WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

Short PPRI / PHIS Pharma Profile

Austria 2013

Gesundheit Österreich GmbH

PPRI Pharmaceutical Pricing and Reimbursement Information

PHIS

BUNDESMINISTERIUM FÜR GESUNDHEIT

Short PPRI / PHIS Pharma Profile Austria

Update: November 2013

PPRI/PHIS Representatives
Gesundheit Österreich GmbH: Sabine Vogler, Claudia Habl, Christine Leopold, Bettina Schmickl, 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

Authors
Gesundheit Österreich GmbH: Sabine Vogler, Bettina Schmickl, Nina Zimmermann

ÖBIG
Österreichisches Bundesinstitut für Gesundheitswesen
WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies
BUNDESMINISTERIUM FÜR GESUNDHEIT

Table of content

List of tables and figures

Introduction

PPRI / PHIS 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 Health Institute (Gesundheit Österreich GmbH / Österreichisches Bundesinstitut für Gesundheitswesen) and the World Health Organization (WHO) developed the so-called 'PPRI Pharma Profiles' as a tool for understanding, collecting and analyzing 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 PPRI project officially ended at the beginning of the year 2008, the PPRI network members continued contributing by updating the PPRI Pharma Profiles.

The PHIS (Pharmaceutical Health Information System) project surveyed, for the first time, information about the in-patient pharmaceutical sector. The PHIS project consortium, consisting of the project leader Austrian Health Institute (GÖG), the International Healthcare and Health Insurance Institute (IHHII) in Bulgaria and the Slovak Medicines Agency (SUKL), encouraged network members to write national PHIS Hospital Pharma reports about medicines management in the hospital sector and a PHIS Pharma Profile as a comprehensive report about the pharmaceutical out-patient and in-patient sectors. As of today, 19 PHIS Hospital Pharma reports and 5 PHIS Pharma Profiles were published. The country reports 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 profiles (now called 'PPRI/PHIS Pharma Profiles') were revised, further developed and updated.

The PPRI/PHIS Pharma Profile 2013 is designed to comprise up-to-date information as of 2013 about pharmaceutical pricing and reimbursement in both the out-patient and in-patient sectors and data for the latest available years.

Templates, glossaries and indicators

All PPRI and PHIS 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 project management, taking into account the experiences made.

The uniform reporting outline of the Pharma Profile Templates provides the benefit that the national reports can easily be used for comparative analyses. The indicators in the PHIS database (http://phis.goeg.at/index.aspx?alias=phisDatabase) are derived from the PPRI and PHIS Pharma Profiles.

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 / PHIS 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 updated 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/PHIS Pharma Profiles are requested to adhere to the Glossary.

PPRI, PHIS, and the 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 was performed 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 28 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 70 institutions: These are public authorities and third party payers from 41 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 (HQ and Regional Office for Europe) and World Bank.

In the on-going PPRI initiative, the networking of the public authorities continues via regular networking meetings and continuous sharing of relevant information for decision-making, including up-dates 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 (EAHC, from 2014 on called CHAFEA), in collaboration with the Health Programme's National Focal Points and the Directorate General for Health and Consumers (DG SANCO), as a good practice example of a EU Public Health project with an important impact for 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 tools, 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 Health Institute was nominated as WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies in summer 2010. 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 analyzing national pharmaceutical pricing and reimbursement systems ('Pharma Profiles'). WHO Collaborating Centre staff are also involved as experts in the development of the WHO Pharmaceutical Country Profiles by supporting to expand the current tool of the PPRI/PHIS 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 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, indicators of the PHIS database, glossaries and templates for reporting of pharmaceutical pricing and reimbursement information.

About this short profile

This short profile aims at providing a concise overview of the pharmaceutical system of the given country.

Unless indicated differently, information and data refer to the situation in 2013.

The report is structured in 6 sections:

1 Health care system
2 Pharmaceutical system
3 Pricing, reimbursement and volume control in the out-patient sector
4 Pricing, reimbursement and volume control in the in-patient sector
5 Interface management and developments
6 Pharmaceutical data fact sheet

1 Health care system

Austria has 8.4 million inhabitants (2012) and a land surface area of 83,878.99 km^2, which correlates to about 100 inhabitants per km^2. 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 age 64 has been increasing while the population under age 14 has been declining in the past decade. An Austrian born in 2012 can expect to live over 80 years on average: 82.8 years (female) and 77.7 years (male) respectively. Since the late 1990s, Austrians have gained about 3 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 19 sickness funds and three further social insurance institutions (e.g. pension funds). About 98.8% of Austria's population are covered by statutory social health insurance (SHI), mainly organised according to regional 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 Health (Bundesministerium für Gesundheit, BMG), 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[1] 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.

