PPRI
Pharmaceutical Pricing and Reimbursement Information

PPRI Pharma Brief: Austria 2023

Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Briefs Series

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

Gesundheit Österreich GmbH

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Information as of December 2023

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Vienna, January 2024
Commissioned by the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection

Gesundheit Österreich GmbH

Suggestion for citation: Vogler, Sabine; Haasis, Manuel Alexander; Zimmermann, Nina (2024): PPRI Pharma Brief: Austria 2023. Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Briefs Series. Gesundheit Österreich (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 ppri.goeg.at

About PPRI Pharma Briefs

This concise report on the pharmaceutical pricing and reimbursement policy framework in Austria is part of the PPRI Pharma Briefs Series launched by the Pharmaceutical Pricing and Reimbursement Information (PPRI) Secretariat in 2019.

PPRI networks

The PPRI network is a collaboration of **pharmaceutical pricing and reimbursement authorities** of 50 – mostly European – countries (as of December 2023) as well as international and European institutions (e.g. European Commission, Organisation for Economic Co-operation and Development, 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 to policy-makers who want to cross-learn and benchmark as well as to researchers who perform policy analyses and require contextual information on national pharmaceutical systems.

PPRI country information

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

The **PPRI Pharma Briefs** Series responds to the interest and need expressed by policy-makers and technical experts in public authorities responsible for the pricing and reimbursement of medicines to read concise reports of pharmaceutical policies established in other countries. They are complemented by PPRI Medical Devices Briefs.

The PPRI Pharma Briefs are based on 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 (1 January 2023)	9.10 million inhabitants
Country size	83,883 km²
Gross domestic product / GDP (2022)	GDP per capita: USD PPP 67,792
Health expenditure / HE (2022, provisional)	HE per capita: € 5,659.2 / USD PPP 7,275.4 HE in % of GDP: 11.4% Public HE as % of total HE: 77.8%
Pharmaceutical expenditure / PE (2021)	PE per capita: € 627.1 / USD PPP 764.8 PE in % of HE: 11.4% Public PE as % of total PE: 67.5%

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

Sources: population – Statistics Austria [1]; country size – Statistics Austria [2]; gross domestic product – OECD statistical profile [3]; health and pharmaceutical expenditure – OECD Health Statistics [4]

Provision of pharmaceuticals

Community pharmacies (31 Dec. 2022)	1,415 community pharmacies, plus 31 branch pharmacies
Dispensing doctors (2023)	884
Wholesale (2023)	6 full-line wholesale companies, plus approx. 35 short-line wholesalers and pre-wholesalers
Pharmaceutical industry (2023)	More than 220 companies (manufacturers or depositors), thereof 23 members of an association of research-based companies

Sources: community pharmacies – Austrian Chamber of Pharmacists [5]; dispensing doctors – PHARMIG [6] (data published in 2023, but no indication on date of data regarding dispensing doctors); wholesale – PHAGO [7] and Short PPRI Pharma Profile Austria [8], pharmaceutical companies – PHARMIG [6, 9] and FOPI [10]

Pharmaceutical market

Pharmaceutical market (2022)	€ 5.7 billion (outpatient and inpatient sectors)
Medicines (2023)	15,976 medicines authorised (counted including different pharmaceutical forms and dosages) (December 2023) 7,517 medicines (counted including different pharmaceutical forms and dosages) included in the outpatient reimbursement list (December 2023)
Generic market shares (2022)	37% in volume of the outpatient reimbursed pharmaceutical market 13% in value of the outpatient reimbursed pharmaceutical market Note: the reimbursed pharmaceutical market relates to those medicines which the social insurance reimburses, data relate to 2022

Sources: pharmaceutical market – PHARMIG [6]; authorised medicines – BASG [11], medicines in the reimbursement list – Austrian Social Insurance [12], generic market shares – OECD [13]

Pharmaceutical pricing (2023)

Price regulation	Yes, in place for outpatient reimbursable medicines
Pricing authorities	**Outpatient**: Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection, supported by the Pricing Committee; the reimbursement authority (Austrian Social Insurance, see below) is also involved in price negotiations **Inpatient**: no pricing authority, price setting and procurement is done by the purchasers (hospitals, hospital owner associations)
Key pricing policies	**External price referencing**: yes, for outpatient reimbursable medicines and those not eligible for general reimbursement having exceeded a defined annual threshold of social insurance expenditure **Value-based pricing**: no, but value-based elements in pricing **Price negotiations**: for some reimbursable medicines in the outpatient sector and for some inpatient medicines **Managed-entry agreements**: used for high-priced medicines in outpatient and inpatient sectors, mainly financial agreements **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 (depending on type of medicines) **Pharmacy:** two regressive mark-up schemes (depending on customers) **Value-added tax**: 10% on medicines (standard: 20%)

