-ups applicable to reimbursed medicines are thus lower than those applied to end consumers (i.e. in case a patient buys a medicine 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, cf. section 3.1.4). Prices of medicines 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, 2012

Pharmacy Purchasing 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

[46] 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]

[47] 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]

[48] ÖAK 2012

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.

3.1.5.3 Remuneration of other dispensaries

Besides the pharmacies, dispensing doctors supply medicines to patients. Dispensing doctors have to procure the medicines through a pharmacy. In practice some wholesalers also have a pharmacy licence, thus supplying medicines to dispensing doctors.

The remuneration scheme of dispensing doctors is regulated via a regressive margin scheme set out in the Austrian Pharmaceutical Tax Enactment (Art. 3 et al.) for all medicines (on- and off-patent, POM and OTC products).[49] These fees are only applicable for medicines, not for medical devices. Also according to the Austrian Pharmaceutical Tax Enactment,[50] dispensing doctors have to pay the Main Association of Austrian Social Security Institutions (HVB) a 3.6% rebate on the turnover from privileged customers, above € 65,400.00 (cf. section 3.1.4).

In Austria medicines are also dispensed in five hospital pharmacies to out-patients; in this case they act as community pharmacies and the same mark-up schemes apply. Remuneration for drugstores in case of dispensing the limited number of OTC products is not regulated.

3.1.5.4 Taxes

3.1.5.4.1 Value-added tax

Since 2009 the sale of medicines is charged a VAT rate of 10%. Previously (1997-2008) the VAT rate on medicines used to be 20% which is the standard VAT rate in Austria. VAT is paid by the private customers for non-reimbursable medicines but also by the sickness funds for reimbursable medicines 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.

3.1.5.4.2 Other taxes

There are no further taxes / fees related to medicine prices in Austria.

3.2 Reimbursement in the out-patient sector

This section describes the scope of the reimbursement system, the regulatory framework and the main authorities in the out-patient sector as of 2012.

[49] Austrian Pharmaceutical Tax Enactment [Österreichische Arzneitaxe, 1962 i.d.F. BGBl. II No. 21/2013]

[50] Art. 3a Austrian Pharmaceutical Tax Enactment [Österreichische Arzneitaxe, 1962 i.d.F. BGBl. II No. 21/2013]

3.2.1 Organisation

Austria is organised as 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 medicines is characterised by reimbursement in kind. Very generally speaking, all duly authorised medicines 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 50,000 prescriptions per month were issued via the individual reimbursement procedure in 2011.[53]

All medicines 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, the pricing and reimbursement system are very closely linked, since there are special pricing rules for medicines 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 (Hauptverband der Österreichischen Sozialversicherungsträger, HVB). The HVB consulted by the Pharmaceutical Evaluation Board (Heilmittel-Evaluierungskommission, HEK) is responsible for deciding whether a medicine 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 medicines at federal level is the Independent Pharmaceutical Commission (Unabhängige Heilmittelkommission, UHK). The UHK functions as an appeal court to whom manufacturers may turn in case of reimbursement applications being rejected.

In order to apply for reimbursement, the holder of a market authorisation needs to send an application for inclusion of the medicine into the EKO to the HVB. Since 1 September 2005 the application can be submitted electronically. The application needs to provide information, including whether the medicine is on the market in other EU Member States and if so, the ex-factory and wholesale prices of the medicine in each of these countries have to be submitted.

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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 BGBl. No. 189/1955 latest amended by BGBl. I No. 4/2013]

[53] Calculation by the HVB, no information on how many were approved; long-term approvals were excluded

[54] Art. 31 (3) 12. ASVG 1955, on the publication of the Reimbursement Code EKO [Art. 31 (3) 12. ASVG 1995; BGBl. No. 189/1955 latest amended by BGBl. I No. 4/2023]

To do this, the companies have to complete a form, which was developed by the Pricing Committee (PK).[55]

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

3.2.2 Appeal procedure

In the case of a negative decision, the manufacturer may appeal to the Independent Pharmaceutical Commission (UHK).[56] All committee members, including those of the Pharmaceutical Evaluation Board (HEK), are independent experts nominated by several public bodies in Austria such as the Federal Chamber of Commerce (WKÖ), the Federal Chamber of Labour (BAK), the ÖÄK (Chamber of Medical Doctors), various sickness funds, the Chamber of Pharmacists (ÖAK) , the GÖG, 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 medicine in the EKO (cf. section 3.2.1). There are monthly sessions which are open to the public.

3.2.3 Delisting

Decisions on delisting, on the change of the insertion of a medicine to a box (i.e. a category of the EKO), or on any restrictions in the wake of new pharmacological, medical-therapeutic or economic findings can be taken by the HVB.[57] The manufacturer has the right to comment or complain against any such decision to the UHK.[58]

3.2.4 Reimbursement schemes

A total of 98 percent of Austria's eight million inhabitants are covered by statutory health insurance. Medicines are granted through benefits in kind. Pharmacies settle their accounts directly with the sickness funds. Medicines 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 3.1.5). This mark-up scheme is applicable to all medicines dispensed on behalf of the sickness funds, regardless of the prescription or reimbursement status.

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55 Price notification form according to Regulation on Procedural Rules for Calculation of the EU average price, http://www.bmg.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.bmg.gv.at/home/Schwerpunkte/Medizin/Arzneimittel/Beiraete_und_Kommissionen/Unabhaengige_Heilmittelkommission

57 Art. 35 of the Procedural Rules for publication of the Reimbursement Code according to Art. 351g ASVG [Verfahrensordnung zur Herausgabe des Erstattungskodex nach § 351g ASVG (VO-EKO)]

58 Details on the UHK, e.g. procedure regulations and topics may be found at http://www.bmg.gv.at/home/Schwerpunkte/Medizin/Arzneimittel/Beiraete_und_Kommissionen/Unabhaengige_Heilmittelkommission

The legal basis for the reimbursement scheme is Art. 31 (3) paragraph 12 of the ASVG[59] and the Procedural Rules for publication of the EKO are fixed by decree (Verfahrensordnung Erstattungskodex, VO-EKO).[60]

3.2.4.1 Eligibility schemes

Eligibility criteria for the decision on reimbursement of a medicine are defined in Art. 351c.2 and Art. 351c.4 (pack sizes) of the ASVG and are mainly product-specific. Some disease-specific criteria are also applied for reimbursement decisions (cf. Table 3.8).

If the medicine qualifies for inclusion on the basis of these rather formal criteria the HEK will study the therapeutic benefits of the medicine in question, basing their analysis on pharmacological, medical-therapeutic, and health-economic data[61].

- The pharmacological analysis mainly aims to classify and evaluate the medicine 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 medicine 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 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 3.2.4.3).

The green box comprises those medicines that can be “freely” prescribed without prior authorisation of a “head physician”. Pharmacy-manufactured medicines are also in the green box, unless the HEK has decided differently.

