PPRI
Pharmaceutical Pricing and Reimbursement Information

PPRI Pharma Brief: Austria 2019

Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Briefs Series

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Commissioned by the Austrian Federal Ministry of Labour, Social Affairs, Health and Consumer Protection

Gesundheit Österreich GmbH

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Final version

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Vienna, December 2019
Commissioned by the Austrian Federal Ministry of Labour, Social Affairs, Health and Consumer Protection

Gesundheit Österreich GmbH

Suggestion for citation: Vogler Sabine, Haasis Manuel Alexander, Zimmermann Nina (2019): PPRI Pharma Brief: Austria 2019. Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Briefs Series. Gesundheit Österreich GmbH (GÖG / Austrian National Public Health Institute), Vienna

No. P4/33/4493

Owner, editor and publisher: Gesundheit Österreich GmbH (GÖG / Austrian National Public Health Institute), Stubenring 6, 1010 Vienna, Austria, Tel. +43 1 515 61, websites: www.goeg.at and https://ppri.goeg.at

About PPRI Pharma Briefs

This concise report on the Austrian pharmaceutical pricing and reimbursement policy framework is part of the new series of PPRI Pharma Briefs published by the Pharmaceutical Pricing and Reimbursement Information (PPRI) secretariat.

PPRI networks

The PPRI network is a collaboration of **pharmaceutical pricing and reimbursement authorities** of 47 – mostly European – countries as well as international and European institutions (e.g. European Commission, OECD, World Health Organization). The aim of this network is to facilitate exchange between public officials, supported by scientific evidence and a common understanding of pharmaceutical policy issues. Under the framework of PPRI, further regional PPRI networks (e.g. in Central Asia) and thematic PPRI networks (e.g. on medical devices) have been established. PPRI networks are coordinated by the PPRI Secretariat which is hosted at the Pharmacoeconomics Department of the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG).

PPRI
Pharmaceutical Pricing and Reimbursement Information

PPRI contributes to the international scientific evidence base, in particular in the areas of (comparative) **pharmaceutical systems research** and pharmaceutical policy analysis, by providing country information that is usually not published in other literature. This is of interest for policy-makers who want to cross-learn and benchmark as well as for researchers who perform policy analyses and require contextual information on national pharmaceutical systems.

PPRI country information

Well-established publications that offer pharmaceutical pricing and reimbursement information on a single PPRI country are the **PPRI Pharma Profiles** that are available as in-depth reports as well as short reports, see https://ppri.goeg.at/ppri_pharma_profiles. Furthermore, one-page graphical abstracts are provided in the **PPRI Posters**, see https://ppri.goeg.at/ppri_posters.

The new series **PPRI Pharma Briefs** responds to the interest and needs expressed by policy-makers and technical experts in public authorities responsible for the pricing and reimbursement of medicines to read concise reports of the pharmaceutical policies in other countries.

The PPRI Pharma Briefs will draw upon the information and data that have been provided by the PPRI network members, in addition to literature and relevant documents, such as legal provisions.

For requests and comments, please contact ppri@goeg.at.

Key data at a glance

General and economic data

Population (2019)	8.86 million
Country size (2019)	83,879 km²
Gross domestic product / GDP (2018)	GDP per capita: USD PPP 55,529
Health expenditure / HE (2017)	HE per capita: € 4,371.3, USD PPP 5,270.2 HE in % of GDP: 10.4% Public HE as % of total HE: 74%
Pharmaceutical expenditure / PE (2017)	PE per capita: € 525.8, USD PPP 634 PE in % of HE: 11.7% Public PE as % of total PE: 69%

GDP = gross domestic product, HE = health expenditure, PE = pharmaceutical expenditure, PPP = Purchasing Power Parties, USD = United States dollars
Pharmaceutical expenditure data relate to the outpatient sector only

Sources: population – Statistics Austria [1]; country size – Chamber of Commerce Statistical Yearbook [2]; gross domestic product – OECD statistical data [3]; health and pharmaceutical expenditure – OECD Health Statistics [4]

Provision of pharmaceuticals

Community pharmacies (31 Dec. 2018)	1,370 community pharmacies, plus 30 branch pharmacies
Dispensing doctors (31 Dec. 2017)	919
Wholesale (2017)	6 full-line wholesale companies, plus 35 short-line wholesalers and pre-wholesalers
Pharmaceutical industry	150 companies, thereof 27 research-based companies

Sources: community pharmacies – Austrian Chamber of Pharmacists [5]; dispensing doctors – PHARMIG [6]; wholesale – PHAGO [7] and Short PPRI Pharma Profile Austria [8], pharmaceutical companies – PHARMIG [9] and FOPI [10]

Pharmaceutical market

Pharmaceutical market (2018)	€ 4.4 billion
Medicines (2018)	9,287 medicines authorised (counted including different pharmaceutical forms and dosages) 7,399 medicines (counted including different pharmaceutical forms and dosages) included in the outpatient reimbursement list (October 2019)
Generic market shares (2017)	50.2% in value (reimbursement segment) 54.8% in volume (reimbursement segment)