Source: overview provided by the PPRI Secretariat

Pharmaceutical reimbursement (2023)

Reimbursement authorities	**Outpatient:** Austrian Social Insurance **Inpatient:** no reimbursement authority, expenses for medicines are usually included in the DRG system
Reimbursement lists	**Outpatient:** national Code of Reimbursement (national positive list) **Inpatient:** hospital pharmaceutical formularies (per hospital or hospital owner)
Reimbursement criteria	**Outpatient:** reimbursement decision is based on pharmacological, medical-therapeutic and health-economic evaluations **Inpatient**: no systematic reimbursement criteria
Co-payments for medicines	**Outpatient:** co-payment in the form of a prescription fee, but no 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 system, 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 Social Affairs, Health, Care and Consumer Protection** is responsible for the overall legislative framework for medicines. It oversees the pricing of medicines and hosts the **Pricing Committee**. The **Austrian Social Insurance** decides on the inclusion of outpatient medicines into the national outpatient reimbursement list (Code of Reimbursement) and negotiates the prices of these medicines.

Pricing policies are in place for medicines for which inclusion in the Code of Reimbursement was requested as well as for medicines that are not included but exceeded € 750,000 in sales incurred by the social health insurance in the 12 preceding months. **External price referencing** is applied for originator medicines subject to price regulation; their price must not exceed the average price of all other 26 EU Member States (for the calculation of the EU average price, price data of at least 2 EU Member States need to be available). Prices of generic and biosimilar medicines included in the Code of Reimbursement are set in relation to the prices of the originator or reference medicines (originator biologicals), and previously listed equivalent generics and biosimilars, respectively ('**price link** policy').

For the launch price of a new medicine or planned price changes of all other medicines, a **price notification** by the pharmaceutical company (marketing authorisation holder) 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**. For medicines with high prices, **managed-entry agreements** have increasingly been concluded in the outpatient sector (concluded by the Austrian Social Insurance) and inpatient sector (concluded by hospitals and hospital owners). They are mainly financial agreements but performance-based arrangements are said to be on the rise.

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 customers (pharmacy). The **value-added tax** (VAT) on medicines is 10% (standard VAT rate: 20%).

The **Code of Reimbursement** ('Erstattungskodex' / EKO) is the national positive list managed by the Austrian Social Insurance and comprises medicines used in the outpatient sector that are funded by social health insurance. It is organised based on different categories ('**boxes**') for which different prescribing rules are applied: 'green box' – free prescribing; 'yellow box' for medicines with 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 medicines, for which the reimbursement application is in process. The Austrian Social Insurance decides on the

listing into the different boxes based on **pharmacological, medical-therapeutic and health-economic evaluations**.

In the inpatient sector, the Pharmaceutical and Therapeutic Committees, which have been established per hospital or hospital owner organisation, decide on the inclusion of in the **hospital pharmaceutical formularies**, again managed by the individual hospitals or hospital owner organisations.

While the medical-therapeutic evaluation as part of decision on inclusion of a medicine into the outpatient Code of Reimbursement is based on the HTA criteria, health technology assessment (HTA) is not systematically applied in the Austrian pharmaceutical system (lack of HTA in the inpatient sector).

All medicines included in the outpatient reimbursement list are **100% reimbursed** (no percentage co-payment). When filling a prescription, patients pay a **prescription fee of € 6.85** (data of 2023) unless an exemption applies. If prices of reimbursed medicines are below the prescription fee, the patient pays the price below the fee. There are no out-of-pocket payments for medicines in the inpatient sector.

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

Keywords

Pricing, reimbursement, pharmaceutical policies, pharmaceutical system, Austria

Kurzfassung

Bestimmungen betreffend Medikamente sind in diversen Rechtsakten (z. B. in 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 bzw. Überschneidungen bestehen zwischen der Preisbildung sowie Beschaffung von Arzneimitteln und dem Erstattungsprozess.

Das **Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz** ist für die Regelung des rechtlichen Rahmens für Arzneimittel verantwortlich. Es wirkt als die zuständige Behörde für die Preisfestsetzung von Medikamenten und ist Sitz der Geschäftsstelle der **Preiskommission.** Der **Dachverband der Sozialversicherungsträger** entscheidet über die Aufnahme von Arzneimitteln in die Positivliste des niedergelassenen Sektors, den sogenannten Erstattungskodex (EKO), und verhandelt auch die Preise für diese Medikamente.