The free prescription of medicines in the green box is considered medically and health-economically sound. Having said this, the condition of approval by a head physician for the

[59] Art. 31 (3)12. ASVG 1955, amended [Art. 31 (3)13 ASVG, i.d.F. BGBl. I No. 4/2013]

[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

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

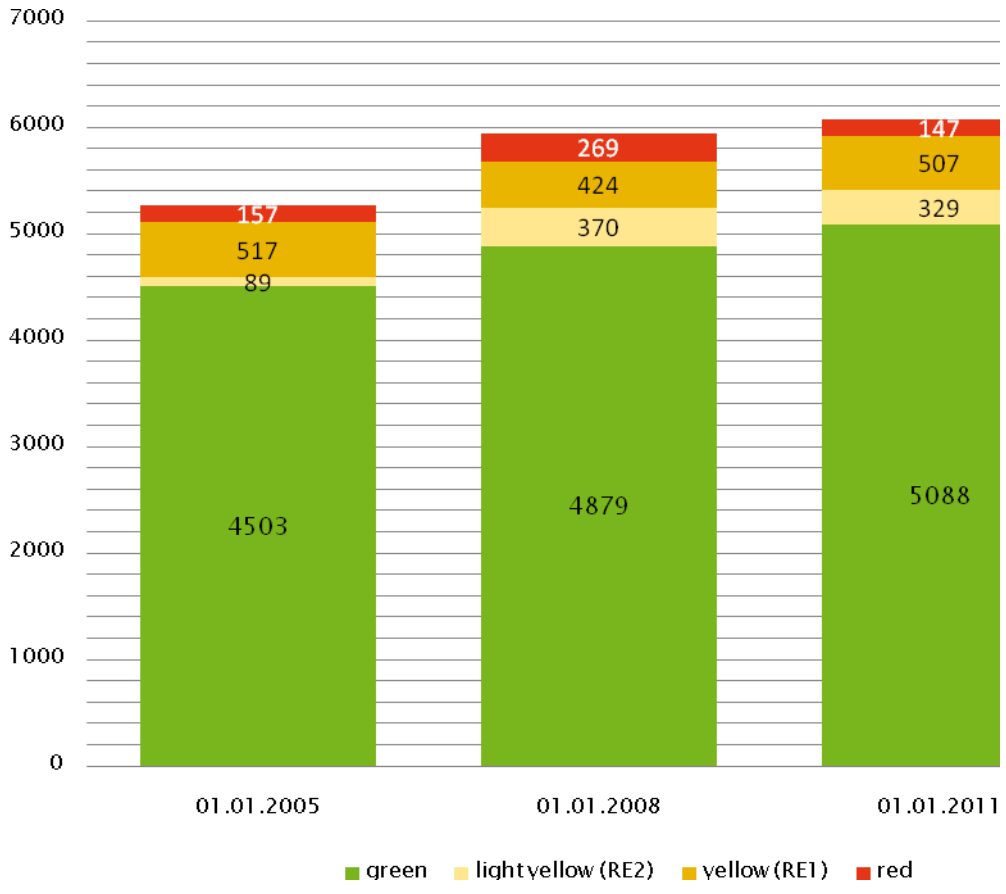
3.2.4.2 Reimbursement lists

Austria has one national positive list for the out-patient sector, the EKO. In addition to the positive list, there is also a kind of negative list ("no box"), which includes pharmaceutical categories not eligible for reimbursement.

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 medicine.

The EKO is primarily relevant for the out-patient sector, but has to be considered when patients are discharged from hospitals.

Figure 3.2: Austria – Development of medicines in Reimbursement Code[1], 2011



[1] number of packages

Source: HVB 2011c

As displayed in Figure 3.2 the number of medicines included in the new EKO has substantially increased since it was introduced. At the beginning of 1999 there were approximately 2,950 medicines listed in the old reimbursement list (Heilmittelverzeichnis); from 1 January 2005 5,266 medicines (counted by packs) are included in the EKO. In 2011 the number was 6,071 packs (and approximately 1,000 substances counted by ATC-5 code).

However, most of the medicines 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 individual reimbursement applications is reduced and access for patients becomes less bureaucratic.

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 medicine included in the EKO goes off-patent and the first followers enter the market the HVB starts a price-lowering process (cf. section 3.1.3.5 for details).

3.2.4.3 Reimbursement categories and reimbursement rates

As soon as a pharmaceutical company has completed its application for the reimbursement, the medicine is included in the red box of the EKO, thus qualifying for full reimbursement. However, the prescriber must seek 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).

All medicines included in the EKO qualify for general reimbursement, but doctors have to prescribe in accordance with the Guidelines on Economic Prescribing of Medicines and Therapeutic Aids (RöV) (cf. section 3.3.4.1). Further, the ex-ante or ex-post approval of the sickness fund “head physician” might be required.

The medicines 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 Figure 3.2 and described in further detail in Table 3.8.

Table 3.8: Austria – Reimbursement categories and rates of medicines, 2012

Reimbursement category[1]	Reimbursement rate	Characteristics of category
Red Box	**100 %**	**Scope:** • Newly launched medicines and all medicines (including off-patents) that have applied for inclusion into the EKO the yellow or green box **Procedure:** • 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 • Decision on inclusion in Green or Yellow Boxes within 90 days (if decision includes also the price, period is extended to 180 days); if negative decision – delisting of the product of the Red Box **Conditions for reimbursement**: • Ex-ante approval of head physician sought by the doctor prescribing the medicine 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 **Medicines (packages) in this Box (01.07.2011):** 195
Yellow Box	**100 %**	**Scope:** • Medicines with fundamental therapeutic benefits or considered important therapeutic innovation ("essential added therapeutic value") **Conditions for reimbursement:** • Medicines 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 medicine to the patient is needed for reimbursement **Price:** • Price must not exceed the EU average price, applications

Reimbursement category[1]	Reimbursement rate	Characteristics of category
		for price increments are decided upon by the HVB within 90 days **Medicines (packages) in this Box (01.07.2011):** 558
Light Yellow Box	**100 %**	**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 medicines 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 medicines **Medicines (packages) in this Box (01.07.2011):** 333
Green Box	**100 %**	**Scope:** • "Standard" medicines (all medicines originally listed in the old Reimbursement List (Heilmittelverzeichnis) and medicines prepared by pharmacists (unless registered in the yellow box) • Medicines considered medically and health-economically sound, identical or similar therapeutic effects to already available medicines – many generics and off-patent products **Conditions for reimbursement:** • In general no conditions, medicines 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 **Medicines (packages) in this Box (01.07.2011):** 5,134

Reimbursement category[1]	Reimbursement rate	Characteristics of category
Not listed medicines	**0 % / reimbursement on individual basis (if applicable → 100 %)**	**Scope:** • Contains medicines that are deemed unsuitable for use in out-patient 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 medicines 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: Data gathered by GÖG 2012

Besides the mentioned categories there are also medicines on the market that did not apply for inclusion into reimbursement. Such medicines comprise OTC and self-medication products but medicines used in the hospital sector (cf. section 4.1.1). As a result these medicines applied in the hospital sector – though publicly funded – are not subject to the pricing and reimbursement regulation.

3.2.5 Reference price system

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

In spring 2008 a possible introduction of a reference price system and generic substitution was discussed. Due to parliamentary election reforms were postponed and have not been taken up yet.

3.2.6 Private pharmaceutical expenses

In Austria, all medicines that are included in the EKO are fully reimbursable. The only private expense for patients, as far as medicines 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 3.2.6.3). The fixed prescription fee does not provide in-

[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

centives for patients to opt for cheaper medicines or treatment alternatives, especially as neither a reference price system (cf. section 3.2.5) nor generic substitution (cf. section 3.3.2.1) are in place in Austria.

3.2.6.1 Direct payments

As mentioned earlier (cf. section 3.2.4.3), medicines not listed in the red, yellow or green boxes of the EKO do not qualify for general reimbursement, which means that if the medicine is not reimbursed on an individual basis patients have to pay directly for those medicines. Furthermore self-medication is paid directly by patients.