Sources: pharmaceutical market – PHARMIG [6]; medicines – Austrian Chamber of Pharmacists [5], Austrian Medicines and Medical Devices Agency (BASG/AGES Medizinmarktaufsicht) [11], BASG [12] and data provided by Main Association of Austrian Social Security Institutions; generic market shares: OECD Health statistics [4]

Pharmaceutical pricing (2019)

Price regulation	Yes, in place for the outpatient reimbursable medicines
Pricing authorities	**Outpatient**: Austrian Federal Ministry of Labour, Social Affairs, Health and Consumer Protection, supported by the Pricing Committee **Inpatient**: no pricing authority, but pricing and procurement is done by the purchasers (hospitals, hospital owner associations)
Key pricing policies	**External price referencing**: yes, for outpatient reimbursable medicines **Value-based pricing**: no, but value-based elements **Price negotiations**: for reimbursable medicines, **managed-entry agreements**: used for high-priced medicines in outpatient and inpatient sectors, mainly financially-based **Tendering**: for some inpatient medicines **Cost-plus pricing**: not used **Generic price link**: yes, for outpatient reimbursable medicines **Biosimilar price link**: yes, for outpatient reimbursable medicines
Pricing in the supply chain	**Wholesale**: two regressive mark-up schemes **Pharmacy**: two regressive mark-up schemes **Value-added tax**: 10% on medicines (standard: 20%)

Source: overview provided by the PPRI Secretariat

Pharmaceutical reimbursement (2019)

Reimbursement authorities	**Outpatient:** Main Association of Austrian Social Security Institutions **Inpatient:** no reimbursement authority, costs for medicines are usually included in the DRG system
Reimbursement lists	**Outpatient:** national code of reimbursement (positive list) **Inpatient:** hospital pharmaceutical formularies
Reimbursement criteria	**Outpatient**: reimbursement decision is based on pharmacological, medical-therapeutic and health-economic evaluations **Inpatient:** no Health Technology Assessment (HTA) systematically applied
Co-payments for medicines	**Outpatient:** a prescription fee, but other co-payments (such as percentage co-payments or a deductible) **Inpatient:** no
Demand-side measures to enhance the uptake of off-patent medicines	**Reference price system:** not in place **Prescribing by International Non-Proprietary Name (INN):** not allowed **Generic substitution:** not allowed

Source: overview provided by the PPRI Secretariat

Summary

Pharmaceutical policy **regulations** are provided in several laws, decrees and legal provisions. The Austrian health care, including the pharmaceutical system, is characterised by a clear **distinction between the outpatient and inpatient sectors**, with separate competences and policies. Pricing and procurement are interlinked with reimbursement policies.

The **Austrian Federal Ministry of Labour, Social Affairs, Health and Consumer Protection** is responsible for the overall regulatory framework. It is in charge of pricing medicines and hosts the **Pricing Committee**. As of 2019, the **Main Association of Austrian Social Security Institutions** is responsible for deciding on the inclusion of outpatient medicines into the reimbursement lists.

Price regulation is in place for medicines with an application for inclusion in the outpatient positive list (so-called code of reimbursement) and for those not included in the code of reimbursement but with 12-months sales at the expense of social health insurance above € 750,000. **External price referencing** is applied for new medicines subject to price regulation and, as a result, their price must not exceed the average price of all other EU Member States except Croatia (minimum data availability from two countries). Prices of generic and biosimilar medicines included in the outpatient reimbursement list are set in relation to the prices of the originator or reference medicines ('**price link** policy').

Regarding the launch price of a new medicine or planned price changes of all other medicines, a **price notification** to the Pricing Committee is sufficient. Thus, there is free pricing for medicines used in hospitals: medicines are procured by the hospitals or hospital groups, and prices are usually directly negotiated with the marketing authorisation holder. In some cases, medicines used in hospitals are **tendered**. **Managed-entry agreements** have increasingly been concluded both in the outpatient and inpatient sectors. They are mainly financially-based agreements and only rarely performance-based arrangements.

Wholesale and pharmacy remuneration is regulated through statutory regressive maximum mark-ups, with two schemes for different types of medicines (wholesale) or different types of clients (pharmacy). The **value-added tax** on medicines is 10% (standard rate: 20%).

The **code of reimbursement** is the positive list managed by the Main Association of Austrian Social Security Institutions. It includes those medicines used in the outpatient sector that are funded by social health insurance. It has different categories ('**boxes'**) for which different prescribing rules are applied: green box – free prescribing; yellow box for medicines with a substantial therapeutic benefit – prescription control (either ex-ante approval by a 'sickness fund' doctor or ex-post control) and the 'red box' as a temporary category for new medicines. The Main Association of Austrian Social Security Institutions decides on the listing and attribution of medicines in the different boxes after **pharmacological, medical-therapeutic and health-economic evaluations**.