Der Preis der Arzneimittel, deren Aufnahme in den EKO beantragt wurde, und jener nicht im EKO gelisteter Medikamente, deren Umsatz zulasten der Sozialversicherung in den letzten zwölf Monaten einen Schwellenwert von € 750.000,– überstieg, werden mittels des **europäischen Durchschnittspreises** festgelegt. Der Preis eines neuen Medikaments darf dabei den Durchschnitt der Preise dieser Arzneispezialität in den übrigen EU-Mitgliedstaaten („EU-Durchschnittspreis“) nicht überschreiten. Als Voraussetzung für die Aufnahme von **Generika und Biosimilar-Medikamenten** in den Erstattungskodex muss deren Preis in einer bestimmten Größenordnung unter jenem des Original- oder Referenzprodukts (originäres Biologikum) bzw. weiterer vergleichbarer gelisteter Generika bzw. Biosimilar-Medikamente liegen *(Generika- bzw. Biosimilarpreisregel)*.

Für alle übrigen Medikamente (sei es hinsichtlich des Preises für ein neues Arzneimittel oder in Bezug auf eine geplante Preisänderung) genügt eine **Preismeldung** an die Preiskommission. Somit besteht freie Preisbildung für Arzneimittel, die in Krankenanstalten verabreicht werden. Diese Arzneimittel werden von Krankenanstalten oder deren Trägern beschafft, und ihre Preise werden in der Regel direkt mit dem Pharma-Unternehmen verhandelt. In manchen Fällen werden Arzneimittel, die in Krankenanstalten verabreicht werden, **ausgeschrieben.** Für hochpreisige Arzneimittel werden immer mehr **Managed-Entry-Agreements** (Rabattverträge, Preismodelle) abgeschlossen (für Medikamente im niedergelassenen Sektor vom Dachverband der Sozialversicherungsträger und für solche im stationären Sektor von einzelnen Krankenanstalten oder deren Trägern), meist in Form finanzieller Vereinbarungen und zunehmend auch als erfolgsabhängige Abkommen.

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

Arzneimittel, für welche die Ausgaben von der Sozialversicherung getragen werden, werden in den vom Dachverband der Sozialversicherungsträger geführten **Erstattungskodex** aufgenommen. Diese Positivliste für Medikamente im niedergelassenen Bereich besteht aus verschiedenen Kategorien **(„Boxen“),** für die bestimmte Verschreibungsregeln gelten: Die „Grüne Box“ beinhaltet frei verschreibbare Arzneimittel, die „Gelbe Box“ umfasst Arzneimittel mit wesentlichem zusätzlichem therapeutischem Nutzen, die nur bei Vorliegen einer Bewilligung des chef- und kontrollärztlichen Dienstes verschrieben werden dürfen bzw. einer nachfolgenden Kontrolle unterliegen, und die

„Rote Box“ enthält neue Arzneimittel, deren Aufnahme in den Erstattungskodex beantragt wurde (zeitlich befristete Kategorie). Der Dachverband der Sozialversicherungsträger entscheidet nach **pharmakologischen, medizinisch-therapeutischen und gesundheitsökonomischen Evaluationen** über die Aufnahme von Arzneimitteln in den EKO und dessen Boxen.

Im stationären Bereich sind Medikamente in **Arzneimittellisten** enthalten, die von den Krankenanstalten oder deren Trägern verwaltet werden. Über die Aufnahme dieser Medikamente in diese Listen entscheiden die jeweiligen pro Krankenanstalt bzw. Träger angesiedelten Arzneimittelkommissionen.

Die medizinisch-therapeutische Evaluation im EKO-Verfahren für Arzneimittel im niedergelassenen Sektor basiert auf Kriterien von Health Technology Assessment (HTA). Allerdings wird in Österreich HTA nicht systematisch bei Arzneimitteln angewandt (kein HTA im stationären Sektor).

Der Preis sämtlicher Arzneimittel, die in den Erstattungskodex für den niedergelassenen Bereich aufgenommen wurden, wird zu 100 Prozent erstattet (es fallen keine sogenannten prozentuellen Zuzahlungen an). Bei der Einlösung eines Rezepts in der Apotheke musste im Jahr 2023 die Patientin / der Patient – außer im Falle einer Befreiung davon – eine Rezeptgebühr von € 6,85 pro verordnetes Medikament zahlen. Wenn die Preise der erstatteten Medikamente unter der Rezeptgebühr liegen, zahlt die Patientin oder der Patient den Preis, der unter der Gebühr liegt. Im stationären Bereich fallen keine Zuzahlungen an.