Selection criteria[64] for the exclusion of medicines from general reimbursement include if the pharmaceutical categories are deemed unsuitable for use in out-patient care, either because they are used in a hospital setting under constant medical supervision 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 medicines used to stimulate or increase the sexual drive.

However, patients may apply for individual reimbursement under very special circumstances (e.g., for hospital products in cases when the patient re-enters the primary care setting, as is often the case for oncology drugs). This individual reimbursement requires the ex-ante approval of a “head physician”. On this occasion the reimbursement price (Kassenpreis) is again calculated on the basis of the mark-up scheme for “privileged customers” (cf. section 3.1.5).

Thus, a medicine that is not listed, e.g. a hormonal medicine 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 medicine 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.

3.2.6.2 Out-of-pocket payments

In Austria, all medicines that are included in the EKO are fully reimbursable. However, patients have to pay a fixed prescription fee out-of pocket. No special co-payment rules apply for parallel traded products.

[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

There have been consideration to lower prescription fees for generics or differentiated prescription fees, thus encouraging demand from patients, but there is no decision yet as to whether such a reduced fee might be put into place.

Table 3.9: Austria – Out-of-pocket payments for medicines, 2012

Out-of-pocket payments	Amount	Vulnerable groups
Fixed co-payments	€ 5.20 *(€ 5.30 in 2013)*	Socially disadvantaged people, patients with certain communicable diseases; asylum seekers;
Percentage payments	n.app.	n.app.
Deductibles	n.app.	n.app.
Reference price system	n.app.	n.app.

Source: HVB 2012

3.2.6.2.1 Fixed co-payments

For medicines sold at the expense of the sickness funds patients have to pay a flat-rate fee per prescription. In 2012, the prescription fee amounts to € 5.20 as it is annually adjusted by the inflation rate (in 2010 it was € 5.00).[65] 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 medicines.

In case the price of the medicine lies below € 5.30, the prescription fee has not to be paid, but only the price of the medicine.

The pharmacies collect this amount on behalf of the sickness funds and pass it on to them. Socially disadvantaged people and people with communicable diseases are exempt from prescription fees (cf. section 3.2.6.3).[66]

3.2.6.2.2 Percentage co-payments

There are no percentage co-payments in Austria.

3.2.6.2.3 Deductibles

In Austria, there are no deductibles.

[65] 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. I No. 4/2013]

[66] Art. 136 (4) and (5) ASVG 1955, amended [Art. 136 (4) und (5) ASVG 1955, i.d.F. BGBl. I No. 4/2013]; The current values for exemption of social reasons are published on the webpage of the HVB: https://www.sozialversicherung.at/portal27/portal/esvportal/channel_content/cmsWindow?action=2&p_menuid=647&p_tabid=4&p_pubid=804

3.2.6.3 Mechanism for vulnerable groups

Some population groups are exempt of the prescription fee:

- Pensioners with an income below the minimum income (€ 793.40 per month) and who are eligible to receive compensation allowances to reach the minimum income
- Persons with communicable diseases such e.g. tuberculosis or HIV infections (exemption only relates to the specific disease)
- Asylum seekers.

Furthermore since January 2008 the prescription fee has been capped statutorily, meaning that all beneficiaries pay at maximum 2% of their annual net income for medicines. As soon as the added paid prescription fees reach a maximum of 2 % of the annual net income of the previous year, the exemption is automatically implemented (via the electronic e-card system).

3.3 Volume control in the out-patient sector

3.3.1 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 the economic prescription of medicines and therapeutic aids (RöV)[67] in which doctors are encouraged to prescribe the most economic medicine out of several therapeutically similar alternatives. The guidelines are explained in more detail later (cf. section 3.3.4.1).

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

3.3.2 Generic policies

3.3.2.1 Generic substitution

In Austria generic substitution by the pharmacist is not allowed.

[67] Guidelines on the economic prescription of medicines and therapeutic aids [Richtlinien über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005)], www.avsv.at

A draft law to introduce generic substitution together with INN prescribing was prepared in 2008 but due to early new election not passed.

As mentioned earlier (cf. section 3.2.6.2), patients do not have financial incentives to ask the doctor to prescribe generics.

3.3.2.2 INN prescribing

Doctors are not permitted to prescribe by International Nonproprietary Name, INN – they always have to use the brand name or the generic product name.

3.3.2.3 Other generic promotion policies

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 Österreichischer Generikaverband, OEGV (Austrian Generics Association), is also trying to promote the use of generics.

The HVB who considers the promotion of generics is an important issue and it is looking to introduce more schemes to prescribe generics designed to increase their use in the future.

3.3.3 Claw-backs / Pay back

There are no explicit claw-backs in Austria, but the HVB may recoup up to 2.5% of pharmacy sales that are above the nationwide average sales (cf. section 3.1.4). Similar provisions apply to dispensing doctors.

Additionally, the profits are influenced by the EU average price system in the following way: in the event that the EU average price, established by the PK, is 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 medicines listed in the red box of the EKO.

According to the Pharma Framework Contract, pharmaceutical companies grant retrospective discounts for sickness funds of about 82 million Euro until the end of 2015. 6.75 million of these discounts will be dedicated for projects on child and youth health.

Public pharmacies also contribute to the financial stability of the Austrian sickness funds (cf. section 3.1.4).

3.3.4 Monitoring, assessment and evaluation

3.3.4.1 Prescription monitoring

As mentioned earlier (cf. section 3.2), the RöV[68] are in use. These guidelines were published in 2004 by the HVB on the basis of the ASVG[69] and set criteria for the coverage of medicines by sickness funds. Thus even medicines not listed in the Reimbursement Code (EKO) have to be reimbursed by the sickness funds on individual application (cf. section 3.2.4), 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 medicines 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 economic prescribing of medicines 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", meaning that the first therapeutic option should be one from the green box, followed by a (light) yellow box medicine. Red box medicines should be used only under special circumstances.

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

3.3.4.2 Decision-making tools

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".[70] 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.

[68] Guidelines on the economic prescription of medicines and therapeutic aids [Richtlinien über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005)], www.avsv.at

[69] Art. 31(5)13 ASVG 1955, amended [Art. 31.5.13 ASVG, i.d.F. BGBl. I No. 4/2013]

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

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 3.2.1). The annexes of the VO-EKO specify in detail, which health-economic data have to be included in reimbursement applications (cf. section 3.2.4.1).[71,]

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.[72]

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 Austrian Medicines and Medical Device Agency (AGES Medizinmarktaufsicht) and
- selected pharmaceutical companies

However, these guidelines are not mandatory but offer guidance.

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

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

4 Pricing, reimbursement and volume control in the in-patient sector

4.1 Pricing and procurement in the in-patient sector

4.1.1 Pricing

4.1.1.1 Framework

In Austria the purchasing of medicines and the setting of the medicine prices in the in-patient sector is decentrally organised, depending on the hospital owner organisation. According to the Federal Hospitals Act[73], medicines dispensed in hospitals have to be included in a hospital pharmaceutical formulary which has to be authorised by as special Pharmaceutical and Therapeutic Committee (cf. section 4.2.3). Each hospital or each hospital owner organisation has its own hospital pharmaceutical formulary.

It is reported by the hospital experts that 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 out-patient sector for patients who have been released from hospital.