In the inpatient sector, medicines are included in the **hospital pharmaceutical formularies** managed at the level of individual hospitals or hospital owner organisations. The respective Pharmaceutical and Therapeutic Committees decide on the inclusion of medicines in these lists.

Any medicine included in the outpatient reimbursement list is **100% reimbursed** (no percentage co-payment). When filling a prescription, patients have to pay a **prescription fee of € 6.10** (data as of 2019). There are no out-of-pocket payments in the inpatient sector.

Neither prescribing by International Non-Proprietary Name nor generic substitution is permitted.

Keywords

Pricing, reimbursement, pharmaceutical policies, pharmaceutical system, Austria

Kurzfassung

Bestimmungen betreffend Medikamente sind in diversen Rechtsakten (z.B. Gesetzen, Verordnungen und Erlässen) geregelt. Wie das österreichische Gesundheitssystem im Allgemeinen, zeichnet sich auch das Arzneimittelsystem durch eine **Trennung der Kompetenzen zwischen niedergelassenem und stationärem Sektor** aus. Ein enger Zusammenhang und eine teilweise Überlagerung bestehen zwischen der Preisbildung und Beschaffung von Arzneimitteln und dem Erstattungsprozedere.

Das **Bundesministerium für Arbeit, Soziales, Gesundheit und Konsumentenschutz** ist für die Regelung des rechtlichen Rahmens verantwortlich. Es wirkt als die zuständige Behörde für die Preisfestsetzung von Medikamenten und ist Sitz der Geschäftsstelle der **Preiskommission.** Der **Hauptverband der österreichischen Sozialversicherungsträger** (zukünftig Dachverband der Sozialversicherung) entscheidet über die Aufnahme von Arzneimitteln in den Erstattungskodex (die Positivliste für den niedergelassenen Sektor).

Der Preis der Arzneimittel, deren Aufnahme in den Erstattungskodex beantragt wurde, und jener nicht im Erstattungskodex aufgenommener Medikamente, deren Umsatz zulasten der Sozialversicherung in den letzten zwölf Monaten einen Schwellenwert von € 750.000 übersteigt, werden mittels des **europäischen Durchschnittspreises** festgelegt. Der Preis eines neuen Medikaments darf dabei den Durchschnitt der Preise dieser Arzneispezialität in den übrigen EU-Mitgliedstaaten mit Ausnahme von Kroatien nicht überschreiten (Minimumanforderung: Preisdaten aus zwei Ländern). Damit **Generika und Biosimilar-Medikamente** in den Erstattungskodex aufgenommen werden, muss ihr Preis in einer bestimmten Größenordnung unter jenem des Original- oder Referenzprodukts liegen.

Für alle übrigen Medikamente (sei es der Preis für ein neues Arzneimittel oder eine geplante Preisänderung) genügt eine **Preismeldung** an die Preiskommission. Somit besteht freie Preisbildung für Arzneimittel, die in Krankenanstalten verabreicht werden. Diese werden von Krankenanstalten oder deren Trägern beschafft, und ihre Preise werden in der Regel direkt mit dem Zulassungsinhaber verhandelt. In manchen Fällen werden Arzneimittel, die in Krankenanstalten verabreicht werden, **ausgeschrieben.** Sowohl im niedergelassenen als auch im stationären Bereich werden zunehmend **Managed-Entry-Agreements** (Rabattverträge, Preismodelle) geschlossen, meist in Form finanzieller Vereinbarungen und nur selten erfolgsabhängige Abkommen.

Die **Abgeltung von Großhandel und Apotheken** erfolgt mittels gesetzlich geregelter Höchstaufschläge, wobei jeweils zwei verschiedene regressiv ausgestaltete Schemen (mit unterschiedlichen Aufschlägen) je nach Medikamentenart (Großhandel) bzw. Kundentyp (Apotheke) zur Anwendung kommen. Die **Umsatzsteuer** auf Arzneimittel beträgt zehn Prozent (Standardsatz: 20 %).

Arzneimittel, deren Ausgaben von der Sozialversicherung getragen werden, werden in den vom Hauptverband der österreichischen Sozialversicherungsträger geführten **Erstattungskodex** aufgenommen. Diese Positivliste für Medikamente im niedergelassenen Bereich besteht aus verschie-

denen Kategorien **(„Boxen")**, für die bestimmte Verschreibungsregeln gelten: die „Grüne Box" beinhaltet frei verschreibbare Arzneimittel; die „Gelbe Box" umfasst Arzneimittel mit einem wesentlichen zusätzlichen therapeutischen Nutzen, die nur bei Vorliegen der Bewilligung des chef- und kontrollärztlichen Dienstes verschrieben werden dürfen bzw. nachfolgender Kontrolle unterliegen, und die „Rote Box" beinhaltet neue Arzneimittel, für deren Aufnahme in den Erstattungskodex ein Antrag gestellt wurde (zeitlich befristete Kategorie). Der Hauptverband der österreichischen Sozialversicherungsträger entscheidet nach einer **pharmakologischen, medizinisch-therapeutischen und gesundheitsökonomischen Evaluation** über die Aufnahme von Arzneimitteln in den Erstattungskodex und dessen Boxen.