In 2011, total spending for health care was at around € 32.41 million (current health expenditure excl. investments € 30.7 million) which equals to 10.8% of the Gross Domestic Product

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

(GDP). Public health expenditure accounted for more than three quarter of the total health expenditure (THE) (76.2% in 2011) and private health expenditure (co-payments, private health insurance fees and other out-of pocket expenses) amounted to almost one quarter of THE (23.8% in 2011).

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 22%; 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 32%) and other contributions (about 1%; non-profit institutions etc.).

Around 44,300 medical doctors (2012) 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 10,300 doctors had a contractual relationship with one or more sickness funds (about 4,100 general practitioners, about 3,300 specialists and about 2,900 dentists). On average, about five doctors were available per 1,000 inhabitants.

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 277 hospitals with 64,703 available beds (as of 31 December 2012). 99 of the 277 hospitals are general hospitals (2012). 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 19 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 found 'group practices' in form of a limited liability company, but not many physicians have made use of this option yet.

2 Pharmaceutical system

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 Federal Ministry of Health (BMG), which is in charge of the regulatory framework.

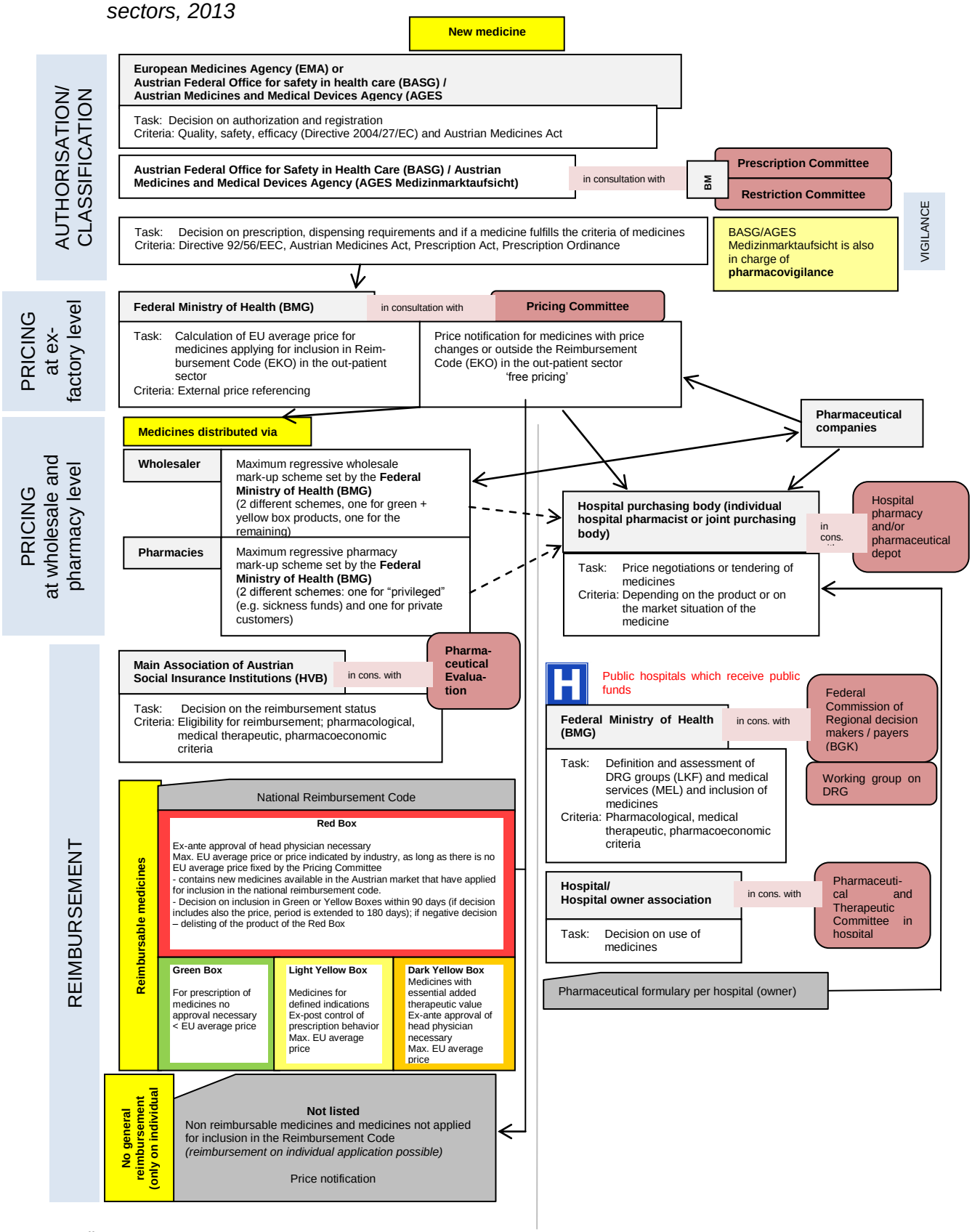
Another important public entity related to medicines is the Austrian Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen, BASG) which is responsible for granting market authorisations and for the vigilance of human and veterinary medicines as well as of medical devices. BASG, which is subordinate to the Federal Ministry of Health (BMG), 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 Health 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.