There is no legal framework in place which regulates the setting of the prices of medicines in hospitals. In general free pricing at the manufacturer level is applied. The price of a medicine is the result of a negotiation or procurement procedure between the hospital pharmaceutical purchasing body and the manufacturer / distributing actor. In general hospital pharmaceutical purchasing bodies (purchasing departments or hospital pharmacists) are directly in contact with pharmaceutical companies. Wholesalers only play a minor role in the in-patient sector.

As already mentioned in section 2.4.3.3 pharmaceutical depots in public hospitals are only allowed to purchase the required medicines from another licensed pharmacy in the EEA. Pharmaceutical depots are generally supplied with medicines by hospital pharmacies of the same hospital owner. Hospital owner organisations which do not run their own hospital pharmacy (e.g. KRAGES in the province of Burgenland) cooperate with community pharmacies (with an affiliated wholesaler) or hospital pharmacies of other hospital owners.

A major prerequisite of success of the hospital purchasing bodies is the good cooperation of the involved persons (chief pharmacist, medical director of the hospital and main doctor).

[73] Art. 19a of the Federal Hospital Act [§19a Krankenanstalten- und Kuranstaltengesetz (KAKuG 1957) i.d.F. BGBI. I No. 108/2012]

Decision making in hospitals

Internal management in hospitals is usually carried out by a committee (with equal voting rights of the members). It consists of representatives of doctors, nurses and the management (Kollegiale Führung).

Medicines are essential in hospitals. From a formal point of view, medicines fall within the agenda of the medical director of a hospital (Ärztlicher Direktor) or hospital owner organisation. He or she is possibly consulted by the pharmaceutical purchasing body (e.g. the chief pharmacist) and the executive of the Pharmaceutical and Therapeutic Committee who is in many cases also the chief pharmacist. Nevertheless, decisions on medicine prices are usually not taken by the high level management of the hospital owners or the hospitals. In practice the price negotiations are led by the pharmaceutical purchasing body. The purchasing bodies are asked to stick within their assigned budget. The chief hospital pharmacist has a key role in the purchase process. Pharmaceutical purchasing bodies always encompass the chief hospital pharmacist and other leaders of hospital pharmacies.

Different criteria are taken into account when negotiating and choosing the provider:

- Prices of similar, substitute or alternative products,
- Medical and therapeutic benefits (on the basis of scientific and evidence based criteria),
- Need for the medicine within the hospital and
- Economic considerations (e.g. granting of discounts, supply management, etc.).

The decision criteria are compiled and evaluated individually for each medicine. In many cases the respective price offered by the pharmaceutical company is the decisive criterion. The decision on the assignment of a certain company is finally taken by the hospital purchasing body in cooperation with the responsible medical bodies.

In most cases negotiations between the pharmaceutical purchasing body and the pharmaceutical companies occur. Procurement procedures are only applied under certain conditions and are rather rare.

Each hospital assigns a certain budget for medicines on a yearly basis. Within this budget possible developments of the forthcoming year are anticipated.

To sum it up, in most Austrian hospitals central hospital pharmaceutical purchasing bodies (either the chief hospital pharmacist or designated purchasing departments) are in charge of purchasing the medicines and controlling the pharmaceutical consumption. Mostly they are in direct contact with the manufacturers and negotiate the prices. Public procurement procedures are only launched in rare cases (e.g. comparable medicines).

4.1.1.2 Hospital prices

In general hospital pharmaceutical purchasing bodies buy medicines directly from any pharmaceutical company at the ex-factory price or a negotiated price, which is lower than the official ex-factory price. In case of cooperation with wholesalers, an individual mark-up (Fakturierungsgebühr) is added on the ex-factory price or discounted price and is charged to the hospitals. Nevertheless the price together with the wholesaler mark-up is still considered as considerably lower than the pharmacy purchasing price (PPP).

Pharmaceutical depots, which do not have the possibility to get the medicines from a hospital pharmacy of the same owner organisation, have to purchase their medicines from community pharmacies which add a mark-up of 8 to 10% or have a cooperation with a wholesaler attached to a community pharmacy.

Hospital pharmacies which serve other hospitals or pharmaceutical depots sometimes charge a service fee for the supply of medicines. The amount of the service fee (5 to 10%) depends on the close relationship to the owner organisation or the other hospital.

The end price of hospital medicines is set in most cases below the manufacturer price. According to Austrian hospital experts, substantial discounts can be reached during the purchasing process due to high pharmaceutical consumption in hospitals.

Cost-free medicines

A small amount of medicines is given free of charge to the hospitals by the pharmaceutical companies.

In this case it can be distinguished between

- Free samples of medicines for hospital doctors (Ärztemuster);
- Cost free medicines (Gratisware).

This is mainly the case for medicines for cardiovascular diseases and chronic diseases. Within these specific disease groups a patient very often is attuned in hospital treatment to a specific medicine which he or she will be taking for the next 10 to 20 years. Pharmaceutical companies follow a strategic provision of cost free samples, as they hope to address the patients at this stage.

Hospital purchasing bodies accept such cost free medicines under specific conditions such as that no other interest is violated (e.g. therapeutic objections) and without any binding agreements. Approximately 10% of the medicines listed on a hospital pharmaceutical formulary (cf. section 4.2.2) are delivered free of charge. Estimations showed that these medicines would account for 2 to 6% of the total pharmaceutical expenditure of a hospital.

Discounts and rebates

Discounts in kind are also quite common in the in-patient sector.[74]

Additionally pharmaceutical companies very often grant special price conditions to hospital pharmaceutical purchasing bodies. Up to 95% of the hospital medicines special prices can be negotiated depending on the bargaining power of the hospital pharmaceutical purchasing body. On average the special hospital prices lie approx. 30 to 35% below the prices in the out-patient sector whereas the discounts range between 0 and 99%.

Transparency of prices

In Austria there are no legal obligations to report the actual prices of medicines used in hospitals. The prices are not publicly available. They are only communicated within the hospital and integrated into the individual hospital IT-system where they can be consulted and checked when monitoring the accounting and performance of hospitals.

Exchange of information with other purchasing bodies

Hospital purchasing bodies only occasionally exchange information on procedures and prices on informal basis. An official exchange platform is not favoured by these bodies.

4.1.2 Purchasing policies

Apart from the international and national public procurement regulations, which differ depending on the legal status of the hospital and the thresholds for the purchase, no other binding legal obligations for pricing policies exist.

It is up to the hospitals on how to receive the best price for the medicines used.

4.1.2.1 Tendering

Public procurement procedures are regulated by the Austrian Federal Act on public tenders (Bundesvergabegesetz 2006, BVergG) and nine Provincial State Acts concerning for post investigation procedures and respective Directives of the EU (General directive: Directive 2004/18/EC, Legal protection: 2007/66/EC, Contracting authorities of the sectors 2004/17/EC, Legal protection in specific sectors 92/13/EEA).

Due to high administrative requirements, public procurement procedures are only chosen as pricing policy if the expected benefit cannot be achieved by applying alternative approaches (e.g. bilateral negotiations) and if the pharmaceutical industry demands for a procurement

[74] Although the granting of discounts in kind is prohibited in Austria since 2005, the Federal Ministry of Health stated within a decree in 2006, that this regulation is not valid for Austrian hospitals.

procedure. The tendering procedure is either launched by the pharmaceutical purchasing body or is outsourced to competent partners such as legal consultancies.

Tendering procedures are therefore only followed in exceptional cases. This approach is rather applied by the biggest hospital owner organisations (e.g. the KAV in Vienna). Examples for tendered medicines are radio contrast medicines or medical gases.