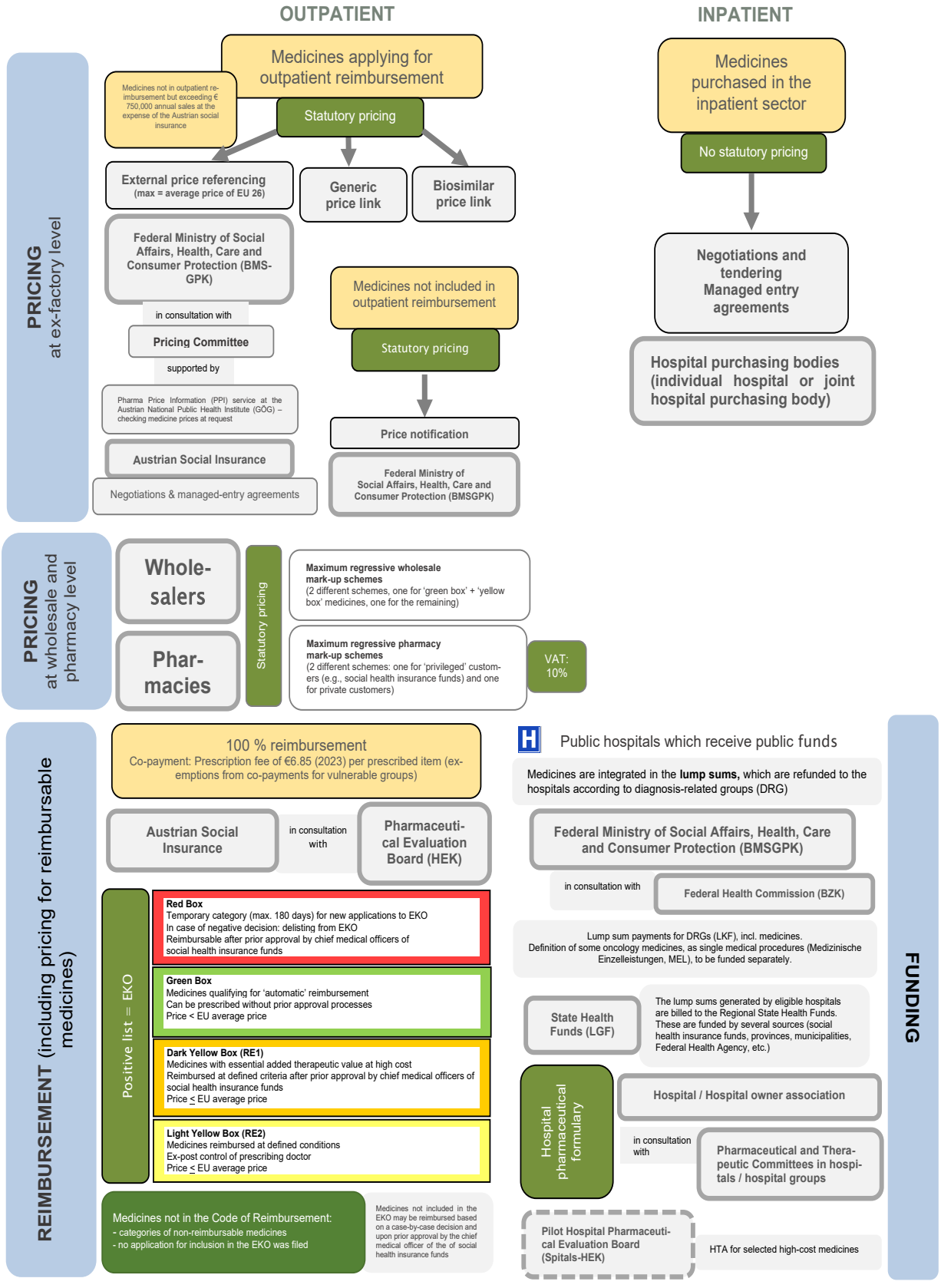
In Österreich sind weder Wirkstoffverordnung noch Generikasubstitution erlaubt.