Im stationären Bereich sind Medikamente in **Arzneimittellisten** enthalten, die von den Krankenanstalten oder deren Trägern verwaltet werden. Über die Aufnahme von Arzneimitteln in diese Listen entscheiden die jeweiligen Arzneimittelkommissionen.

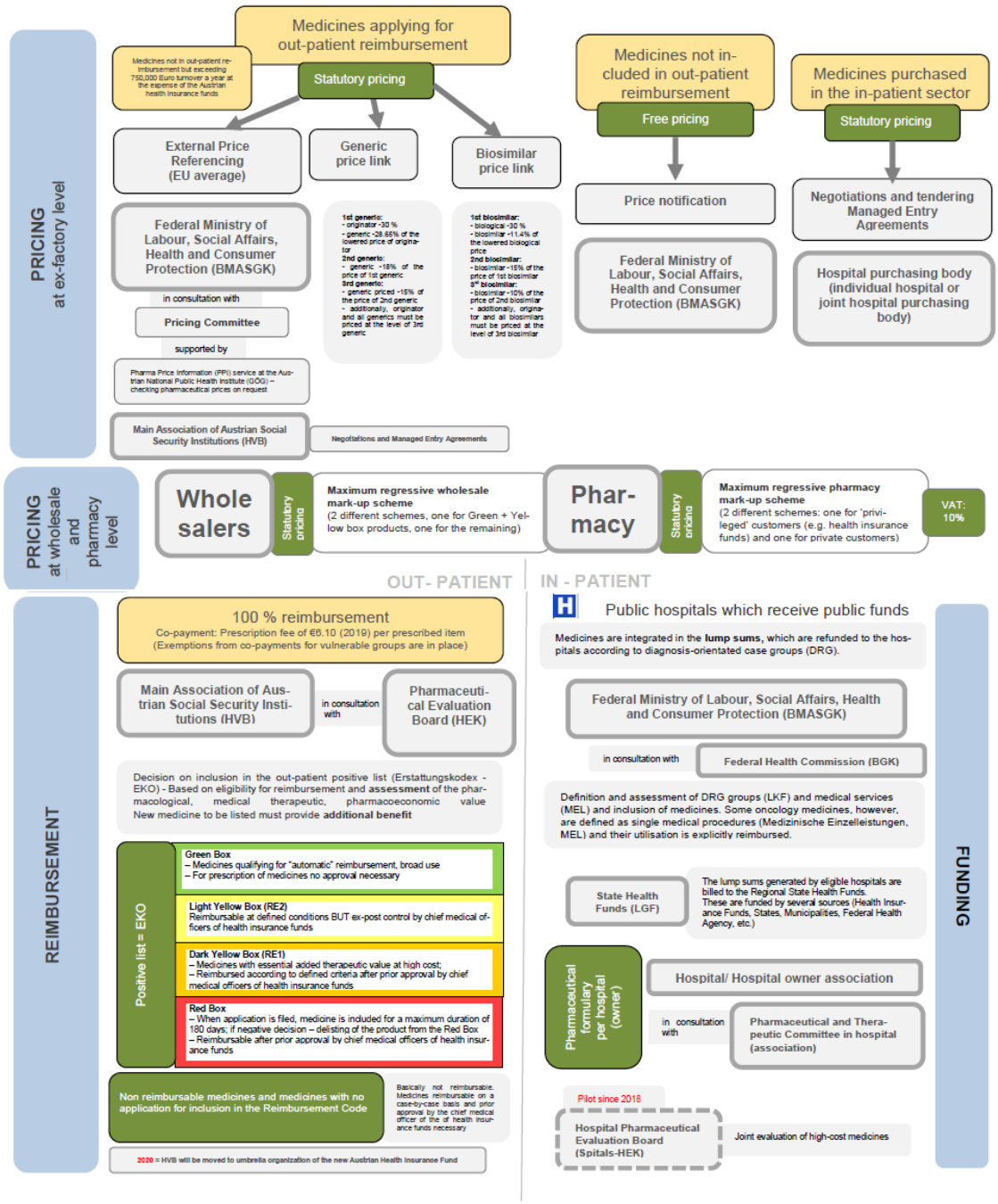
Der Preis sämtlicher Arzneimittel, die in den Erstattungskodex für den niedergelassenen Bereich aufgenommen wurden, wird zu 100 Prozent erstattet (es fallen keine prozentuellen Zuzahlungen an). Bei der Einlösung eines Rezepts in der Apotheke muss im Jahr 2019 die Patientin / der Patient eine Rezeptgebühr von € 6,10 pro verordnetes Medikament zahlen. Im stationären Bereich fallen keine Zuzahlungen an.

In Österreich sind weder Wirkstoffverordnung noch Generikasubstitution erlaubt.