The procedure (e.g. thresholds, publication notices, etc.) is clearly defined within the Federal Act on public tenders[75].

As selection criteria, the price is the decisive factor (e.g. around 95%), although qualitative criteria such as storage, supply conditions, availability of different dosage forms (e.g. for children) etc. are also of importance.

The result of the procurement procedure and awarding of the contract is made public to the participants in the procurement procedure.

Still, a trend towards the increased use of public procurement procedures currently exists within the Austrian hospital owner organisations.

4.1.2.2 Negotiations

Conducting direct negotiations is the most common way to purchase medicines in the inpatient sector. Pharmaceutical companies are asked to present offers and compete with each other to get the assignment. In case of medicines with identical active ingredients in many cases pragmatically the best offer is selected. If the direct comparison of the medicines is not feasible, further decision criteria are: effectiveness, application method of the pharmaceutical, medical and therapeutic criteria, etc.

If there are no alternative medicines or alternative pharmaceutical companies – as this is very often the case with oncology medicines –, the hospital pharmaceutical purchasing body tries to achieve a special discounted price for these medicines.

In general linked offers (“if you buy medicine A, we will give you medicine B free of charge”) is not accepted by hospital purchasing bodies as internal transparency in the pricing policy is preferred.

As the pharmaceutical market is a very dynamic one, hospital pharmacists observe the market constantly. Some pharmaceutical purchasing bodies conduct price updates on a regular basis (e.g. once a year). As soon as the market position of a medicine changes, the companies are asked to present new offers.

[75] Federal Act on public tenders [Bundesvergabegesetz BGBl. I No. 17/2006 i.d.F. BGBl. I No. 461/2012]

Each hospital pharmaceutical purchasing body disposes of a different level of bargaining power towards the pharmaceutical companies. This is mainly due to the different amount of medicines needed and the differing services offered. Therefore the prices achieved cannot be directly compared as different frameworks and conditions are considered at the time of the price offer.

Negotiations are considered as an efficient solution as this pricing policy allows for the required flexibility to react quickly to changed conditions. Public procurement procedures might lead to unclear and complex situations and requires legal consulting, which might be quite cost-intensive and time-consuming.

4.1.2.3 Other purchasing policies

There are no other purchasing policies.

4.1.3 Organisation of procurement

The different hospital owners or hospital ownership associations very often unite their hospitals in purchasing groups and perform the price negotiations or public procurement procedures on behalf of their hospitals. These harmonisation trends emerged in the 1990's. These hospital purchasing bodies only operate within a specific province or within a specific owner organisation which runs hospitals in different provinces.

In Austrian hospitals the different purchasing policies are organised by

- designated purchasing departments (either specialised on medicines or on all medical devices needed);
- chief hospital pharmacist (who is in charge of the hospital pharmacy or pharmaceutical depot of the biggest hospital within the owner organisation) and/or
- several hospital pharmacists in the same owner organisation (e.g. lead buyer system in the province of Lower Austria taking into account a provincial pharmaceutical strategy).

Due to the different size and number of the appending hospitals the owners dispose of diverse levels of bargaining power within the negotiation or procurement processes which has consequences on the price building.

Within one of the biggest hospital owner organisation, the Krankenanstaltenverbund (KAV) in Vienna, a special purchasing committee (Apothekeneinkaufsgremium) is established at the general management level and composed of the executive of the staff unit on medical economics and pharmacy affairs and the chief hospitals pharmacists. The work focuses on the purchase of new innovative medicines and very cost intensive medicines on a general basis. At the same time the hospital pharmacies purchase common, daily needed medicines.

4.2 Reimbursement in the in-patient sector

4.2.1 National framework

In Austria hospital services including medicines are reimbursed via the diagnosis orientated reimbursement system[76] – the Austrian DRG model (Leistungsorientierte Krankenanstaltenfinanzierung, LKF) – using lump sums for each case groups, which are based on principal diagnoses and (single) medical service items (cf. section 1.3.4).

The core of the Austrian DRG model is that the disease and the treatment applied determine the reimbursement of the hospital services. Other characteristics (e.g. the age of the patient with certain diseases or structural quality criteria, etc.) also contribute to the calculation of the reimbursement scheme.

The system was developed on the basis of 20 reference hospitals which provided data on costs and it was refined by an interdisciplinary team (doctors, statisticians, economists etc.) in 1996. Standardised treatments and quality criteria also contribute to the valuation and calculation of the diagnosis-related-groups (DRG). The DRG system gets annually evaluated and adjusted. The Austrian DRG system is not considered as a very flexible system, sometimes lagging behind the developments on the pharmaceutical market. Changes might be implemented belatedly.

The information on the current valid regulations and procedures regarding the Austrian DRG model can be found on the homepage of the Austrian Ministry of Health.[77]

Medicines are integrated in the lump sums which can be generated for the procedure- and diagnosis-orientated case groups in hospitals. An average consumption of medicines per diagnosis was considered when calculating the lump sums. Patients do not have to provide extra payments as the expenditure of medicines is covered by the DRG lump sums.

According to the Austrian Law[78], the basis for the eligibility of a medicine to be reimbursed in the in-patient sector is the hospital pharmaceutical formulary (cf. section 4.2.2). Each hospital, hospital association or hospital owner implements its own hospital pharmaceutical formulary. No extra national reimbursement list of medicines used in hospitals exists. The decision making body is the Pharmaceutical and Therapeutic Committee (Arzneimittelkommission; cf. section 4.2.3).

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[76] Based on the Agreement according to the Federal Constitution Article 15a on the organisation and financing of the health care system 2008-2013; Austrian Social Insurance Law (ASVG); Federal Hospitals Act (KAKuG); Nine provinces Hospitals Acts (Landeskrankenanstalten- und Kuranstaltengesetze); Act on the financing of private hospitals (Privatkrankenanstalten-Finanzierungsfondsgesetz - PRIKRAF-G)

[77] http://www.bmg.gv.at/cms/site/thema.html?channel=CH0719

[78] Art. 19a of the Federal Hospital Act [§19a Krankenanstalten- und Kuranstaltengesetz (KAKuG 1957) i.d.F. BGBI. I No. 108/2012]

Oncology medicines present the only exception of the DRG lump sum system, as these medicines are recorded as own diagnosis-orientated case groups. Approximately 50 defined single medical services (Medizinische Einzelleistungen, MEL) exist within the system where explicitly the dispensing of a specific oncology medicine is reimbursed to the hospital owner.

In the province of Carinthia a separate financing approach for high cost, mainly oncology medicine existed. In these provinces the main public hospital owner organisations have concluded agreements with the regional sickness funds (StGKK, KGKK) stating that the expenditure of oncology medicines will be covered by the sickness fund even if they are dispensed in the in-patient sector. A similar agreement existed for another province but was stopped.

To sum it up, medicines are covered by the lump sums calculated for the reimbursement according to the Austrian DRG model.

4.2.2 Hospital pharmaceutical formularies

Only medicines which are included in the hospital pharmaceutical formulary are reimbursed by the hospital funds. In general approximately 1,500-2,500 medicines are included in hospital formularies.

When prescribing medicines for the time after discharge from hospital, the economically most favourable and therapeutically equal medicines should be selected. Furthermore the Reimbursement Code (EKO) of the Main Association of Austrian Social Security Institutions (MASSI), which is the basis for the reimbursement of medicines in the out-patient sector and the Guidelines on Economic Prescribing of Pharmaceuticals and Therapeutic Aids (Richtlinien über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen, RöV[79]) should be considered, unless there are objections from the medical perspective.

