WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

Short PPRI Pharma Profile

Austria 2017

Gesundheit Österreich GmbH

PPRI Pharmaceutical Pricing and Reimbursement Information

Short PPRI Pharma Profile Austria

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WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

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Introduction

PPRI Pharma Profiles: national reporting systems on pharmaceutical pricing and reimbursement

The need for accurate and up-to-date country information has been broadly acknowledged. Information about specific issues of a country is of key importance for decision makers and researchers, even if their needs with regard to the level of detail may vary.

Within the framework of the PPRI (Pharmaceutical Pricing and Reimbursement Information) research project (2005 – beginning of 2008), the project consortium, consisting of the Austrian Public Health Institute (Gesundheit Österreich GmbH) and the World Health Organization (WHO) developed the so-called 'PPRI Pharma Profiles' as a tool for understanding, collecting and analysing pharmaceutical pricing and reimbursement information. A key principle of the PPRI Pharma Profiles was that the Profiles were written by national country experts, usually staff of competent authorities for pharmaceutical pricing and reimbursement (Ministries of Health, Medicines Agencies, Social Health Insurance Institutions) represented in the PPRI network and that they were critically reviewed by project consortium members.

PPRI Pharma Profiles, which primarily focused on the out-patient pharmaceutical sector, for 23 countries were published within the years 2007 to 2009. Even if the European Commission co-funded PPRI project officially ended at the beginning of the year 2008, the PPRI network maintained and PPRI network members continued contributing by updating the PPRI Pharma Profiles.

As a further development, information on the in-patient sector was integrated: The PHIS (Pharmaceutical Health Information System) project surveyed, for the first time, information about the in-patient pharmaceutical sector. The PHIS project consortium, including the Austrian Public Health Institute, the International Healthcare and Health Insurance Institute (IHHII) in Bulgaria and the Slovak Medicines Agency (SUKL), developed the PHIS Hospital Pharma Report about medicines management in the hospital sector and the PHIS Pharma Profile as a comprehensive report about the pharmaceutical out-patient and in-patient sectors. The principle of involving national experts as authors remained the same. 19 PHIS Hospital Pharma Reports and 5 PHIS Pharma Profiles were published. All published country reports and profiles are publicly accessible at the website of WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies at http://whocc.goeg.at/Publications/CountryReports.

Additionally, in order to allow information at a glance, posters about pharmaceutical systems and policies were produced. They are also available at the WHO Collaborating Centre's website at http://whocc.goeg.at/Publications/CountryPosters.

In order to support the production of the PPRI and PHIS Pharma Profiles, templates were made available to the authors. In the course of the years, the templates for the comprehensive profiles (in 2015 the 'PPRI/PHIS Pharma Profiles' were renamed to 'PPRI Pharma Profiles') were revised, further developed and updated.

The PPRI Pharma Profile 2017 is designed to comprise up-to-date information as of 2017 (or latest available year) about pharmaceutical pricing and reimbursement in both the out-patient and in-patient sectors and data for the latest available years.

Templates and glossaries

All PPRI Pharma Profiles are based on a template, which provides a homogenous outline for reporting. The templates were developed in the PPRI and PHIS projects, were circulated for review and feed-back to the PPRI/PHIS network members, were tested by the authors of the profiles and afterwards revised by consortium members, taking into account the experiences made.

Editorial guidelines provide advice to authors and reviewers and aim to increase the readability of the profiles. Readers can expect a universal approach with regard to citations, data presentations, spelling etc. across the PPRI Pharma Profiles.

To achieve clarity for authors, reviewers and readers and thus to create a common understanding of the concepts and terms used, a glossary was developed in the early times of the PPRI project. It has been regularly updated since. The most up-to-date version of the glossary of WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies can be found at the WHO Collaborating Centre's website at http://whocc.goeg.at/Glossary/About. Authors of the PPRI Pharma Profiles are requested to adhere to the glossary.

PPRI, PHIS, and WHO Collaborating Centre

Pharmaceutical Pricing and Reimbursement Information (PPRI) was originally a research project, co-funded by the European Commission, Directorate-General Public Health and Consumers. It ran from 2005 till early 2008. In the course of the project the PPRI network was established, and a set of pharmaceutical indicators, filled with real data from 27 PPRI countries, as well as more than 20 country reports (PPRI Pharma Profiles) and brief overviews on the pharmaceutical systems (country information) were produced.

Today, Pharmaceutical Pricing and Reimbursement Information (PPRI) is a networking and information-sharing initiative on burning issues of pharmaceutical policies from a public health perspective. The PPRI network involves representatives from around 80 institutions: These are public authorities and third party payers from 46 countries (mainly European countries, including all 28 EU Member States) as well as European and international institutions such as European Commission services and agencies, OECD, WHO (Headquarters and Regional Office for Europe) and World Bank.

Within the on-going PPRI initiative, networking of the public authorities continues via regular meetings and continuous sharing of relevant information for decision-making, including updates of country-specific information. The PPRI secretariat is hosted at the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (see below).

The PPRI project was selected by the Executive Agency for Health and Consumers, in collaboration with the Health Programme's National Focal Points (NFP) and the Directorate

General for Health and Consumers (DG SANCO), as a good practice example of EU Public Health projects with an important impact for EU Member States (http://whocc.goeg.at/Literaturliste/Dokumente/FurtherReading/EAHC_NFP_EUHealthProgramme_ImpactProjects.pdf).

Pharmaceutical Health Information System (PHIS) was a European Commission co-funded project which ran from September 2008 to April 2011. The project aimed to increase knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the EU Member States, covering both the out-patient and the in-patient sectors. A special focus of the project was on Hospital Pharma, with a European survey of medicines management in hospitals in the EU Member States and an investigation and analysis of official and actual prices of medicines in hospitals in selected case study countries. Methodology approaches, in particular with regard to terminology, indicators and reporting tools, were further developed based on work started in PPRI.

The Health Economics Department of the Austrian Public Health Institute (GÖG) was nominated as WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies in summer 2010 and redesignated in 2014. The Centre continues methodology work started under the framework of the PPRI and PHIS projects: One of the Centre's explicit tasks is to develop the tool for describing and analysing national pharmaceutical pricing and reimbursement systems ('Pharma Profiles'). WHO Collaborating Centre staff were also involved as experts in the development of the WHO Pharmaceutical Country Profiles by supporting to expand the current tool of the 'PPRI Pharma Profiles' for the European countries, and adapting it so that it can describe the pharmaceutical sector in other health system arrangements.