Schlüsselwörter

Preisbildung, Erstattung, Arzneimittelpolitik, Arzneimittelsysteme, Österreich

Graphical summary



1 Framework

Austria has no uniform **pharmaceutical policy** document but legislation is provided in several laws, decrees and further regulations. Key **legal documents** include the Medicines Act (*Arzneimittelgesetz*) [13], the General Social Insurance Law (*Allgemeines Sozialversicherungsgesetz*, ASVG) [14] and the Price Act (*Preisgesetz*) [15].

The **competences** for regulatory and pharmaceutical policy matters (such as ➲ Marketing authorisation, ➲ Pricing and ➲ Reimbursement; for terms labelled with the ➲ sign consult the glossary in Annex 3 which can easily accessed by clicking at the labelled terms) are divided among public authorities, and different public institutions are responsible for policy implementation in the outpatient and inpatient sectors. Linkage exists between pricing and reimbursement ➲ Policies.

Key competent **authorities** for pricing and reimbursement and public payers in Austria are the Austrian Federal Ministry of Labour, Social Affairs, Health and Consumer Protection (*Bundesministerium für Arbeit, Soziales, Gesundheit und Konsumentenschutz*, BMASGK), which is responsible for the overall regulatory framework and for pricing medicines; the Main Association of Austrian Social Security Institutions (MASSI, *Hauptverband der österreichischen Sozialversicherungsträger*, from 2020 on: *Dachverband der Sozialversicherung*), which is in charge of reimbursement decisions for outpatient medicines; the social health insurance institutions (sickness funds, organised at the regional or professional levels) that cover the expenses of outpatient medicines included in reimbursement; and state health funds (*Landesgesundheitsfonds*) which pool resources for funding care, including inpatient medicines, in the hospitals they own. The Medicines Agency 'AGES Medicines & Medical Devices business segment' (*AGES Medizinmarktaufsicht*) of the Austrian Federal Office for Safety in Healthcare (*Bundesamt für Sicherheit im Gesundheitswesen*, BASG) is not involved in pricing and reimbursement matters but it is in charge of marketing authorisation, pharmacovigilance and inspections (see Annex 1 for an overview of key stakeholders).

2 Pricing

Pricing at manufacturer price level

➲ **External price referencing** (EPR) is applied for ➲ Reimbursable medicines with an application for inclusion in the code of reimbursement (*Erstattungskodex*, EKO), which is the outpatient positive list. EPR also applies for those medicines not included in the EKO whose sales at the expense of social health insurance exceed a defined threshold (see below). As of 2019, reference countries are all other European Union (EU) Member States except Croatia[1]; the price must not exceed the EU average [16]. A minimum of price data of two EU Member States is required to derive the benchmark price.

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[1] Croatia will be included from June 2020 on.

The Pricing Committee (*Preiskommission*) of the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection, which comprises several stakeholders (other Federal Ministries and the 'social partners' such as the Federal Chamber of Commerce and the Federal Chamber of Labour), is tasked to calculate the EU average price based on price data submitted by the marketing authorisation holder. According to the General Social Insurance Law (*Allgemeines Sozialversicherungsgesetz*, ASVG) [14], the Pricing Committee can ask the Austrian National Public Health Institute (*Gesundheit Österreich*, GÖG) to review this price information. A price is determined within six months upon receipt of a company's price application. Price evaluations are mandatory after 24 and 48 months; another re-evaluation is possible after 66 months. The EU average price serves as basis for further negotiations of the Main Association of Austrian Social Security Institutions with the pharmaceutical company on the reimbursement price (see below). Managed-entry agreements may be concluded.

A ➲ Price link policy applies for the 'follower medicines' (generics and biosimilars) included in the code of reimbursement: The first generic is priced at least 50% below the price of the originator medicine which went off-patent. The second and all subsequent generics are required to have a price difference in relation to the previously included generics (18% and 15% respectively). The price of the originator has to be reduced by at least 30% within three months after the inclusion of the first generic into the EKO. In case of a third follower, the marketing authorisation holders of the originator medicine and the first and second generics have to decrease their prices to the price of the third generic. Further generics have to offer a price reduction of at least € 0.10 in order to be included in the code of reimbursement. For biosimilars, the following rates apply: the first biosimilar – at least 38% below the reference medicine; second and third biosimilars – at least 15% and 10% respectively. The same procedure and percentage rates as for originators and generics apply for the reference medicine and further biosimilars included in the EKO [14].

For all other medicines (including those solely used in hospitals), there is, in principle, free pricing. Pharmaceutical companies, however, have to notify the Ministry of Labour, Social Affairs, Health and Consumer Protection about the ex-factory price for new medicines and about price changes. If a notified price is considered too high in the context of the Austrian economy, the Ministry can officially start a price setting process. If such a process is not started within six weeks, the proposed price will automatically be granted [15].

In addition, for medicines which are not included in the EKO but exceed a sales worth of € 750,000 (at ex-factory price basis) at the expense of the Austrian social health insurance during the last twelve months, prices are set ex-post based on EPR. If the EU average price determined by the Pricing Committee is lower than the price that was set by the marketing authorisation holder, the company has to repay the difference from the point in time when the turnover threshold was first exceeded [14].