Process of inclusion of a medicine in the hospital pharmaceutical formulary

In general each hospital senior chief doctor (Oberarzt) can suggest a medicine to be included in the list via an official request signed by his/her medical executive to the head of the Pharmaceutical and Therapeutic Committee . The request is often accompanied by scientific documents of the medicine which should allow for supporting the decision-making.

At their regular meetings (usually on a quarterly basis) the commission then decides on the basis of different criteria if the medicine will be included in the list or not. These criteria could be:

- Therapeutic;
- Medical;
- Economic or
- Cost-effective etc.

[79] http://www.avsv.at

It is mainly a decision depending on individual factors in each case, conflicts of interests may occur. In some more complex cases the proposing doctor is invited to give a personal statement at these sessions to comment on the necessity of the inclusion of the specific medicines.

The inclusion of generics is mainly dependant on the position of the chief pharmacist. No official guidelines exist regarding the use of generics in the in-patient sector.

Usually the hospital pharmaceutical formulary is updated 2–4 times a year.

Some Pharmaceutical and Therapeutic Committee s implemented specific guidelines ("conflict of interest") which clarify the reasons and motivation of requesting persons to suggest specific products. This is done in order to find out if a doctor who has received special funds to conduct research proposes this specific product. Pharmaceutical companies follow the specific interest to have their products in the formulary as the prescription behaviour of the hospital doctor has an important impact on the out-patient market.

As soon as the decision is taken to include the medicine in the hospital formulary, the executive of the Pharmaceutical and Therapeutic Committee (mostly the chief hospital pharmacist) prepares information on the new medicine to be disseminated to the hospital employees (e.g. via the intranet or posters or by email).

Whether generics or parallel imported products are purchased, this is mainly a decision of the hospital pharmacist and the Pharmaceutical and Therapeutic Committee.

In general the needs of the sickness funds in the out-patient sector are positively received by Austrian hospitals. Nevertheless the cooperation between the out-patient sector and the in-patient sector varies between the provinces and depends on individuals. Especially for long term therapies, pharmaceutical therapy in hospitals has consequences on the further treatment in the out-patient sector, representatives of the sickness funds try to express their view in the Pharmaceutical and Therapeutic Committee s (cf. section 4.2.3).

Use of medicines which are not on the hospital pharmaceutical formulary

In case of a required use of a medicine which is not included in the formulary, the prescribing doctor officially needs to request for it by using a standardised form. The filled in form stating the reasons and the necessity of the use of the special medicine has to be authorised by the respective responsible hospital pharmacist in consultation with leading doctors.

IT- system

Hospital pharmaceutical formularies are electronically available in each hospital's IT systems. They are often part of an intranet system of each hospital and all hospital employees can have access.

The information on the medicine varies in many hospitals. A standardised software is often used including information on the product, the active ingredient, alternative products and also price information as well as information on the reimbursement status in the out-patient sec-

tor. Furthermore, medicines can be tracked with the help of the IT system within a hospital. The hospital controller might exactly know how many packages of a specific medicine have been dispensed to a department. But the traceability to the patients is limited.

4.2.3 Pharmaceutical and Therapeutic Committees

The organisation and use of hospital pharmaceutical formularies and the Pharmaceutical and Therapeutic Committee is regulated by Austrian law.[80]

Austrian hospitals are obliged to establish a Pharmaceutical and Therapeutic Committee . Joint Pharmaceutical and Therapeutic Committee s for hospital associations or all hospitals of one owner organisation are common. Nevertheless some hospital owner organisations prefer the decentralised organisation of the Pharmaceutical and Therapeutic Committee per hospital, as they expect to achieve a higher commitment of the involved persons.

The defined tasks of a Pharmaceutical and Therapeutic Committee are:

- Compilation of a list of medicines that are purchased by the hospital and can thus be used within the hospital (hospital pharmaceutical formulary);
- Updates of the hospital pharmaceutical formulary;
- Formulation of guidelines on the purchasing and handling of medicines.

When doing this the Pharmaceutical and Therapeutic Committee has to consider the following guidelines:

- For the use of medicines in hospitals the health condition of the patient is exclusively decisive.
- The selection and use of medicines has to be done on the basis of medical and pharmaceutical scientific evidence and recognised methods (e.g. requests for adding a medicine to the hospital pharmaceutical formulary has to be accompanied by scientific evaluation documents; IT software in the hospital often helps to document the scientific reports and recommendations)
- In the process of the setting up of the hospital pharmaceutical formulary the purpose and the services of the hospital have to be considered to guarantee the provision of the required medicines to the patients.

[80] Art. 19a of the Federal Hospital Act [§19a Krankenanstalten- und Kuranstaltengesetz (KAKuG 1957) i.d.F. BGBI. I No. 108/2012]

For the formulation of guidelines on the purchasing and handling of medicines, the usefulness and economic efficiency need to be taken into account:

- If therapeutically equal medicines are available, the economically more favourable medicine has to be taken.
- In case other therapeutically equal treatment possibilities exist, which are more useful and economically more favourable, the use of medicines should be disregarded.

The following points are regulated in the nine provinces Acts[81]:

- Members of the Pharmaceutical and Therapeutic Committee (head of the hospital pharmacy, the chief doctor, the chief nurse, the administrative director and, in some cases, specialist doctors and as well a representative of the sickness funds);
- Statutes of the Pharmaceutical and Therapeutic Committee (organisation and decision-making);
- Specific tasks of a Pharmaceutical and Therapeutic Committee (e.g. monitoring of the medicines, etc.).

The chief pharmacist of a hospital organisation clearly has a leading expert role within the Pharmaceutical and Therapeutic Committee . The decisions within this commission are taken on a democratic basis. The administrative directors are involved on a formal basis, also in view of the role as controllers.

Hospitals are autonomous in purchasing medicines on the hospital formulary and they may also purchase medicines which are not on the national reimbursement list (the Reimbursement Code) in the out-patient sector.

4.3 Volume control in the in-patient sector

4.3.1 Monitoring

This section provides an overview of the programmes and methods used to evaluate the pharmaceutical policies and system in the in-patient sector, and its impact on health, access to medicines, and cost-containment. It mainly focuses on monitoring of prices, pharmaceutical expenditure and consumption.
Medicines in hospitals are a very sensible and difficult topic, as the monitoring (steering) of medicines may be seen as an intervention in the medical therapy. Different contexts may collide (individual freedom of therapy vs. centralisation and quality standardisation).

[81] cf. section 6.2

Standardised documentation has been implemented in the in-patient sector for many years. As a basis for performance-related reimbursement, public hospitals have to present monthly diagnoses and services reports to the provincial government and/or State Health Fund in accordance with provincial legal provisions. Hospitals are obliged to document their services performed and to deliver the data to the provinces.[82]

The IMS[83] conducts market research on the consumption of medicines in hospitals and provides the data to the pharmaceutical companies. Hospitals which deliver data for this project do have access to consumption data of other hospitals and can benchmark their consumption with the results of other Austrian hospitals. But the data are not publicly available.

By law a quality assurance commission[84] and a hygienic commission need to be implemented in hospitals. They also cover topics where the use of medicines is discussed but under other perspectives than pricing and reimbursement. The quality assurance commission is headed by a competent person; at least a representative of the medical doctors, nurses, the medical-technical and administrative staff has to participate in the commission. The main task of the quality assurance commission is to initiate, to coordinate, to support and to foster the implementation of quality assurance measures. Furthermore the commission is entitled to consult the hospital owners and leading persons in view of necessary quality insurance measures.