Within the PPRI and PHIS projects, websites were established. Policy makers, researchers and the interested public are thus offered open access to the Centre's findings and methodological tools developed. The PPRI and PHIS project websites are no longer maintained, all relevant PPRI and PHIS information was integrated in the website of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies: http://whocc.goeg.at. The website of the Centre is designed to serve as an information platform about pharmaceutical policies, and it includes published profiles, studies and analyses, glossaries and templates for reporting of pharmaceutical pricing and reimbursement information.

Since September 2016 the Centre is located at the Pharmacoeconomics Department of the Austrian Public Health Institute (GÖG).

Content

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List of abbreviations

AGES	Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH / Austrian Agency for Health and Food Safety
ASVG	Allgemeines Sozialversicherungsgesetz / Austrian Social Insurance Law
BASG	Bundesamt für Sicherheit im Gesundheitswesen / Austrian Federal Office for Safety in Health Care
BMASGK	Bundesministerium für Arbeit, Soziales, Gesundheit und Konsumentenschutz / Austrian Federal Ministry of Labour, Social Affairs, Health and Consumer Protection
BMGF	Bundesministerium für Gesundheit und Frauen / Federal Ministry of Health and Women's Affairs
DG SANCO	Directorate General for Health and Consumers
DRG	Diagnosis-Related Groups
EKO	Erstattungskodex / Reimbursement list for medicines
EU	European Union
GDP	Gross Domestic Product
GÖG	Gesundheit Österreich GmbH / Austrian Public Health Institute
HEK	Heilmittel-Evaluierungskommission / Pharmaceutical Evaluation Board
HTA	Health Technology Assessment
HVB	Hauptverband der österreichischen Sozialversicherungsträger / Main Association of Austrian Social Security Instititutions
IHHII	International Healthcare and Health Insurance Institute
INN	International Non-proprietary Name
MEA	Managed-entry Agreement
MEL	Medizinische Einzelleistungen / Single medical procedures
NFP	National Focal Points
OECD	Organisation for Economic Co-operation and Development

OPPs	Out-of pocket payments
OTC	Over-the-counter medicines
PHIS	Pharmaceutical Health Information System
PK	Pricing Committee
PM	Preismodell / A type of managed-entry agreement
POM	Prescription-only medicines
PPRI	Pharmaceutical Pricing and Reimbursement Information
PTC	Pharmaceutical and Therapeutic Committee
RöV	Richtlinien über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen / Guidelines on the economic prescription of medicines and therapeutic aids
SHI	Social Health Insurance
SUKL	Štátny ústav pre kontrolu liečiv / Slovak Medicines Agency
THE	Total current health expenditure
VAT	Value-added tax
VO-EKO	Verfahrensordnung Erstattungskodex / Procedural Rules for publication of the EKO
WHO	World Health Organization

1 Health care system

Austria has 8.77 million inhabitants (2017) and a land surface area of 83,878.99 km^2, which correlates to about 105 inhabitants per km² (Statistics Austria 2017d). The population of the capital Vienna represents about a quarter of the country's population.

As a result of declining mortality and persistently low fertility, the share of the population over the age of 64 has been increasing while the population under the age of 14 has been declining in the past decade. An Austrian born in 2016 can expect to live over 80 years, on average: 83.95 years (female) and 79.14 years (male) respectively (Statistics Austria 2017c). Since the late 1990s, Austrians have gained about 3-4 years in life expectancy, with men showing a higher increase than women.

Health care is based on a social insurance model. The Main Association of Austrian Social Security Institutions (Hauptverband der österreichischen Sozialversicherungsträger, HVB) is the umbrella organisation of 18 sickness funds and three further social insurance institutions (e.g. pension funds). About 99.9% of Austria's population are covered by statutory social health insurance (SHI), mainly organised according to regional employment affiliation and vocational groups; there is no free choice of the 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 key legal basis for the social health insurance system is the Austrian Social Insurance Law (Allgemeines Sozialversicherungsgesetz, ASVG). 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.

The responsibilities in the Austrian health system are divided among several players: the Government of Austria, represented by the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection, BMASGK[1], that is responsible for assuring health care at central level, and further ministries, the regions (Bundesländer) and local communities, the Main Association of Austrian Social Security Institutions (HVB), professional bodies (doctors' association, pharmacists' association), statutory associations and hospital associations. The basis for the split of responsibilities is laid down in Art. 12 of the Federal Constitution Act[2] stating that the Federal State is responsible for enacting basic principles and laws, whereas the legislation on implementation and the execution and enforcement thereof is the responsibility of the regions.

[1] In 2017 the responsibilities were within the Federal Ministry of Health and Women's Affairs (Bundesministerium für Gesundheit und Frauen, BMGF). In January 2018 the Ministry was renamed.

[2] Art. 12 of the Federal Constitution Act [Bundes-Verfassungsgesetz BGBl. No. 1/1930 i.d.F. BGBl. I No. 138/2017]

In 2015, total spending for health care was at around € 37.578 million (current health expenditure excl. investments € 35.077 million) which equals 11.1% of the Gross Domestic Product (GDP). Current public health expenditure accounted for more than three quarters of the total current health expenditure (THE) (75.6% in 2015) and current private health expenditure (co-payments, private health insurance fees and other out-of-pocket expenses) amounted to almost one quarter of the current THE (24.4% in 2015) (Statistics Austria 2017b).

For details on health expenditure see the data fact sheet in chapter 6.

Current health expenditure is financed through a mix of health insurance contributions (about 45%), personal contributions (about 23%; in the form of out-of pocket payments (OPPs) and private health insurance), tax contributions provided by the general government pooled from federal, provincial and municipal budgets (about 31%) and other contributions (about 2%; non-profit institutions etc.).