Schlüsselwörter

Preisbildung, Erstattung, Arzneimittelpolitik, Arzneimittelsysteme, Österreich

Graphical summary

Pharmaceutical pricing and reimbursement policies in the inpatient and outpatient sectors



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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*) [14], the General Social Insurance Law (*Allgemeines Sozialversicherungsgesetz* / ASVG) [15], the Price Act (*Preisgesetz*) [16] and the Procedural Rules for publication of the Code of Reimbursement (*Verfahrensordnung zur Herausgabe des Erstattungskodex* / VO-EKO [17].

The **competences** for regulatory and pharmaceutical policy matters (such as ➲ marketing authorisation, ➲ pricing and ➲ reimbursement; for terms with the ➲ sign consult the glossary in Annex 3 which can be accessed by clicking on the term) 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.

The Medicines Agency (*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 oversees marketing authorisation, pharmacovigilance, inspections and monitoring of medicine shortages. Key competent **authorities** for pricing and reimbursement and public payers in Austria are

» the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection *(Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz* / BMSGPK), which is responsible for the overall legislative framework with regard to medicines, and for pricing medicines;
» the Austrian Social Insurance (*Dachverband der Sozialversicherungsträgen*), which is in charge of reimbursement decisions, including pricing negotiations, for outpatient medicines;
» the social insurance institutions (sickness funds, organised according to membership of occupational groups[1]) 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 hospital owner associations or individual hospitals procure and negotiate prices of medicines in the inpatient sector. The Austrian Institute for Health Technology Assessment (AIHTA) is an independent entity for scientific support to decision-makers in the public sector but it is at the time of writing not officially involved in the pricing and reimbursement procedures (see Annex 1 for an overview of key stakeholders).

1
Following a social insurance reform, which entered into force in 2020, the regional social health insurance funds of each of the nine Austrian provinces and company-based health insurance funds were merged into the Austrian Health Insurance Fund (*Österreichische Gebietskrankenkasse*). In addition, a few merged social health funds exist for defined professional groups [18].

2 Pricing

Pricing at manufacturer price level

The policy of ➲ external price (EPR) is applied for ➲ reimbursable medicines for which an application for inclusion into the Code of Reimbursement (*Erstattungskodex* / EKO) was submitted. The Code of Reimbursement functions as the positive list in the outpatient sector.

Since a reform in 2017, EPR has also been applied to medicines not included in the Code of Reimbursement whose sales at the expense of the social health insurance exceed the threshold of € 750,000 in the 12 preceding months.

The Pricing Committee (*Preiskommission*) of the Federal Ministry of Social Affairs, Health, Care 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) [15], the Pricing Committee can request the Austrian National Public Health Institute (*Gesundheit Österreich* GmbH / 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 18 months after the first time a price was set and 24 months after the second time a price was set; another re-evaluation is possible 18 months after the third time a price was set. The EU average price serves as basis for further negotiations of the Austrian Social Insurance with the pharmaceutical company on the reimbursement price.

As of 2023, reference countries are all other 26 European Union (EU) Member States; the price must not exceed the EU average [19]. A minimum of price data of two EU Member States is required to calculate the benchmark price. With regard to medicines included in the Code of Reimbursement, their price must either not exceed the EU average price (in case of additional therapeutic benefit, 'yellow boxes') or must be below the EU average price ('green box'), depending on the medicine's reimbursement category (for details on the so-called 'boxes' of the Code of Reimbursement see also below the chapter 'Reimbursement') [17]. This is guided by the rationale that medicines included in the Code of Reimbursement must demonstrate an added value in medical-therapeutic terms and an economic advantage (see below the regulation for generic and biosimilar medicines).

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 the third generic are subject to price reductions in relation to the previously included generics (18% and 15%, respectively). 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 to be included in the Code of Reimbursement. For biosimilars, the following rates apply: the price of the first biosimilar must be at least 38% below the

price of the reference medicine (biological originator); second and third biosimilars at least minus 15% and 10%, respectively, and further biosimilars to offer a price reduction of at least € 0.10. The price of the originator, including the biological originator, has to be reduced by at least 30% within three months after the inclusion of the first generic and biosimilar into the Code of Reimbursement [15].

The different price reduction rates for generic and biosimilar medicines (colloquially referred to as *'biosimilar price regulation' / 'Biosimilarpreisregel')* were introduced as part of the 2017 reform of the General Social Insurance Law (before this legal change, same reduction rates were applied to generics and biosimilars). This measure was introduced on a temporary basis, with a deadline set for December 2021, and it was prolonged twice for two years, respectively (until end of 2023 and end of 2025).