Procurement

Public hospitals are mainly owned by the Austrian provinces, and ➲ Procurement of medicines used in hospitals is organised in a decentralised manner. The hospital purchasing bodies (the chief

hospital pharmacist and/or a designated purchasing department) are usually in charge of purchasing medicines. In most cases, there is direct procurement through negotiations between the marketing authorisation holder and the hospital (or hospital group), and a ➲ Managed-entry agreement (MEA) can be concluded.

➲ Tendering is less common, but on the rise. Public procurement procedures are regulated by the Austrian Federal Act on public tenders and nine regional laws. In recent years, some hospital owner organisations have been exploring options for joint procurement. Tendering in the outpatient 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).

Pricing in the supply chain

Pharmaceutical ➲ Wholesale is remunerated via two statutory regressive mark-up schemes: the allowed maximum mark-ups for medicines vary with regard to different groups of outpatient reimbursable medicines [17] (the schemes are presented in Annex 2).

➲ Community pharmacyies are remunerated via statutory regressive mark-up schemes applicable to all outpatient medicines. There are also two schemes with different maximum add-ons allowed: one scheme provides reduced mark-ups for 'privileged customers', such as the sickness funds, the State, the provinces, municipalities, funds and institutions held by these, as well as non-profit hospitals, and the other is the basic scheme for 'private customers', in which an additional flat 'private customer mark-up' of 15% is added [18] (cf. Annex 2).

The value-added tax (VAT) on medicines is 10% while the standard VAT rate is 20% in Austria.

3 Reimbursement

Reimbursement for outpatient medicines

The Main Association of Austrian Social Security Institutions is responsible for deciding whether or not a medicine is included in the outpatient **code of reimbursement** (Erstattungskodex, EKO). This decision is based on a three-tier process of a pharmacological **evaluation**, a medical-therapeutic evaluation and a health-economic evaluation [19]. In the case of a negative decision, the pharmaceutical company may appeal to the Federal Administrative Court (*Bundesverwaltungsgericht*). Disbursement is done by 'sickness funds' (regional or professional social health insurance institutions) based on the decisions of MASSI that are applicable for the whole country.

All medicines included in the EKO qualify for general reimbursement but the prescribing rules differ. The EKO has three main **categories**: the 'green box', the 'yellow box' (subgroup: 'light yellow') and the 'red box':

» The 'green box' includes medicines that qualify for automatic reimbursement; these may be prescribed by any 'contract doctor' (i.e. a doctor on contractual relationship with a sickness fund).

» The 'yellow box' includes medicines which provide a substantial added therapeutic benefit. Reimbursement is only granted if defined criteria (e.g. specific disease or age group) are met.

» The 'red box' is a temporary category for medicines for which an application for inclusion in the EKO has been submitted. In accordance to the Transparency Directive [20], MASSI decides within 180 days upon receipt of the reimbursement application on the further status of the medicine.

  For medicines in the red and the yellow boxes, an ex-ante approval of a 'head physician' of a sickness fund has to be sought. For medicines in the light yellow box, ex-post control of the records kept by the prescribing doctor might be applied instead.

In addition, a list defines some categories of medicines, which are not eligible for reimbursement (e.g. contraceptives).

The price of all medicines included in the EKO is 100% reimbursed; no percentage ➲ Co-payments apply. When filling a prescription in a community pharmacy, patients are charged a **prescription fee** of € 6.10 (2019) per item on the prescription (unless the pharmacy retail price is below the prescription fee, then the patient pays that amount). Vulnerable groups (e.g. low-income pensioners, people suffering from communicable diseases) are **exempt**. Furthermore, the spending of prescription fees is statutorily capped at 2% of the net annual family income.

Reimbursement for inpatient medicines

Medicines are integrated in the lump sums, which are refunded to the hospitals according to diagnosis-related groups (**DRG**). The lump sums generated by eligible hospitals are billed to the state health funds. An average consumption of medicines per diagnosis is considered for determining the lump sums. Oncology medicines, however, are defined as single medical procedures (*Medizinische Einzelleistungen*, MEL) and their utilisation is explicitly reimbursed.

There is no national positive list of medicines used in hospitals but the hospitals (or hospital groups of the same hospital owner such as a province) have their own **hospital pharmaceutical formulary** (HPF): Only medicines which are included in the HPF are procured by the hospitals.

The Pharmaceutical and Therapeutic Committee of a hospital (group) decides on the inclusion of medicines in the HPF on the basis of different criteria (e.g. therapeutic value, cost-effectiveness). However, no systematic ➲ Health Technology Assessment (**HTA**) process is applied in the inpatient sector (in a current pilot project, three inpatient medicines are undergoing an HTA-like process, see the chapter on developments, below).

No co-payments of medicines are applicable for inpatients.