Around 47,000 medical doctors (2015, incl. dentists) provide in-patient and out-patient health care for the Austrian population – several of them work in a hospital and have their own practice. The basis for payment of out-patient doctors is contracts with one or more social health insurers (sickness funds), which are based on framework agreements between the Main Association of Austrian Social Security Institutions (HVB) and the Chamber of Medical Doctors. The 'contract doctors' are remunerated by flat-rate fees, providing a fixed amount per health insurance voucher and per quarter, and in addition, by fee for services. About 10,500 doctors had a contractual relationship with one or more sickness funds (about 4,100 general practitioners, about 3,800 specialists and about 2,800 dentists). On average, about five doctors were available per 1,000 inhabitants. (GÖG 2017)

Traditionally, in-patient care has been playing a very important role in Austria. In 2016 the in-patient medical care of the Austrian population is provided by 273 hospitals with 64,838 available beds (BMGF 2017a; BMGF 2017c). 94 of the 273 hospitals are general hospitals (BMGF 2017b). Hospitals may either be public hospitals (owned by regions, municipalities), or privately non-for-profit hospitals (e.g. owned by a religious order), or private for-profit hospitals. Hospitals are funded on the basis of a Diagnosis-Related Groups (DRG) system. Hospitalised patients in standard class accommodation pay a fee of around € 12 to 21 per day for a maximum of 28 days per year.

Since the beginning of the 1980's the number of hospital beds has declined, as has the average length of stay.

Out-patient clinics and out-patient departments in hospitals also play an important 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').

Since 2001, doctors have been allowed to share consulting rooms or medical equipment within the framework of a group practice as independent medical care providers. Since August 2010

it has been possible to establish ‘group practices’ in form of a limited liability company, but not many physicians have made use of this option yet.

In 2015 the first primary health centre (doctors, nurses, therapists and further health specialists work together at an out-patient facility) opened in Vienna, offering a mix of health care professionals and extended opening hours to reduce the burden on the much frequented out-patient departments in hospitals. Currently, further primary health care centres are being established under the ongoing reform of the health care system.

2 Pharmaceutical system

This section provides a description of the pharmaceutical system; its organisation, regulatory framework and authorities, the market players and the funding of the system for the out-patient and the in-patient sectors.

2.1.1 Regulatory system

The health care system, including the pharmaceutical system, in Austria is characterised by the interplay of a number of actors.

The main competent authority at federal level is the Ministry of Labour, Social Affairs, Health and Consumer Protection, BMASGK[3], which is in charge of the regulatory framework.

Another important public entity related to medicines is the Austrian Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen, BASG) which is responsible for granting market authorisations of medicines and for the vigilance of human and veterinary medicines as well as of medical devices. BASG, which is subordinate to the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection (BMASGK), 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 BASG in its work. AGES Medizinmarktaufsicht (Austrian Medicines and Medical Devices Agency), which is a subdivision of this Agency, takes care of the pharmaceutical agenda.

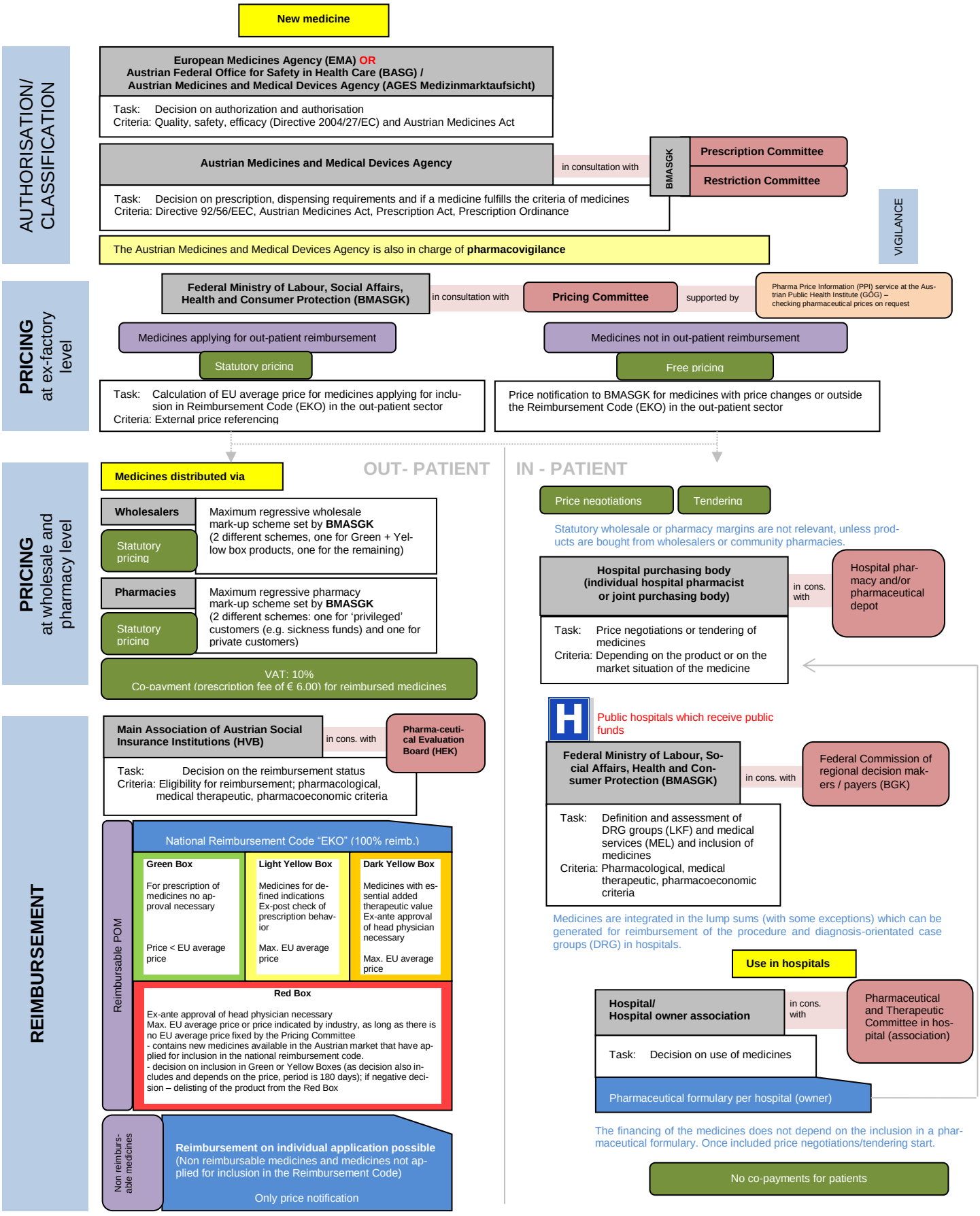
Pricing activities are the competence of the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection, assisted by the Pricing Committee (PK), especially in terms of the EU average pricing system introduced in 2004 for reimbursed medicines in the out-patient sector (see section 3.1.1).