Additionally, the 2017 reform introduced a **price corridor** ***('Preisband')*** for medicines included in the 'green box' of the Code of Reimbursement (for details on the boxes of the Code of Reimbursement see below the chapter on 'Reimbursement'). Medicines listed in the Code of Reimbursement (thus publicly funded) may be priced maximum 20% higher (reduced from initially 30%) than the lowest equivalent generic of the same active ingredient. The Austrian Social Insurance is mandated to monitor the compliance with this maximum price corridor at defined dates and to start delisting in cases of non-compliance [15].

For all other medicines (including those solely used in hospitals), there is, in principle, free pricing (no statutory pricing). The legislation provides that pharmaceutical companies, however, have to notify the Ministry of Social Affairs, Health, Care 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 has not been launched within six weeks, the proposed price will automatically be granted [16].

In addition, for medicines which are not included in the Code of Reimbursement but exceed sales value of € 750,000 (at ex-factory price basis) incurred by the Austrian Social 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 sales threshold was first exceeded and grant a discount of 6.5% of the price determined based on EPR (discount regulation in place since April 2022) [15].

Procurement

In contrast to centralised procedures in the outpatient sector, ➲ procurement of medicines used in hospitals (public hospitals mainly in the ownership of Austrian provinces) 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 for some medicines a ➲ managed-entry agreement (MEA) is concluded (see below also the section 'Agreements').

The policy of ➲ tendering is less common. 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.

National tendering is conducted by the National Procurement Agency (*Bundesbeschaffung GmbH* / BBG) but it is limited to vaccines and medicines that are mainly used as strategic reserve (for armed forces or against pandemic influenza). During the COVID-19 pandemic, Austria, through the Federal Ministry of Social Affairs, Health, Care and Consumer Protection, was involved in the EU procurement of COVID-19 vaccines.

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 [20] (the schemes are presented in Annex 2). Separate remuneration for low-priced medicines was agreed upon in November 2023 (see chapter 'Developments').

The ➲ community pharmacies 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 Federal 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 [21] (cf. Annex 2).

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

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3 Reimbursement

Reimbursement for outpatient medicines

The Austrian Social Insurance is responsible for deciding whether a medicine will be included in the outpatient positive list, the **Code of Reimbursement** (*Erstattungskodex* / EKO). This decision is based on a three-tier process consisting of a pharmacological **evaluation**, a medical-therapeutic evaluation and a health-economic evaluation [17]. In the case of a negative decision, the pharmaceutical company may appeal to the Federal Administrative Court (*Bundesverwaltungsgericht*). Disbursement is done by sickness funds (social health insurance institutions) based on the decisions of the Austrian Social Insurance that are applicable for the whole country.

All medicines included in the Code of Reimbursement qualify for general reimbursement but the prescribing rules differ. The Code of Reimbursement 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 boxes' include medicines which provide a substantial added therapeutic benefit. Reimbursement is only granted if defined criteria (e.g., specific disease or age group) are met. There is a division into the 'light yellow box' and the 'dark yellow box', for which different prescription rules (see below) apply.
» The 'red box' is a temporary category for medicines for which an application for inclusion in the Code of Reimbursement has been submitted. In accordance with the Transparency Directive [22], the Austrian Social Insurance is responsible for deciding within 180 days upon receipt of the reimbursement application whether or not the respective medicine will be included in the Code of Reimbursement and at which price (otherwise, without decision on the price, to be decided within 90 days).

For medicines in the red and the dark yellow boxes, an ex-ante approval of a 'chief medical officer' 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) and not included in the Code of Reimbursement.

Medicines which are not included in the Code of Reimbursement may still be funded by the social insurance based on a patient-named prescription. This category is colloquially called 'No Box'; it comprises, for example, medicines for which the marketing authorisation holder has never requested inclusion into the Code of Reimbursement. After 2010, the share of the social insurance expenditure on 'No Box' medicines has grown considerably, which resulted in retrospective price regulation for medicines with high social insurance sales (see above chapter 'Pricing').

When filling a prescription in a community pharmacy, patients are charged a **prescription fee** of € 6.85 (2023) per item on the prescription (unless the pharmacy retail price is below the prescription fee, then the patient pays the pharmacy retail price). Vulnerable groups (e.g., low-income pensioners, people suffering from a communicable disease) are **exempt** from the prescription fee. Furthermore, the spending of prescription fees is statutorily capped at 2% of the net annual family income [23]. Apart from the prescription fee, no other forms of ➲ co-payments, such as a percentage co-payment on the price of medicines or a deductible, are charged on outpatient reimbursable medicines in Austria.