Figure 2.1: Flowchart of the Austrian pharmaceutical system – out-patient and in-patient sectors, 2013



Source: GÖG

2.1.2 Statistics

A total of about 9,617 medicines (as of 1 January 2013) are authorised in Austria (counting different pharmaceutical forms and dosages) including homeopathics. 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 physican. The number of reimbursable medicines has substantially increased since 1 January 2005 when the new reimbursement list for medicines (Erstattungkodex, EKO) was introduced (cf. section 3.2). As of 1 January 2012, the EKO contained 6,462 medicines (counting different pharmaceutical forms, different dosages and different pack sizes).

In 2012 the Social Health Insurance covered the cost for around 120 million prescribed packages, amounting to a total of € 2.7 billion. This corresponds to 15 prescribed packs and costs of € 329 per insured person.

With 26.1 percent (in volume) and 15.6% (in value, data as of 2010) of the out-patient market, generic shares are comparably low in Austria. For further data on generic shares and other statistics see chapter 6.

2.1.3 Market players

There are approximately 220 pharmaceutical companies based in Austria, which employ around 11,000 people. Pharmaceutical industry is characterised by small- and medium-sized enterprises.

Though direct delivery to community pharmacies is allowed, it plays a minor role (three percent). Most deliveries are handled via pharmaceutical wholesale. There are about 35 wholesalers, including short-liners and pre-wholesalers. Eight 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 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 1,303 community pharmacies plus 26 branch pharmacies (31 December 2012). All community pharmacies are private pharmacies. 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) and demographic criteria (the number of people who continue to be supplied by adjoining pharmacies must not fall below 5,500 as a result of establishing a new pharmacy).

Furthermore, Austria has a comparably high number of dispensing doctors (around 900).

There are 46 hospital pharmacies (31 December 2012), thus 16.5% of all hospitals have a pharmacy. In hospitals without a pharmacy of its own, pharmaceutical provision is provided by so-called 'pharmaceutical depots', which are served by the hospital pharmacy of another hospital or a community pharmacy.

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

2.1.4 Pharmaceutical expenditure

Total pharmaceutical expenditure in the out-patient sector amounted to € 3,800 million in 2011 and thus corresponded to a share of 12% of total current health care expenditure. Public pharmaceutical expenditure accounted for 8.4%.

Pharmaceutical expenditure has risen by 50% since 2000 (€ 2,529 million) and by 17% since 2005 (€ 3,261 million), and the growth rates for public pharmaceutical expenditure were 48% and 18% respectively.

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

3.1 Pricing

3.1.1 Pricing at manufacturer price level

Pricing of medicines is a responsibility of the Federal Ministry of Health, which is assisted in doing so by the Pricing Committee. The Pricing Committee is established at the Federal Ministry of Health 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 Labour).

The Pricing Committee's activities are based on the Price Act, which, in fact, does not apply to medicines only 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. According to Price Act of 1992[2], the Ministry of Health is entitled and obliged to determine a 'national price justified in terms of the national economy'.

Since 1 September 1999, the Price Act has been accompanied by a price notification agreement between the Federal Chamber of Commerce and the Federal Chamber Labour. Manufacturers have to notify the Ministry of Health about the ex-factory price for new medicines or about price changes.