Decisions on the inclusion of medicines into reimbursement in the out-patient sector 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).

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

[3] In 2017: Federal Ministry of Health and Women's Affairs (BMGF)

Figure 2.1: Overview chart of the Austrian pharmaceutical pricing and reimbursement policies, 2017/2018



Source: GÖG

2.1.2 Statistics

A total of about 9,182 medicines (2017) are authorised in Austria (counting different pharmaceutical forms and dosages) including homoeopathics (Austrian Medicines Agency 2017). About 50-60% of the authorised medicines are available on the market.

Around 80 percent of the authorised medicines are prescription-only medicines, i.e. they require a prescription of a physician. The number of reimbursable medicines has substantially increased since 1 January 2005 when the new reimbursement list for medicines (Erstattungskodex, EKO) was introduced (cf. section 3.2). As of 1 January 2018, the EKO contained 7,372 medicines (counting different pharmaceutical forms, different dosages and different pack sizes) (HVB 2017a).

In 2016 the Social Health Insurance covered the cost for around 119 million prescribed packages, amounting to a total of € 3.01 billion. This corresponds on average to 13.8 prescribed packs per person and costs of € 25.29 per pack in 2016 (HVB 2017b).

2.1.3 Market players

There are approximately 220 pharmaceutical companies based in Austria, which employ around 18,000 people. The pharmaceutical industry is characterised by small- and medium-sized enterprises.

Though direct delivery to community pharmacies is allowed, it plays a minor role. Most deliveries are handled via pharmaceutical wholesale. There are about 35 wholesalers, including short-liners and pre-wholesalers. Six wholesalers provide a full range of medicines on the market (full-line wholesalers); together they hold a market share of 95%.

Pharmaceutical wholesale is organised as a multi-channel system. Pharmaceutical wholesalers deliver to pharmacies about three times a day. In case of emergencies; immediate delivery is possible.

In the out-patient sector, medicines are mainly dispensed by community pharmacies, or branch pharmacies, which practise under the supervision of a community pharmacy. There were 1,352 community pharmacies plus 28 branch pharmacies on 31 December 2016 (Austrian Chamber of Pharmacists 2017). All community pharmacies are private pharmacies (i. e. there are no pharmacies in public ownership). The establishment of a new pharmacy in Austria is statutorily regulated in the Pharmacy Act, based on the geographic criteria (the minimum distance between the new pharmacy and the nearest existing pharmacy has to be at least 500 metres, the absence of a dispensing doctor within the community if the number of the population within reach of the next existing pharmacy is not lowered under 5,500 persons).

Austria has a comparably high number of dispensing doctors (841) (Pharmig 2017).

There are 38 hospital pharmacies (April 2017), thus only around 14% of all hospitals have their own pharmacy (Pharmazeutische Gehaltsklasse 2017). In hospitals without a pharmacy, pharmaceutical provision is done via so-called 'pharmaceutical depots', which are supplied by a hospital pharmacy of another hospital or a community pharmacy. However, a trend of outsourcing pharmaceutical provision to logistics centres and centralisation of hospital pharmacy services can be observed in recent years, leading to a decreasing number of hospital pharmacies.

Most hospital pharmacies in Austria serve in-patients only, but for historic reasons five of the hospital pharmacies also operate a community pharmacy and serve the out-patient sector.

2.1.4 Pharmaceutical expenditure

Total pharmaceutical expenditure (Prescription-only medicines, POM, as well as over-the-counter medicines, OTC) in the out-patient sector amounted to € 4,270 million in 2015 and thus corresponded to a share of 12.2% of total current health care expenditure. Public pharmaceutical expenditure accounted for 8.5% (Statistics Austria 2017a).

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

This section covers a description of the organisation of the pricing system and policies. It describes also the organisation of the reimbursement system, the reimbursement schemes, private pharmaceutical expenses and the volume control mechanisms in the out-patient sector as of 2017.

3.1 Pricing

3.1.1 Pricing at manufacturer price level

Pricing of medicines is a responsibility of the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection (Bundesministerium für Arbeit, Soziales, Gesundheit und Konsumentenschutz, BMASGK)[4] which is assisted in doing so by the Pricing Committee (Preiskommission). The Pricing Committee[5] is established at the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection, which also acts as chair of the Committee; further members are representatives of other Federal Ministries and of the 'social partners' (such as the Federal Chamber of Commerce and the Federal Chamber of Labour).

Since 1 September 1999[6] manufacturers have to notify the Ministry of Health and Women's Affairs about the ex-factory price for new medicines or about price changes. These prices are maximum prices, therefore medicines may be priced below.

According to the Price Act, if such a notified price is deemed too high from the perspective of the Austrian economy, the Ministry of Health and Women's Affairs has the opportunity to start an official price-fixing process. 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.

In addition, there are specific pricing rules for medicines whose manufacturers apply for their inclusion onto the positive list (Erstattungskodex, EKO). Since 2004 medicines included in the EKO have to be priced at maximum at the EU average price, as established by the Pricing

4 In 2017: Federal Ministry of Health and Women's Affairs (BMGF)

5 The Pricing Committee's activities are based on the Price Act, which, in fact, does not apply to medicines only, but also to other important products for society such as raw materials: it states rather general criteria for setting prices, such as the affordability for consumers and the economic circumstances of the industry. According to the Price Act of 1992 (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]), the Ministry of Health and Women's Affairs is entitled and obliged to determine a 'national price justified in terms of the national economy'.

6 The Price Act has been accompanied by a price notification agreement between the Federal Chamber of Commerce and the Federal Chamber of Labour.

Committee. 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).

The relevant legal basis is the Regulation on Procedural Rules for Calculation of the EU average price (first published on 1 October 2005, several amendments and most recent one of December 18, 2017)[7]. This sets out the relevant procedures and the methodological approach including the country basket, which covers all EU Member States.