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 part of the DRG system.

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 a **hospital pharmaceutical formulary** (HPF): Medicines which are included in the HPF should primarily be used in the respective hospital. The use of other medicines must be requested on a patient-specific and medically justified basis.

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 (for the planned establishment of an evaluation board see the chapter 'Developments' below).

To manage funding of single therapies with very high price tags, the establishment of additional funds can be jointly decided by the Federal State, the provinces and social insurance. As of 2023, such funds exist for Zolgensma® and Luxturna®; and others may follow.

No co-payments of medicines are applicable for inpatients.

Agreements

In recent years, **managed-entry agreements** (MEA) were concluded for new high-priced medicines in the outpatient and inpatient sectors. While the Austrian Social Insurance negotiates MEA for medicines for outpatient use, in the inpatient sector individual hospital owners (or even individual hospitals) conclude these agreements, resulting in different coverage by MEA and type of MEA for medicines used in hospitals. Most MEA are financial agreements (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 marked in the Code of Reimbursement (with the label 'PM' as abbreviation for '*Preismodell*').

Demand-side measures

To comply with prescribing guidelines issued by the Austrian Social Insurance (so-called 'Rules of Economic Prescribing of Pharmaceuticals and Medicinal Products'), contract doctors are obliged to prescribe the most economic medicine out of therapeutically similar alternatives [24]. Austrian sickness funds **monitor the prescription behaviour** of contract doctors with a view to their compliance to the prescribing guidelines. No prescribing budgets for doctors are in place.

Austria has no ➲ reference price system, in which identical or similar medicines would be clustered and reimbursed at the same amount. A ➲ 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 Law** in April 2017. It introduced changes in the EPR process (updated intervals for the re-evaluation of medicine prices, the application of EPR and possible pay-backs for medicines not included in the Code of Reimbursement in certain cases) as well as revised reduction rates for the price link policies applicable for reimbursable generic and biosimilar medicines (see also chapter 'Pricing'). With regard to the latter, a change in the design of generic pricing came into effect in October 2023, when the 'price corridor' between the highest-priced and lowest-priced medicine of the same active ingredient included in the 'green box' of the Code of Reimbursement was reduced from 30% to 20%. Further changes as of 2023 related to the 'price corridor' provided that the comparator for medicines of the same active substance would refer to the medicine in the most frequently prescribed strength and that the price decrease should not reach a price level below the prescription fee [15]. The legislation on different **price reductions for generics and biosimilars as part of the price link policy** ('*Biosimilarpreisregel*'), in force since April 2017, was scheduled to expire end of 2023, which would have implied application of the previous uniform reduction rates for generics and biosimilars. End of 2023, the legislation was prolonged on a temporary basis for another two years.

Austria has been working on measures to manage and mitigate **medicine shortages**, which, similar to other countries, have been increasing. In April 2020, reporting of existing and upcoming medicine shortages to the shortage register managed by the Medicines Agency has become mandatory for marketing authorisation holders. This shortage register, which is updated daily, is publicly accessible [25]. The Medicines Agency may impose export bans for some medicines in short supply, which is indicated in a second shortage register also managed by the Agency [26]. Furthermore, a multi-stakeholder task force to discuss solutions to manage medicine shortages was established, with the secretariat being located with the Medicines Agency. In April 2023, the same reimbursement rules (i.e. dispensing without prior approval of the 'chief medical officer' of the social insurance) as for finished pharmaceuticals of these active ingredients were introduced for magistral preparations of two antibiotics (amoxicillin trihydrate and cefaclor monohydrate) produced in the community pharmacy [27].

At the beginning of November 2023, the Federal Ministry of Social Affairs, Health, Care and Consumer Protection announced that it reached an agreement with the pharmaceutical wholesaler association on the procurement and stockpiling of important active pharmaceutical ingredients (for common antibiotics and medicines for cold symptoms), to offer pharmacies the opportunity to call them off in periods of high demand and to produce magistral preparations [28].

Aiming to enhance the uptake of generic medicines, **prescribing by INN**, which had been listed as one of the projects of the health reform (*'Zielsteuerung Gesundheit'*), was intended to be introduced in Austria, potentially from January 2024 [29]. Despite preparatory activities, this plan was discontinued.

Ensuring patient access to medicines with high price tags while remaining the sustainability of the solidarity-based health care system has increasingly become a major challenge, which is aimed to be tackled by different measures (either implemented or under discussion). To identify potentially high-impact medicine candidates in the pipeline, Austria joined the **International Horizon Scanning Initiative** (IHSI) in 2022 [30]. The latter is considered a spin-off of the **Beneluxa Initiative**, a cross-country collaboration of Austria, Belgium, the Netherlands, Luxemburg and Ireland [31].