Thus, prices (of non-reimbursable medicines, for reimbursable medicines see below) are either calculated by the Ministry of Health advised by the Pricing Committee (via the method of the European Union (EU) average price) or notified by companies (price notification at manufacturer price level). 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 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 in the positive list (Erstattungskodex, EKO). Medicines included in the EKO have to be priced either according to the EU average price, as established by the Pricing Committee, 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). The HVB decides in accordance to the Transparency

[2] 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]

Directive[3] within 90 days (180 days in the case of pricing and reimbursement) from the date it receives the recommendation of HEK.

In 2004, external price referencing, called the 'European Union average price system', was introduced in Austria The EU average price is only set for medicines applying for inclusion into the EKO and it is applied at the ex-factory price level. The relevant legal basis is the Regulation on Procedural Rules for Calculation of the EU average price, published on 1 October 2005[4]. This sets out the relevant procedures and methodological approach including the country basket, which covers all EU Member States.

The regulation states that the market authorisation holder which 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 and 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).[5] According to General Social Insurance Law (ASVG), the research and planning institute Gesundheit Österreich GmbH (GÖG) may be asked at a random basis 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 inclusion into reimbursement. The prices are compared per unit to presentations of the same strength, the same pack size and the same dosage. The EU average price can be determined in case that 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 determined, 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 determined on the basis of the information available, i.e. the available countries.

In addition to the common price setting method of the EU average price, price negotiations may take place in case of reimbursable medicines. Therefore, starting from the determined EU average price at manufacturer price level, the Main Association of Social Security Institutions (HVB) can then further negotiate the price. The legal framework of the price negotiations is provided by the Procedural Rules for the publication of the EKO[6]. As soon as an agreement is reached, negotiations end, and the ex-factory price is then binding. If negotiations fail, companies have the possibility to appeal to the Independent Pharmaceutical Commission (Unabhängige Heilmittelkommission, UHK).

---

[3] Council Directive 89/105/EEC

[4] 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/home/Schwerpunkte/Medizin/Arzneimittel/Arzneimittelpreise/EU_Durchschnittspreise_laut_ASVG]

[5] 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

[6] 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

Internal price referencing is applied for so-called 'follower' medicines, such as generics, which apply for inclusion in the EKO. According to the Procedural Rules for publication of the EKO[7] the first generic product or other 'follower' is priced at least 48% below the price of the original brand which went off-patent. The second and each subsequent 'followers' are required to have a price difference related to the previously included generic: The price of the second 'follower' has to be 15% lower than the one of the first 'follower', and the price of the third 'follower' has to be 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.

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).

There are no other pricing policies. Cost-plus pricing is not applied.

The profits of pharmaceutical companies are, on the basis of the Procedural Rules for publication of the Reimbursement Code, influenced by the 'Pharma Framework Contract' ('Rahmen-Pharmavertrag'). Under this framework agreement, pharmaceutical companies and wholesalers paid as a kind of ex-post rebate around € 180 mio. (including value-added tax and out-standing contributions resulting from a previous regulation) between 2008 and mid 2011 to the Austrian sickness funds. At the beginning of July 2011 the 'Pharma Framework Contract' was prolonged for another 4.5 years. Until the end of September 2015 pharmaceutical industry will contribute another € 82 million 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[8]. 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).

[7] 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

[8] 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 3.1: Wholesale mark-up scheme for medicines included in the yellow and green boxes of the Reimbursement Code

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

Table 3.2: Wholesale mark-up scheme for medicines not included in the green and yellow boxes of the Reimbursement Code

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

According to the Austrian Pharmaceutical Tax Enactment ('Österreichische Arzneitaxe', pharmacy mark-up regulation)[9] pharmacies are remunerated via a statutorily fixed mark-up scheme applicable to all medicines.

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

Table 3.3: Pharmacy mark-up scheme for privileged customers

Pharmacy purchasing price (PPP) in €	Mark-up as a % on the 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

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 which are always fully exploited, i.e. actual mark-ups correspond to statutory mark-ups.

Wholesalers may grant discounts to pharmacies which is a rather common practice.

Community pharmacies grant to the sickness funds an ex-post discount of an annual amount of € 6 million (including value-added tax) in the years 2012 to 2015.