The regulation states that the market authorisation holder, who applies for inclusion of a medicine into the EKO, has to provide information, including whether the product is on the market in other EU Member States. If this is the case, the ex-factory and wholesale prices of the medicine in all EU Member States have to be submitted. To do this, pharmaceutical companies have to use a standard form, which was developed by the Pricing Committee (PK).[8] According to Austrian Social Insurance Law (ASVG), the research and planning institute Austrian Public Health Institute / Gesundheit Österreich GmbH (GÖG) may be asked by the Pricing Committee to check the prices submitted by the industry.

Then the Pricing Committee calculates the EU average price of the medicines applying for reimbursement. The prices are compared per unit to presentations of the same strength, the same or closest pack size and the same pharmaceutical form at the ex-factory price level. An EU average price can be calculated if ex-factory prices are reported of at least two EU Member States (excl. Austria). When price data are available from fewer than two EU Member States, the price reported by the pharmaceutical company is considered to be the EU average price until the next evaluation.

The first evaluation by the Pricing Committee takes place 6 months after its application for reimbursement is submitted at the HVB. According to the legal amendments in April 2017, the price committee has to re-evaluate the EU average price 18 months after the first calculation and 24 months after the second calculation. Additionally, it can be evaluated again 18 months after the third calculation.

Since April 2017, an additional provision for medicines which are not included in the EKO (hence only price notification and free pricing applies), but exceed annual sales worth 750,000 Euros (on ex-factory price basis, within 12 months, not calendar year) at the expense of the Austrian health insurance institutions is in place: as soon as this threshold is exceeded for a specified pharmaceutical (incl. all packages and strengths), the Main Association of Social

[7] Regulation on Procedural Rules for Calculation of the EU average price [Regelung für die Vorgehensweise der Preiskommission bei der Ermittlung des EU-Durchschnittspreises according to Art. 351c.6 ASVG; http://www.bmgf.gv.at/home/Schwerpunkte/Medizin/Arzneimittel/Arzneimittelpreise/EU_Durchschnittspreise_laut_ASVG] and the Amendment of 18/12/2017

[8] Price notification form according to Regulation on Procedural Rules for Calculation of the EU average price, available for download http://www.bmgf.gv.at/home/Schwerpunkte/Medizin/Arzneimittel/Arzneimittelpreise/EU_Durchschnittspreise_laut_ASVG

Insurance Institutions has to notify the Pricing Committee. Within eight weeks of this notification, the Pricing Committee has to determine an EU average price for this pharmaceutical. If the determined EU average price is lower than its indicated price, the company will be asked to repay the difference between the price and the determined EU average price from the point in time on when the turnover threshold was first exceeded.

For reimbursed medicines, the determined EU average price at manufacturer price level acts as a minimum requirement for the inclusion into the EKO. The Main Association of Social Security Institutions (HVB) applies the price determining principles put forth in the Procedural Rules for the publication of the EKO[9] as well as the economic guiding principles of the Pharmaceutical Evaluation Board[10] and will, on this basis, negotiate the reimbursement price. As soon as an agreement is reached, the reimbursement price then listed in the EKO is binding. If negotiations fail, companies have the possibility to appeal to the Federal Administrative Court (Bundesverwaltungsgericht).

In Austria a price link is in place for reimbursed 'follower' medicines - generics and biosimilars. Details/specifications were changed in spring 2017. For generics: The first generic 'follower' is priced at least 50% (48% prior to April 2017) below the price of the original brand product, which went off-patent. The second and each subsequent 'follower' is required to have a price difference related to the previously included generic: The price of the second generic 'follower' has to be 18% (formerly 15%) lower than the one of the first 'follower', and the price of the third 'follower' has to be 15% (formerly 10%) lower than the price of second 'follower'. The price of the original product has to be reduced by at least 30% within three months after the inclusion of the first generic into the EKO. If there is a 3rd follower, all marketing authorisation holders of that product have to decrease the price to the price of the 3rd follower. Further followers have to offer price deductions of at least € 0.10 to be included in the reimbursement code. Specific rules also apply for mee-too products.

The price linkage between original brands and biosimilars since April 2017 is as follows: The first follower has to be priced at least 38% below the originator. The price of the second follower has to be at least 15% lower than the first follower and the third follower has to be priced at least 10% below the second follower, Then the same procedure as for generics applies (originator has to decrease its price by 30% within three months, etc.).

In Austria, tendering in the out-patient sector (e.g. for generics) is not applied, except for vaccines or for medicines that are mainly used as strategic reserve (for armed forces or against pandemic influenza).

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9 Procedural Rules for publication of the Reimbursement Code according to Art. 351g ASVG [Verfahrensordnung zur Herausgabe des Erstattungskodex nach § 351g ASVG (VO-EKO)], https://www.ris.bka.gv.at/SVRecht

10 Objective and verifiable economic guiding principles of the Pharmaceutical Evaluation Board [Ökonomische Beurteilungskriterien der Heilmittel-Evaluaierungs-Kommission], available for download http://www.hauptverband.at/portal27/hvbportal/content?contentid=10007.693798&viewmode=content

Since 2008 the profits of pharmaceutical companies are, on the basis of the Procedural Rules for publication of the Reimbursement Code, addressed by the 'Pharma Framework Contract' ('Rahmen-Pharmavertrag'). Under this framework agreement, pharmaceutical companies and wholesalers pay a kind of ex-post rebate to the Austrian sickness funds. Under the current Framework Contract (2016-2018) pharmaceutical companies and wholesalers pay € 125 million in 2016, and in 2017 and 2018 up to another € 160 million (€ 10 million per percentage point increase in pharmaceutical expenditure per year) to the Austrian sickness funds.

3.1.2 Mark-ups and taxes

In Austria, wholesalers are remunerated via a statutory regressive mark-up scheme applicable to all medicines[11]. There are two regressive mark-up schemes – one for medicines included in the yellow or green boxes of the reimbursement list EKO (cf. Section 3.2) and one for the remaining medicines (see Table 3.1 and Table 3.2).