To strengthen its **HTA** processes, a pilot project was launched in 2018 by the provinces in collaboration with the Austrian Social Insurance to evaluate three medicines used in hospitals where no systematic HTA process is in place (so-called *'Spitals-HEK'*, to be translated as 'Hospital Pharmaceutical Evaluation Board'). In addition, as a result of the negotiations on the allocation of resources for the next five years between the Federal State, the provinces and Austrian Social Insurance held in 2023 (so-called '*Finanzausgleich'* / FAG), it was agreed to establish a 'Pharmaceutical Evaluation Board' ('*Bewertungsboard'*) in 2024 to support HTA processes relating to medicines for inpatient use and medicines 'at the interface' of inpatient and outpatient sectors. Furthermore, it supports national implementation of the EU HTA Regulation [32], which provides for cooperation in the evaluation of some medicines and medical devices ('joint HTA') from 2025 on.

Building on the experience with special funds for high-priced medicines (currently Zolgensma® and Luxturna®), expansion of this funding mechanism is under discussion for further medicines (e.g. gene therapies).

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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) / AGES Medical Market Surveillance	www.basg.gv.at
Competent authority for pricing of medicines	Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz (BMSGPK)	www.sozialministerium.at
Competent authority for reimbursement of medicines (outpatient)	Dachverband der Sozialversicherungsträger	www.sozialversicherung.at
Public payers for outpatient medicines: social health insurance institutions (sickness funds)	e.g. Österreichische Gesundheitskasse (ÖGK), Sozialversicherungsanstalt für Selbständige (SVS)	e.g. www.gesundheitskasse.at, www.svs.at
Public payers for inpatient medicines: state health funds	e.g. Wiener Gesundheitsfonds, Gesundheitsfonds Steiermark, Kärntner Gesundheitsfonds	e.g. gesundheitsverbund.at, www.gesundheitsfonds-steiermark.at, www.gesundheitsfonds.at/
National procurement agency	Bundesbeschaffung GmbH (BBG)	www.bbg.gv.at
Health Technology Assessment (HTA) institute	Austrian Institute for Health Technology Assessment (AIHTA)	aihta.at
National Public Health Institute; supporting the Pricing Committee	Gesundheit Österreich (GÖG)	goeg.at
Patient 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 (FOPI), Österreichischer Generikaverband, Biosimilarsverband Österreich	www.pharmig.at, www.fopi.at, www.generikaverband.at, 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 2023)

Wholesale remuneration schemes

Wholesale mark-up scheme for medicines 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	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 [20]

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 [21]

Annex 3: Glossary

community pharmacies	Health care facilities which dispense 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 insurer. 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 takes into account production costs, promotional expenses, research & development, administration costs, overheads and a profit to determine a price.
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 dispensing 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) at pharmacy level without consulting the prescriber.
Health Technology Assessment (HTA)	A multidisciplinary process that that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.
INN prescribing	Requirement 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 brand name. INN prescribing may be allowed (indicative INN prescribing) or required (mandatory/obligatory INN prescribing).
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 financial-based and performance-based MEA. The latter links price (reward for manufacturers) to health outcomes.
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, on-patent medicines, serums and vaccines, vitamins and minerals and oral contraceptives. Other medical nondurables include a wide range of 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)	Action by a government authority to set the price of a medicine and/or indirectly influence it (e.g. through pricing policies) for different price types (e.g. ex-factory price, pharmacy retail price) and to monitor and review and eventually adapt it.
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 similar medicines (ATC 4 level) are clustered (reference group). The public payer funds a maximum amount (= reference price), while the patient must pay the difference between the reference price and the pharmacy retail price of the medicine, in addition to any co-payments (such as prescription fees or percentage co-payment rates).
reimbursable medicines	Medicines which are eligible for reimbursement. Costs of reimbursable medicines may be fully covered by third party payers, or only partially (a specific percentage).
reimbursement	Coverage of the costs of reimbursable medicines by a public 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). Reimbursement lists may target either the out-patient sector (usually positive lists or negative lists) or the in-patient sector (typically called hospital pharmaceutical formulary), or both.

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.

Further terms and their definitions can be found in the Glossary of Pharmaceutical Terms of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, as indicated below.

Source: Glossary of Pharmaceutical Terms [33]