Table 3.4: Pharmacy mark-up scheme for private customers

Pharmacy purchasing price (PPP) in €	Mark-up as a % on the PPP	Pharmacy retail price (PRP) in €	Margin as a % of PRP
0.00-7.29	55	-	35.5
7.30-7.58	-	11.30	-
7.59-15.70	49	-	32.9
15.71-16.25	-	23.40	-
16.26-26.25	44	-	30.6
26.26-27.19	-	37.80	-
27.20-63.09	39	-	28.1
63.10-65.44	-	87.70	-
65.45-90.74	34	-	25.4
90.75-94.26	-	121.60	-
94.27-108.99	29	-	22.5
109.00-113.38	-	140.60	-
113.39-130.80	24	-	19.4
130.81-135.73	-	162.20	-
135.74-203.43	19.5	-	16.3
203.44-211.39	-	243.10	-
211.40-363.30	15	-	13.0
363.31-371.37	-	417.80	-
more than 371.37	12.5	-	11.1

Source: Austrian Pharmaceutical Tax Enactment, 14 July 2000

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 99% 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[10] and the Procedural Rules for publication of the EKO (Verfahrensordnung Erstattungskodex, VO-EKO)[11] which are fixed by decree.

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

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

[11] 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

based on pharmacological analysis, medical-therapeutic evaluations and health-economic considerations.

In the case of a negative decision related to the inclusion into reimbursement, the manufacturer may appeal to the Independent Pharmaceutical Commission (UHK). The UHK will end its activities at the end of 2013; it will be replaced by Federal Administrative Courts from 2014 on.

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 prescription. 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 decision on inclusion in the green or yellow boxes is taken within 90 days (if the decision also addresses the price, the period is extended to 180 days). In case of a negative decision, the medicine will be delisted from the red box. The yellow box includes medicines fulfilling certain criteria (e.g. specific disease or age group). 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 volume control of the prescribing doctor might take place. The green box includes medicines qualifying for automatic reimbursement; these are prescribed by any contract doctor. Inclusion is based on certain criteria relating to medicine usage, such as disease group or mode of application. In addition to the positive list, there is a kind of negative list, which includes medicines not eligible for reimbursement.

Medicines are either fully reimbursed or not reimbursed at all (thus there are neither percentage reimbursement rates nor percentage co-payment rates). If medicines are reimbursed, patients have to pay out-of pocket a fixed prescription fee amounting to € 5.30 (2013). Since January 2008 the prescription fee has been capped statutorily, i.e. all beneficiaries spend a maximum 2% of their net annual income on medicines. Vulnerable groups (e.g. low income pensioners, people suffering from communicable diseases) are exempt from the prescription fee.

Austria has no reference price system.

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 individual sickness funds with a view to their compliance with the HVB's Guidelines on the economic

prescription of medicines and therapeutic aids (RöV)[12] 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 or the generic product 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.

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

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

4.1 Pricing and procurement

In Austria the purchasing of medicines in the in-patient sector is organised in a decentralised way, with decisions taken by the hospital owner organisations. In case that a marketing authorisation holder does not apply for inclusion into reimbursement in the EKO in the out-patient sector (see section 3.2), then this medicine does not have a regulated price, but the price is the outcome of negotiations between the purchaser (e.g. individual hospital) and the manufacturer.

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) etc. are also of importance.

In Austrian hospitals, discounts are common. They range from 0% to 99% 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.

Medicine prices are not publicly available. They are only communicated within the hospitals and integrated into the individual hospital IT system where they can be consulted.

4.2 Reimbursement

Medicines are integrated in the lump sums which can be generated for reimbursement of the procedure and diagnosis-orientated case groups (DRG) in hospitals. An average consumption of medicines per diagnosis was considered when calculating the lump sums. Some oncology medicines are exceptions in the DRG lump sum system, 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 explicitly the dispensing of a specific oncology medicine is reimbursed.

In the province of Carinthia a separate financing approach for high cost, mainly oncology, medicines exists. In this region the main public hospital owner organisation concluded an agreement with the regional sickness fund in order to ensure that the expenditure of onco-

logy 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.

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 hospital pharmaceutical formulary are reimbursed by the hospital funds. In general, approximately 1,500-2,500 medicines are included in hospital formularies. There is no separate 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 also 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 State Health Fund in accordance to regional legal provisions. The Pharmaceutical and Therapeutic Committee can be authorised to monitor and control pharmaceutical expenditure within a hospital, a hospital owner organisation or hospital associations. In general, using statistics of the consumption and expenditure the hospital pharmacy 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 controls the activities of those hospitals receiving public funds to finance the hospitals.