Table 3.1: Wholesale mark-up scheme for medicines included in the yellow and green boxes of the Reimbursement Code, 2017

Ex-factory price in €	Maximum mark-up as a % on the 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's Affairs (BMGF) on the maximum mark-ups in pharmaceutical wholesale 2004

[11] 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 3.2: Wholesale mark-up scheme for medicines not included in the green and yellow boxes of the Reimbursement Code, 2017

Ex-factory price in €	Maximum mark-up as a % on the 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's Affairs (BMGF) on the maximum mark-ups in pharmaceutical wholesale 2004

According to the Austrian Pharmaceutical Tax Enactment ('Österreichische Arzneitaxe', pharmacy mark-up regulation)[12] pharmacies are remunerated via a statutorily fixed mark-up scheme applicable to all medicines.

[12] Austrian Pharmaceutical Tax Enactment 1962, amended in 2016 [Österreichische Arzneitaxe, 1962 i.d.F. BGBl. II No. 338/2017]

Table 3.3: Pharmacy mark-up scheme for privileged customers, 2017

Pharmacy purchasing price (PPP) in €	Mark-up as a % on the PPP	Pharmacy retail price (PRP) in €
0.00-10.00	37.0	-
10.01-10.15	-	13.70
10.16-20.00	35.0	-
20.01-20.45	-	27.00
20.46-30.00	32.0	-
30.01-30.94	-	39.60
30.95-60.00	28.0	-
60.01-62.44	-	76.80
62.45-100.00	23.0	-
100.01-104.24	-	123.00
104.25-120.00	18.0	-
120.01-124.21	-	141.60
124.22-150.00	14.0	-
150.01-155.45	-	171.00
155.46-200.00	10.0	-
200.01-207.55	-	220.00
207.56-350.00	6.0	-
350.01-357.07	-	371.00
more than 357,08	3.9	-

Source: Austrian Pharmaceutical Tax Enactment, 30 December 2003

Pharmacy mark-ups are regressively staggered and are based on the pharmacy purchasing price. There are two different schemes, one scheme applying reduced mark-ups for ‘privileged customers’, such as the Austrian sickness funds, the State, the Austrian regions, communities, funds and institutions held by these, as well as non-profit hospitals, and a basic scheme for ‘private customers’, in which an additional flat ‘private customer mark-up’ of 15% is added (see Table 3.3 and 3.4).

The wholesale and pharmacy mark-ups are regulated as maximum mark-ups. In practice, actual mark-ups correspond to statutory mark-ups.

Wholesalers may grant discounts to pharmacies, and this is common practice. Pharmacies may also grant discounts to patients.

Table 3.4: Pharmacy mark-up scheme for private customers, 2017

Pharmacy purchasing price (PPP) in €	Mark-up as a % on the PPP	Pharmacy retail price (PRP) in €
0.00-7.29	55	-
7.30-7.58	-	11.30
7.59-15.70	49	-
15.71-16.25	-	23.40
16.26-26.25	44	-
26.26-27.19	-	37.80
27.20-63.09	39	-
63.10-65.44	-	87.70
65.45-90.74	34	-
90.75-94.26	-	121.60
94.27-108.99	29	-
109.00-113.38	-	140.60
113.39-130.80	24	-
130.81-135.73	-	162.20
135.74-203.43	19.5	-
203.44-211.39	-	243.10
211.40-363.30	15	-
363.31-371.37	-	417.80
more than 371.37	12.5	-

Source: Austrian Pharmaceutical Tax Enactment, 14 July 2000

The value-added tax (VAT) rate on medicines is 10%. This is a lower rate than the standard VAT rate of 20% in Austria. Before 2009, the VAT rate on medicines used to be equal to the 20% standard rate. There are no further taxes / fees related to medicine prices in Austria.

3.2 Reimbursement

Medicines are granted in kind to the insured (nearly 100% of Austrian's population are covered by statutory health insurance).

The legal basis for the reimbursement scheme is Art. 31 (3) paragraph 12 of the ASVG[13] and the Procedural Rules for publication of the EKO (Verfahrensordnung Erstattungskodex, VO-EKO)[14], which are fixed by decree.

[13] Art. 31 (3)12. ASVG 1955, amended [Art. 31 (3)12 ASVG, i.d.F. BGBl. I No. 151/2017]

[14] Procedural Rules for publication of the Reimbursement Code according to Art. 351g ASVG [Verfahrens-ordnung zur Herausgabe des Erstattungskodex nach § 351g ASVG (VO-EKO)], https://www.ris.bka.gv.at/SVRecht

The Main Association of Social Security Institutions (HVB) is responsible for deciding whether a medicine should be reimbursed or not. Eligibility criteria for reimbursement are based on pharmacological evaluation, medical-therapeutic evaluation and health-economic evaluation.

In the case of a negative decision related to the inclusion into reimbursement, the manufacturer may appeal to the Federal Administrative Court.

In Austria, there is a positive list of medicines, the Erstattungskodex (EKO). All medicines included in the EKO qualify for general reimbursement; however, there are different conditions regarding the prescribing rules. The EKO has three main segments: the red box, the yellow box (subgroup: light yellow) and the green box. The red box includes all medicines (including off-patent medicines) that have applied for inclusion into the EKO. The HVB decides in accordance to the Transparency Directive[15] within 180 days (for pricing and reimbursement) from the date it receives the application by the marketing authorization holder (MAH). In case of a negative decision, the medicine will be delisted from the red box. The yellow box includes medicines, which have a substantial therapeutic benefit, and reimbursement will be granted only if specific criteria (e.g. specific disease or age group) are met. For medicines in the red and the yellow boxes, an ex-ante approval of a sickness fund 'head physician' has to be sought by the prescribing doctor. In the subgroup of the light yellow box, instead of an ex-ante approval an ex-post control of the records kept by the prescribing doctor might take place. The green box includes medicines qualifying for automatic reimbursement; these may be prescribed by any contract doctor. In addition to the positive list, there is a list of categories of medicines, which are not eligible for reimbursement (e.g. contraceptives).

Since 2016 it has been indicated in the EKO whether a discount agreement or a similar managed-entry agreement (MEA) has been concluded between the Main Association of Social Security Institutions and pharmaceutical industry. Medicines subject to these arrangements are marked by '(PM)' (Preismodell).