Additionally, hospitals are also looking for possible ways to contain costs. The pharmaceutical sector within a hospital is very often not touched because – as already mentioned – the expenditure of medicines seems to be not that important in comparison to other expenditure (e.g. implants). Furthermore it can be assumed that the knowledge on the pharmaceutical system and expenditure within the in-patient sector is rather incomplete.

4.3.1.1 Pharmaceutical expenditure

Based on the regulation on cost accounting for hospitals funded by provincial health funds[85] hospitals are also urged to survey their expenditure. Based on the implementation status of the cost accounting system, it is possible for the individual hospitals to calculate the expenses per patient as well as the amount of medicines per package (via “cost unit accounting”). Data are derived from the IT-system of the hospital. But these data stay within the management of the hospital, they are not publicly available. Only the total expenditure (per department and cost category e.g. medical products and supplies) is reported to the authorities.

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82 Art. 2 of the Regulation on the documentation of diagnoses and services in the inpatient sector (§2, Diagnosen- und Leistungsdokumentationsverordnung)

83 http://www.imshealth.com/

84 Art. 5b of the Federal Hospitals Act [§5b Krankenanstalten- und Kuranstaltengesetz (KAKuG 1957) i.d.F. BGBI. I No. 108/2012]

85 Regulation on cost accounting for hospitals financed via provincial health funds (Kostenrechnungsverordnung BGBl II No. 638/2003 i.d.F. BGBl. II No. 18/2007)

On the basis of the incurred costs per patient and the incomes generated on the basis of the DRG points, the hospital management eventually decides on the service portfolio of the hospital.

As already mentioned in section 4.2.3 the Pharmaceutical and Therapeutic Committee can be authorised to monitor and control the expenditure of medicines within a hospital, a hospital owner organisation or hospital associations. The realisation is mainly due to the personal commitment of the persons involved and the individual pressures for cost controlling and reduction.

In general, based on regular statistics of the consumption and expenditure the hospital pharmacy analyses on a regular basis (twice or four times a year) the incurred pharmaceutical expenditure. Responsible persons of affiliated hospitals also have to deliver reports on a regular basis. This report is then shared with the other members of the Pharmaceutical and Therapeutic Committee , the Executive Board of the hospital owner organisation and other important persons involved. Noticeable differences to the funds budgeted and the actual expenditure as well as significant outliers (disproportionate expenditure for certain medicines) are reported. Having the controlling reports in hands the Pharmaceutical and Therapeutic Committee tries to determine the reasons for the expenditure growth. Depending on the reasons the commission sets appropriate steps (e.g. personal conversations with the departments / persons concerned) to curb these developments. Benchmarks like consumption data, turnover rate as well as ABC-analyses (mechanism for identifying products which will have a significant impact on overall expenditure) and hit lists are used as typical instruments.

Example: In one department of the hospital a high use of antifungal agents is reported. It is suspected that these medicines are applied according to a “principle of indiscriminate all-round distribution”. After conversations with the leading doctor the use of the antifungal agents declines substantially.
Also a trend towards a higher cost consciousness can be observed in Austrian hospitals

4.3.1.2 Consumption monitoring

The persistence, competence and the accuracy of the chief hospital pharmacist and the medical director should be mentioned as a factor of success for cost containment. Another important factor is to have the hospital doctors on board when discussing the expenditure of medicines to guarantee better commitment to prescription guidelines. The personal contact to the persons involved has proven to have effects on the cost containment of a hospital and on the prescription behaviour of the doctors. Hospital doctors are consulted by hospital pharmacists to potential curb over-medication (e.g. a proton pump inhibitor where experts indicate that 80% of the prescriptions are unnecessary). Formal instructions on the prescription of a certain medicine could help but only up to the point where the commitment of the involved persons is assured.

Therefore trainings on critical issues and medicines for the medical personnel is organised. Furthermore representatives of the sickness funds organise presentations on the national out-patient reimbursement codes to bring this knowledge and cost awareness to hospital doctors. It is a constant effort and project to train the medical staff in the key items of the

pharmaceutical system (e.g. market mechanisms and approaches of pharmaceutical companies). The strong involvement of the prescribing doctors in decisions has proven to be successful in reaching the appropriate commitment of this medical profession in hospitals.

Hospitals in Austria usually monitor the consumption of medicines in the in-patient sector. However it is not possible to provide ranking figures due to the fact that different units are used in the hospitals (e.g. packs, ml, m³ etc.).

4.3.1.3 Other Important topics concerning the monitoring of medicines in hospitals

Rational use of medicines in hospitals

In the out-patient sector Guidelines on Economic Prescription of Pharmaceuticals exist. Hospital doctors are instructed by law[86] to consider these guidelines as well in the in-patient sector. But in fact no sanctions for non-compliance exist and therefore these guidelines only tend to have a marginal effect on the prescription of medicines in hospitals. Doctors decide on a single case basis, if a medical therapy is justified by presenting scientific and evidence-based arguments.

Role of hospital pharmacists

The tasks of hospital pharmacists can be divided into three broad categories:

- Supply of medicines;
- Production of medicines (sterile and non-sterile);
- Pharmaceutical services (safe and efficient use of medicines, preparation and information on medicines, teaching and contribution to education programs of medical staff, etc.).

Basically the hospital pharmacist has to promote safe and efficient use of medicines in hospitals. The role of the hospital pharmacist is understood on the basis of a partnership with other medical professionals and also involves face-to-face contacts with patients from time to time. Hospital pharmacists also draft guidelines and recommendations on important topics such as the appropriate use of medicines.

In Austria there were in total 46 chief hospital pharmacists in 2011, which is considered as a rather small group. Informal contacts and exchange work very well within this homogeneous group. Austrian hospital pharmacists are organised within the Austrian Association of Hospital Pharmacists (AAHP) which is a branch of the union of employed pharmacists (Verband Angestellter Apotheker Oesterreichs, VAAOE). AAHP is a member of the European Association of Hospital Pharmacists (EAHP).[87]

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[86] Art. 19a and Art. 24 of the Federal Hospitals Act [§19a and §24 Krankenanstalten- und Kuranstaltengesetz (KAKuG 1957) i.d.F. BGBI. I No. 108/2012]

[87] http://www.aahp.at

In general the group of hospital pharmacists is quite small in Austria. Due to the lack of qualified staff they are not much involved in the work at hospital departments.

The establishment of clinical pharmacologists has no tradition in Austria. Although the employment of clinical pharmacologists contributes substantially to the increase of the safety of patients, this profession has not experienced a special focus. With the increasing importance of patient and pharmaceutical safety in hospitals, this situation could change. Furthermore the hospital pharmacists would like to include the knowledge and training of the pharmaceutical system in the educational system for medical personnel.

Use of antibiotics

In many Austrian hospitals a task force or guidelines are in place, which deal with critical issues concerning the use of antibiotics to avoid overuse and potential creation of resistance. In hospitals of the Tyrolean hospital owner organisation (Tiroler Landeskrankenanstalten GmbH, TILAK) doctors are asked to have a print-out of the guidelines on antibiotics with them to have them present at every incidence.

Safety of medicines

The safety of medicines (e.g. danger of confusion, handling of the product, information provided on the package etc.) used within hospitals plays an important role. In many Austrian hospitals a responsible person is nominated to take care of the safety of medicines. Topics like pharmacovigilance and polypragmasy are covered by this person.