Independent scientific reports and analyses (e.g. in international journals) have been systematically 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.

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. In recent times, 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.

Currently, Austria is undergoing a major health care reform which aims at strengthening primary health care and which established the concept of 'best point of service'. This follows that every service offered by the health system should be provided wherever it is optimally located – both in terms of resources and quality.

Part of the health care reform is the establishment of a new commission (so-called 'Medicines Commission') which will decide on the use of high-cost and specialized medicines in both the in-patient and out-patient sectors.

Another current change concerns the Independent Pharmaceutical Commission (Unabhängige Heilmittelkommission, UHK) which acts as an appeal court to whom manufacturers could turn in case of reimbursement applications being rejected. The UHK will end its activities at the end of 2013; it will be replaced by Federal Administrative Courts from 2014 on.

6 Pharmaceutical data fact sheet: Austria

		2011	2012	Source	Notes
Demography					
Population	total	8,408,121	8,451,860	Eurostat 2013	Data as of 31 December
	0-14 years	1,224,134	1,219,363	Eurostat 2013	
	15-64 years	5,687,630	5,705,240	Eurostat 2013	
	> 64 years	1,496,357	1,527,257	Eurostat 2013	
Life expectancy	at birth	80.4	80.3	Eurostat 2013	
	at age 65	20.1	19.8	Eurostat 2013	
Economic data in million Euro					
Gross Domestic Product		299,240.40	307,003.8	Eurostat 2013	-
Health expenditure	Total	32,408	n.a.	Statistics Austria 2013	
	Public	24,708	n.a.	Statistics Austria 2013	
	Private	7,699	n.a.	Statistics Austria 2013	
Health expenditure in the out-patient sector (only current expenditure)	Total	17,510	n.a.	Statistics Austria 2013	
	Public	12,464	n.a.	Statistics Austria 2013	
	Private	5,046	n.a.	Statistics Austria 2013	
Health expenditure in the in-patient sector (only current expenditure)	Total	13,190	n.a.	Statistics Austria 2013	
	Public	11,250	n.a.	Statistics Austria 2013	
	Private	1,940	n.a.	Statistics Austria 2013	
Prescriptions					
No. of prescriptions	In volume	120,348,529	120,140,100	Statistical Handbook of the Main Association of Austrian Social Insurance Institutions 2013	Prescription in volume = number of items prescribed.
Prescriptions	In value (in million Euro)	2,654	2,720	Statistical Handbook of the Main Association of Austrian Social Insurance Institutions 2013	Prescription in value = public expenditure of prescribed medicines.
Pharmaceutical consumption					
Total	In packs (thousands)	233,607	n.a.	Pharmig Facts and Figures 2013	-
Out-patient sector	In packs	210,299	n.a.	Pharmig Facts and Figures 2013	-
In-patient sector	In packs	23,308	n.a.	Pharmig Facts and Figures 2013	-

		2011	2012	Source	Notes
Generic shares					
Shares in % of total market (in-patient / out-patient)	In volume	n.a.	n.a.	-	Volume: Expressed in number of pre-scriptions Value: Expressed in expenditure [1] for the third quarter 2010 [2] for the second quarter 2013
	In value	19%	n.a.	IMS Dec. 2011	
Shares in % of total out-patient market	In volume	26.1%[1]	n.a.	IMS 2010	
	In value	15.6%[1]	n.a.	IMS 2010	
Shares in % of out-patient off-patent market	In volume	n.a.	43.8%[2]	IMS 2013	
	In value	34%	35.7%[2]	IMS 2012 and 2013	
Retailers of medicines (out-patient sector)					
Number of community pharma-cies (all private)		1,292 plus 24 branch pharmacies	1,303 plus 26 branch pharmacies	Austrian Chamber of Pharmacists 2013	Data as of 1 January
Number of hospital pharmacies for out-patients		5	5	Austrian Chamber of Pharmacists 2013	Data as of 1 January
Number of dispensing doctors		902	n.a.	Statistics Austria 2013	Data as of 1 January
Pharmaceutical expenditure (million Euro)					
Pharmaceutical expenditure in the out-patient sector	Total	3,800	n.a.	Statistics Austria 2013	-
	Public	2,567	n.a.	Statistics Austria 2013	-
	Private	1,233	n.a.	Statistics Austria 2013	-

n.a. = not available; n.app. = not applicable