Medicines are either fully reimbursed or not reimbursed at all (there are neither percentage reimbursement rates nor percentage co-payment rates). If medicines are reimbursed, patients have to pay a fixed prescription fee out-of-pocket amounting to € 6.00 (2018, € 5.85 in 2017) per item on the prescription. Since January 2008 the spending of prescription fees has been capped statutorily, i.e. all beneficiaries spend a maximum 2% of their net annual (family) income on medicines. Vulnerable groups (e.g. low income pensioners, people suffering from communicable diseases) are completely exempt from the prescription fee.

Austria has no reference price system (i.e. internal price referencing).

[15] Council Directive 89/105/EEC

3.3 Volume control

In Austria there are no pharmaceutical budgets being applied for doctors or other health care providers, e.g. there is no prescribing budget.

The prescription volume and pattern of GPs and specialists are monitored by the sickness funds with a view to their compliance with the HVB's Guidelines on the economic prescription of medicines and therapeutic aids (RöV)[16] in which doctors are encouraged to prescribe the most economic medicine out of several therapeutically similar alternatives.

In Austria, generic substitution by the pharmacist is not allowed. Doctors are not permitted to prescribe by International Non-proprietary Name (INN), they always have to use the trade name. Generics uptake (see section 2.1.2 and data in chapter 6) is comparatively low, this might be attributable to the fact that neither generic substitution nor INN prescribing is allowed.

[16] Guidelines on the economic prescription of medicines and therapeutic aids [Richtlinien über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005)], https://www.ris.bka.gv.at/SVRecht/

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

4.1 Pricing and procurement

Hospitals may either be public hospitals (owned by regions, municipalities), privately non-for-profit hospitals (e.g. owned by a religious order), or private for-profit hospitals.

In Austria the purchasing of medicines in the in-patient sector is organised in a decentralised way, with decisions taken by the individual hospital owner organisations. The medicine price is the outcome of negotiations between the purchaser (e.g. individual hospital) and the manufacturer. For medicines included in the out-patient reimbursement list, the regulated price is the starting point of negotiations.

In many hospitals, hospital purchasing bodies (either the chief hospital pharmacist or a designated purchasing department per hospital owner organisation) are in charge of purchasing of medicines. In most cases, they are in direct contact with the manufacturers and negotiate the prices. Tendering is less common, but on the rise. Public procurement procedures are regulated by the Austrian Federal Act on public tenders and nine regional acts. 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) are also of importance.

In recent years, some hospital owner organisations have been exploring options for joint procurement.

Commercial discounts granted by manufacturers to hospitals are common. They range from 0% to 100% of the list prices. Discounts and rebates tend to be granted for medicines for which therapeutic alternatives are available, and/or which tend to be used in the follow-up out-patient treatment, whereas hospitals pay the non-discounted list prices for new, usually high-cost medicines. The provision of medicines cost-free to hospitals is allowed, and it takes place. In recent years, managed entry agreements (MEA) have been increasingly concluded between manufacturers and hospitals (for mainly hospital based medicines).

Medicine prices in the in-patient sector are not publicly available. They are only communicated within the hospitals (or hospital owner organisations) and integrated into the individual hospital IT system where they can be consulted.

4.2 Reimbursement

Medicines are integrated in the lump sums, which are refunded to the hospitals according to diagnosis-orientated case groups (DRG). The lump sums generated by eligible hospitals are billed to the Regional Health Funds. An average consumption of medicines per diagnosis was considered when calculating the lump sums. Some notable exceptions in the DRG lump sum

system are oncology medicines, since these medicines are recorded as own diagnosis-orientated case groups. Approximately 50 defined single medical procedures (Medizinische Einzelleistungen, MEL) exist within the system, where the dispensing of a specific oncology medicine is explicitly reimbursed.

According to the Austrian Law (Federal Hospitals Act) the basis for the eligibility of a medicine to be used and to be reimbursed in the in-patient sector is the hospital pharmaceutical formulary: Only medicines which are included in the individual hospital pharmaceutical formulary are procured by the hospitals. In general, approximately 1,500-2,500 medicines are included in hospital formularies. There is no national positive list of medicines used in hospitals.

The decision making body related to the inclusion of medicines in the hospital pharmaceutical formulary is the Pharmaceutical and Therapeutic Committee (PTC). Each hospital can have its own PTC, but joint hospital commissions per owner organisation are also common.

The Pharmaceutical and Therapeutic Committee consists of the chief hospital pharmacist (the head of the hospital pharmacy), the chief doctor, the chief nurse, the administrative director as well as a representative of the regional sickness funds (dependant on different regional regulations) and in some cases, specialist doctors. The defined tasks of a PTC are the compilation of a list of medicines, which are used in hospital care (hospital pharmaceutical formulary), the update of the formulary and the formulation of guidelines on the purchasing and handling of medicines. The PTC decides on the basis of different criteria (therapeutic value, cost-effectiveness, etc.) at their regular meetings (usually at a quarterly basis) if a medicine should be included in the list or not.

Hospital pharmaceutical formularies are electronically available in the different hospital IT systems, but are not publicly accessible.

Patients do not have to provide extra payments for medicines they receive during their in-patient stay.

4.3 Volume control

As a basis for performance-related reimbursement, public hospitals have to present monthly diagnoses and services reports to the regional government and/or Regional Health Funds in accordance to regional legal provisions. The Pharmaceutical and Therapeutic Committee can be authorised to monitor and control pharmaceutical expenditure within a hospital or a hospital association. In general, using statistics of the consumption and expenditure the hospital pharmacy / the hospital owner analyses on a regular basis (twice or four times a year) the incurred pharmaceutical expenditure. Based on these data, the PTC aims to explore the reasons behind expenditure growth and, as a result, takes appropriate measures (e.g. personal conversations with the departments / persons concerned) to curb these developments.

The financial conduct of public authorities is reviewed by the Austrian Court of Audit (Rechnungshof), which also reviews the activities of those hospitals receiving public funds to finance the hospitals.

Independent scientific analyses (e.g. of international journals) were reported to be considered in decisions on the use and purchase of medicines in Austrian hospitals. Health Technology Assessment (HTA) reports of medicines are only consulted on a rare basis, but more commonly used when purchasing medical devices.

5 Interface management and developments

In Austria, different payers are responsible for funding medicines in the out-patient sector and the in-patient sector. Since the start of the treatment with specific medicines in the in-patient sector impacts the further use of medicines in the out-patient sector, there is a need for improved interface management.