Several pilot projects (e.g. MEDSAFE[88] – with the help of a questionnaire hospitals can conduct a self-evaluation and succeeding benchmarking with the other participating hospitals) in a range of hospitals have been carried out in this field to increase the safety of medicines in hospitals.

Quality management systems and medicines

The quality of the medicines is considered to be guaranteed by the strict authorisation conditions. But medicines play a rather minor role within the quality management system of a hospital, which looks at processes and procedures, although medicines present an integral part in the most important processes of hospital performance.

Different quality management systems are in place in all Austrian hospitals. Either they are applied at certain specific departments (e.g. ISO 9,000) or they cover the whole organisation of the hospital. Standard clinical paths and guidelines are prepared for individual hospitals or hospital owner organisation as a whole (e.g. Joint Commission).

[88] http://www.ipg.uni-linz.ac.at/fr_medsafe.htm

External audits

The financial conduct of public authorities is reviewed by the Austrian Court of Audit (Rechnungshof)[89] which also controls the activities of those hospital owners receiving public funds to finance the hospitals. External audits of whole hospitals or certain aspects are conducted irregularly. The final reports are published on the websites of the Austrian Court of Audit or the respective provincial Courts of Audit.

Expenditure of oncology medicines

Cost-intensive medicines in hospitals are mainly oncology medicines. These are medicines with the highest growth rates (e.g. plus 25% in comparison to the values of the previous year). A study of the Karolinska Institute[90] states that modern (antibody-) therapies are offered in Austria at a rather early and expensive stage. Other countries tend to wait before offering the therapies.

The decision on the use of oncology medicines is critical and complex and also poses an ethical issue in some cases (e.g. to prolong the life of a cancer patient for 2 months by using an oncology medicine that costs € 4,000 per application).

4.3.2 Assessment and evaluation

4.3.2.1 Decision-making tools

According to Evidence Based Medicine independent scientific reports and analyses (e.g. in international journals) have been regularly considered in decisions on the use and purchase of medicines in Austrian hospitals. Either the proposing person delivers accompanying scientific information when suggesting a medicine or the chief hospital pharmacist provides for the required information. The appropriate consideration and interpretation of research reports has proved to be a key factor for successful decisions. Hospital pharmacists suggest including training on finding and reading international scientific reviews within their educational programmes.

4.3.2.2 Health Technology Assessments (HTAs)

However, HTA reports of medicines are only considered in some cases. In Austria different institutes conduct research on HTAs. A national HTA strategy which arranges the different responsibilities of the players in this field was published in 2009.

An online guide on HTAs[91] delivers an overview of the institutes, results and sources of HTA in Austria, selected countries and also cross-national. It is planned to involve hospital owners in the decision on HTA topics.

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89 www.rechnungshof.at

90 http://ki.se/content/1/c4/33/16/Cancer_Report.pdf

91 http://hta-guide.biqg.at/HTA/

Hospital owner organisations expressed an increased need for evaluating the effectiveness of expensive medicines, as expensive medicines do not always seem to be the best solution. Furthermore guidelines on the advantages of expensive medicines and comparisons dealing with the question if the use of innovative products pays off would be needed.

5 Interface management

The use of medicines in hospitals (often brands) influences the prescribing behaviour of out-patient doctors.

Hospital pharmacies purchase their medicines at lower prices than the out-patient pharmacies due to the strategic importance of hospitals. It might happen that the hospital formularies are not aligned to the national out-patient Reimbursement Code (Erstattungskodex, EKO). Furthermore a change of the prescribed medicine in the out-patient sector and vice versa might lead to uncertainty from the patient's perspective.

Representatives of the different provincial sickness funds are members of the Pharmaceutical and Therapeutic Committees in hospitals. But the degree of participation and the role of the out-patient sector within these commissions differ between the Austrian provinces. A better alignment of the hospital pharmaceutical formulary and the national out-patient Reimbursement Code could lead to potential expenditure reductions in the out-patient sector. Additionally a higher pharmaceutical compliance could be achieved as the patient's needs are also considered.

Information exchange between the in-patient and out-patient sector

When patients are discharged from hospitals the patient himself/herself or the responsible doctor receives a discharge letter containing information on the pharmaceutical therapy. Pharmaceutical therapy needs to comply with the Reimbursement Code (EKO) and the Guidelines on Economic Prescribing of Medicines and Therapeutic Aids (RÖV)[92]. Mostly a sentence is added that from the side of the hospital no objections exist to substitute the recommended medicine by a cost-saving medicine (e.g. generics). However, in practice the breach of the regulation does not lead to consequences.

Improvements in the communication between the in-patient and out-patient sector would also have a positive impact on safety and quality in pharmaceutical care. One approach for a better exchange of information could be a centralised collection of the information on the use of medicines at one point. This task could be taken over by clinical pharmacologists, but this profession does not have tradition in Austria and is not very well developed.

Certain projects that deal with an improved cooperation between the in-patient and out-patient sector exist.

Medical service (Medizinischer Dienst) at hospitals

Medical staff of the sickness funds is placed in hospitals and helps to organise the provision of medicines also in the out-patient sector. They are consulted by the hospital pharmacists and eventually clinical pharmacologists. This is mainly a service offered to the patients to al-

[92] According to Art. 24 Sect. 2 of the Federal Hospitals Act [§24 (2) Krankenanstalten- und Kuranstaltengesetz (KAKuG 1957) i.d.F. BGBI. I No. 108/2012]

low for a smooth continuation of the medical therapy with medicines also in the out-patient sector.

Automatic electronic approval service (Arzneimittelbewilligungsservice) at the time of discharge

Agreement between the provincial sickness funds and hospital owner organisations stipulated that medicines which can be prescribed relatively freely in the out-patient sector (medicines in the green box of the Reimbursement Code (EKO)) are not subject to an evaluation and can be used in the in-patient sector and in the following in the out-patient sector. If medicines require a special authorisation (within the yellow or red box of the Reimbursement Code), chief doctors of the sickness funds evaluate the use of the medicine on the basis of single requests of patients. Currently pilot projects on the electronic approval of such medicines (elektronisches Bewilligungsservice) in the out-patient sector are running using the e-card as communication tool. These electronic services also contain a tool, which indicates the most economic alternative medicine in the out-patient sector.

Shift of expensive treatment between the in-patient and out-patient sector

Due to coordination problems between the out-patient and in-patient sector a consistent therapy with medicines might not be guaranteed. The dual (and separated) financing system of the in-patient and out-patient sector might cause a potential shifting of expensive treatments respectively to the other sector. The first use of a medicine is often realised in the in-patient sector whereas the follow-up-medication is taken care of by out-patient doctors. This is mainly due to the fact that at the time of first prescription of a certain medicine an extensive medical observation is required which can only be offered in the in-patient sector. But the current funding and reimbursement situation does not allow for an appropriate financing of certain services in the hospital out-patient departments.

In the Austrian province Tyrol a pilot project (Medicines at the interface, Heilmittel an der Schnittstelle) initiated by the Tyrolean sickness fund is currently running which exactly deals with such shifts of expensive pharmaceutical treatments (oncology medicines and rheumatologic medicines) between the in-patient and out-patient sector. One of the main aims is to realise an adequate financial approach for reimbursing these services in the sector where those medicines are applied.

Interface management is also organised by transition nursing (Überleitungspflege) and coordinators of cases and care.

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