Agreements

In recent years, **managed-entry agreements** (MEA) were concluded for new high-priced medicines both in the outpatient and inpatient sectors. Most of them are financially-based (e.g. price-volume agreements) but performance-based MEA are said to be on the rise. Prices and content of the MEA

are kept confidential. In the outpatient sector, however, medicines subject to such an agreement have been labelled in the EKO.

In addition, based on the provisions of a 'Framework Pharma Contract' (*'Rahmen-Pharmavertrag'*), pharmaceutical companies and wholesalers committed to pay a kind of ex-post rebate to the Austrian sickness funds. The last **framework contract** ran from 2016 till 2018.

Demand-side measures

Austrian sickness funds **monitor the prescription behaviour** of contract doctors with a view to their compliance to the prescribing guidelines. Doctors are requested to prescribe the most economic medicine out of therapeutically similar alternatives [21]. No prescribing budgets for doctors are in place.

Austria has no ➲ Reference price system, in which identical or similar medicines are clustered and reimbursed at the same amount. ➲ **Generic substitution** by the pharmacist is **not allowed**. Furthermore, doctors are **not permitted to prescribe by International Non-proprietary Name** (➲ INN prescribing), they always have to use the trade name.

4 Developments

A major legislative change was the **amendment of the General Social Insurance Act** [14] in April 2017. It introduced updated intervals for the re-evaluation of medicine prices in the EPR process, the application of EPR and possible pay-backs for medicines not included in the code of reimbursement in case of excess of expenditure thresholds as well as revised percentage rates for the price link policy applicable for reimbursable generic and biosimilar medicines (see also chapter 2).

In the health reform (*'Zielsteuerung Gesundheit'*) that has been on-going for the last years, a few projects related to medicines were included. Austria aims to strengthen its **HTA** processes and launched a pilot project for the evaluation of three medicines used in hospitals where no systematic HTA process is yet in place (so-called *'Spitals-HEK'*, to be translated as 'Hospital Pharmaceutical Evaluation Board'). Additionally, the Austrian Institute for Health Technology Assessment will be launched in January 2020. Furthermore, the health reform addressed a possible introduction of **INN prescribing** [22].

In June 2016, Austria joined the **Beneluxa initiative** which fosters cross-country collaboration in the areas of horizon scanning, HTA, information sharing and pricing and reimbursement. Further members of the Beneluxa initiative are Belgium, the Netherlands, Luxemburg and Ireland [23].

During the **presidency of the Council of the EU** in the second half of the year 2018, Austria put access to medicines on the agenda: Contributions to the debate included policy briefs of the European Observatory on Health Systems and Policies [24, 25] and a 'matchmaking' conference that brought together stakeholders, including research funding institutions and policy-makers.

5 References

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6 Annex

Annex 1: Stakeholders

Role	Name in local language (German)	Website(s)
Competent authority for marketing authorisation of medicines	Bundesamt für Gesundheit im Gesundheitswesen (BASG)	www.basg.gv.at/startseite/
Competent authority for pricing of medicines	Bundesministerium für Arbeit, Soziales, Gesundheit und Konsumentenschutz (BMASGK)	www.sozialministerium.at
Competent authority for reimbursement of medicines (outpatient)	Hauptverband der österreichischen Sozialversicherungsträger	www.hauptverband.at
Public payers for outpatient medicines: social health insurance institutions (sickness funds)	e.g. Wiener Gebietskrankenkasse, Niederösterreichische Gebietskrankenkasse, Oberösterreichische Gebietskrankenkasse	e.g. www.wgkk.at, www.noegkk.at, www.ooegkk.at
Public payers for inpatient medicines: state health funds	e.g. Wiener Gesundheitsfonds, Gesundheitsfonds Steiermark, Kärntner Gesundheitsfonds	e.g. www.wien.gv.at/gesundheit/einrichtungen/gesundheitsfonds/index.html, www.gesundheitsfonds-steiermark.at, http://www.gesundheitsfonds.at/
Patients organisations	e.g. Bundesverband Selbsthilfe Österreich, Pro rare Austria – Allianz für Seltene Erkrankungen, Verein für Spina Bifida & Hydrocephalus, Osteogenesis imperfecta Austria	e.g. www.bundesverband-selbsthilfe.at, www.prorare-austria.org, www.sbho.at, www.glasknochen.at
Consumers organisations	e.g. Verein für Konsumenteninformation	e.g. www.vki.at
Pharmacy associations	e.g. Österreichische Apothekerkammer, Arbeitsgemeinschaft österreichischer Krankenhausapotheker	e.g. www.apotheker.or.at/, www.aahp.at
Industry associations	Verband der pharmazeutischen Industrie Österreichs (PHARMIG), Forum der forschenden pharmazeutischen Industrie in Österreich, Österreichischer Generikaverband, Biosimilarverband Österreich	www.pharmig.at, www.fopi.at, www.generikaverband.at, www.biosimilarsverband.at
Wholesale association	Verband der österreichischen Arzneimittel-Vollgroßhändler (PHAGO)	www.phago.at

Source: overview provided by the PPRI Secretariat

Annex 2: Regulation of wholesale and pharmacy remuneration (as of 2019)