During the last years, awareness for improved interface management has risen. Representatives of the regional sickness funds have become (non-voting) members of the Pharmaceutical and Therapeutic Committees in hospitals. Their participation has contributed to an increased understanding between the sectors. Furthermore some single projects are realised between regional sickness funds and hospitals (e.g. aiming at the reduction of polypharmacy or providing trainings for hospital staff).

At the time of writing, Austria is undergoing a major health care reform (Zielsteuerung Gesundheit) which aims at strengthening the primary health care sector. Additionally, some initiatives tackle the pharmaceutical provision targeting an effective and efficient supply of medicines across sectors and regions: e.g. exploring options for consolidated and/or joint procurement or negotiations or INN prescribing.

In 2013 a Medicines Commission (‘Medikamentenkommission’) was set up with representatives from the Ministry, regional governments, Main Association of Social Security Institutions and sickness funds. The Commission had the aim to develop joint provision models for the in-patient and out-patient sector for high priced and specialized medicines. Its task was to establish the eventual ‘best point of service’ reflecting medical, therapeutical, health economic and health care considerations. In 2016 it was decided to terminate the Commission since no agreement could be reached and to continue with other approaches to address the issues.

In June 2016, Austria joined the initiative of Belgium, the Netherlands and Luxembourg on pharmaceutical policy - The BeNeLuxA Initiative[17]. BeNeLuxA aims to ensure sustainable access to innovative medicine at affordable cost for patients in the four countries.

[17] http://beneluxa.org

6 Pharmaceutical data fact sheet: Austria

		2016	2015	2014	Source	Notes
Demography						
Population	total	8,700,471	8,584,926	8,507,786	Statistics Austria	-
	0-14 years	1,246,847	1,226,013	1,218,844		
	15-64 years	5,848,657	5,774,985	5,732,284		
	> 64 years	1,604,967	1,583,928	1,556,658		
Life expectancy	at birth	n.a.	81.16	81.40		
	at age 65	n.a.	19.68	20.00		
Economic data in million Euro						
Gross domestic product		353,297	344,493	333,063	Statistics Austria	-
Current health expenditure	total	n.a.	35,077	33,987	Statistics Austria – System of Health Accounts	According to SHA classification: HE = total current HE Out-patient sector = HP3-9 In-patient sector = HP1-2 Public = HF1 Private = HF2-3
	public	n.a.	26,513	25,655		
	private	n.a.	8,564	8,331		
Current health expenditure in the out-patient sector	total	n.a.	18,560	17,937		
	public	n.a.	12,499	12,068		
	private	n.a.	6,061	5,869		
Current health expenditure in the in-patient sector	total	n.a.	16,517	16,050		
	public	n.a.	14,013	13,587		
	private	n.a.	2,503	2,462		
Prescriptions						
No. of prescriptions	in volume	116,089,192	118,802,404	120,996,215	HVB	Prescription in volume = number of items prescribed.
Prescriptions	in value (in million Euro)	3,113,952	3,037,301	2,892,607	HVB	Prescription in value = public expenditure of prescribed medicines. Based on reimbursed price excl. VAT

		2016	2015	2014	Source	Notes
Pharmaceutical consumption						
Total	In packs	n.a.	240,717,000	236,973,000	Pharmig	DDD = defined daily doses Sold packages
	In DDD	n.a.	n.a.	n.a.		
Out-patient sector	In packs	n.a.	217,947,000	214,595,000	Pharmig	
	In DDD	n.a.	n.a.	n.a.		
In-patient sector	In packs	n.a.	22,771,000	22,378,000	Pharmig	
	In DDD	n.a.	n.a.	n.a.		
Generic shares						
Shares in % of total market (in-patient/ out-patient)	In volume	n.a.	n.a.	n.a.		Volume: Expressed in number of prescriptions Value: Expressed in expenditure
	In value	n.a.	n.a.	n.a.		
Shares in % of total out-patient market	In volume	n.a.	n.a.	n.a.		
	In value	n.a.	n.a.	n.a.		
Shares in % of out-patient reimbursement market[18]	In volume	32.06%	32.51%	32.00%	HVB	
	In value	13.93%	14.29%	14.73%	HVB	
Shares in % of out-patient off-patent market[19]	In volume	53.10%	52.73%	52.11%	HVB	
	In value	48.43%	47.47%	46.91%	HVB	
Shares in % of the in-patient market	In volume	n.a.	n.a.	n.a.		
	In value	n.a.	n.a.	n.a.		
Retailers of medicines						
No. of community pharmacies	private	1,352	1,340	1,328	Austrian Chamber of Pharmacists	Data as of 31 December Hospital pharmacies dispensing to out-patients are not included in this figure

[18] The market is divided in 'initial products' included in the EKO and follower products. Biosimilars are treated as chemical followers and biologics as other initial products.

[19] Figures relate to the out-patient substitutable market – i.e. all products in the reimbursement list which could be substituted by a generic or biosimilar. Should a product be off-patent but without alternatives, it is not included here.

		2016	2015	2014	Source	Notes
No. of hospital pharmacies for out-patients		38	40	41	Pharm. Ge-haltsklasse	Data as of 31 December
No. of dispensing doctors		857*	841	866	Pharmig, HVB	Data as of 31 December *Data as of 1 July 2016
Total no. of POM dispensaries		2,247	2,221	2,235		
Pharmaceutical expenditure in million Euro						
Pharmaceutical expenditure	Total	n.a.	5,362	n.a.	GÖG	POM and OTC (HC5.1.1 and HC5.1.2 according to SHA classification)
	Public	n.a.	3,964	n.a.	GÖG	
	Private	n.a.	1,397	n.a.	GÖG	
Pharmaceutical expenditure in the out-patient sector	Total	n.a.	4,270	4,110	Statistics Austria	
	Public	n.a.	2,978	2,844	Statistics Austria	
	Private	n.a.	1,292	1,266	Statistics Austria	
Pharmaceutical expenditure in the in-patient sector	Total	n.a.	1,092	n.a.	GÖG	
	Public	n.a.	968	n.a.	GÖG	
	Private	n.a.	105	n.a.	GÖG	

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