Wholesale remuneration schemes

Wholesale mark-up scheme for medicines included in the yellow and green boxes of the code of reimbursement

Ex-factory price	Maximum mark-up on the ex-factory price	Pharmacy purchasing price
€ 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%	–
> € 339.15	€ 23.74	–

Wholesale mark-up scheme for medicines not included in the green and yellow boxes of the code of reimbursement

Ex-factory price	Maximum mark-up on the ex-factory price	Pharmacy purchasing price
€ 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%	–
> € 339.15	€ 30.52	–

Source: Enactment of the Federal Ministry of Health and Women's Affairs on the maximum mark-ups in pharmaceutical wholesale 2004 [17]

Pharmacy remuneration schemes

Pharmacy mark-up scheme for 'privileged customers'

Pharmacy purchasing price (PPP)	Mark-up on the PPP	Pharmacy retail price
€ 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
> € 357,08	3.9%	–

Pharmacy mark-up scheme for 'private customers'

Pharmacy purchasing price (PPP)	Mark-up on the PPP	Pharmacy retail price
€ 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
> € 371.37	12.5%	–

Source: Austrian Pharmaceutical Tax Enactment 2019 [18]

Annex 3: Glossary

Community pharmacy	Health care facility dispensing medicines (prescription-only medicines and/or non-prescription medicines, reimbursable and/or non-reimbursable medicines) to outpatients.
Co-payment	Insured patient's contribution towards the cost of a medical service covered by the health insurance. Can be expressed as a percentage of the total cost of the service (percentage co-payment), as a fixed amount (prescription fee) or a deductible.
Cost-plus pricing	Pricing policy that determines a medicine price by taking into account production costs, promotional expenses, research & development, administration costs, overheads and a profit that is considered 'reasonable'.
Dispensing doctors	Physicians who have been granted the right to dispense medicines to their patients.
External price referencing	The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.
Generic substitution	Practice of substituting a medicine, whether marketed under a trade name or generic name (branded or unbranded generic), with a less expensive medicine (e.g. branded or unbranded generic), often containing the same active ingredient(s).
Health Technology Assessment (HTA)	A multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.
INN prescribing	Requirements for prescribers (e.g. physicians) to prescribe a medicine by its International Non-Proprietary Name (INN), i.e. the active ingredient name instead of the trade name.
Managed-entry agreement (MEA)	An arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms and are usually classified into financially-based and performance-based MEA.
Marketing authorisation	A licence issued by a medicines agency approving a medicine for market use based on a determination by authorities that the medicine meets the requirements of quality, safety and efficacy for human use in therapeutic treatment.
Mark-up	Percentage of the purchasing price added on to get the selling price.
Pharmaceutical expenditure	Total expenditure on pharmaceutical and other medical nondurables. This comprises medicinal preparations, branded and generic medicines, patent medicines, serums and vaccines, vitamins and minerals and oral contraceptives and other medical nondurables such as bandages, elastic stockings, incontinence articles, condoms and other mechanical contraceptive devices.

Policies	Instruments, tools and approaches that allow policy-makers to achieve defined objectives.
Price link policy	Practice of setting the price of a medicine (e.g. a generic or a biosimilar) in relationship to the price of another medicine (e.g. originator, biological reference medicine), usually at a certain percentage lower.
Pricing (price setting)	Act of determining the medicine price which is either taken by a pharmaceutical company (free pricing) or is the competence (responsibility) of a competent authority (price control).
Procurement	A process to purchase goods and services (e.g. medicines) that involves many steps and many stakeholders based on national, or supranational, regulation, policies, structures and procedures.
Reference price system	A reimbursement policy in which identical medicines (ATC 5 level) or therapeutically similar medicines (ATC 4 level) are clustered (reference group). The third party payer funds a maximum amount (= reference price), while the patient must pay the difference between the reference price and the actual pharmacy retail price of the medicine, in addition to any co-payments.
Reimbursable medicines	Medicines which are eligible for reimbursement. Expenses of reimbursable medicines may be fully covered by third party payers, or only partially (a specific percentage).
Reimbursement	Coverage of the expenditure by a third party payer (e.g. social health insurance/National Health Service).
Reimbursement list	A list that contains medicines with regard to their reimbursement status. It may either include medicines eligible for reimbursement (positive list) or those explicitly excluded from reimbursement (negative list).
Tendering	Any formal and competitive procurement procedure through which tenders (offers) are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender/offer is the most advantageous.
Value-based pricing	Policy of authorities to set the prices of a new medicine and/or decide on reimbursement based on the therapeutic value that a medicine offers, usually assessed through health technology assessment (HTA) or economic evaluation. In a full-fledged VBP, the pricing and reimbursement systems are integrated, and the price and reimbursement decision is taken jointly based on a value assessment.
Wholesale	All activities consisting of procuring, holding, supplying or exporting medicines, apart from supplying medicines to the public.

Source: Glossary of Pharmaceutical Terms [26]