PPRI Pharma Brief:
Country 2021

Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Briefs Series

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

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Template

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This report contributes to the implementation of the 2030 Agenda for Sustainable Development, in particular to Sustainable Development Goal (SDG) 3 "good health and well-being" and its target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

About PPRI Pharma Briefs

This concise report on the pharmaceutical pricing and reimbursement policy framework in Country is part of the series of PPRI Pharma Briefs 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 52 - mostly European – countries (as of January 2021) 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 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. They are complemented by PPRI Medical Devices Pharma Briefs which will be produced from 2021 on.

The PPRI Pharma Briefs 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

Guide for authors:

Kindly include the required data for the **latest available** year and indicate the year**.**

List the **sources** below the tables and include the full reference in the References chapter 5.

Provide any **specifications** (e.g. on how medicines are counted, with or without different packs; whether or not data such as expenditure data or generic market shares relate to specific segments such as the outpatient sector or the reimbursement market) in the tables or below. Please have a look at the Brief Pharma Profile for Austria for an example: <https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PPRI_Pharma_Brief_AT_2019_April2020_1.pdf>) Key technical terms are defined in the glossary in Annex 3.

General and economic data

|  |  |
| --- | --- |
| **Population** (year)  |  million  |
| **Country size** (year)  |  km2  |
| **Gross domestic product** / GDP (year)  | GDP per capita: USD PPP k  |
| **Health expenditure** / HE (year)  | HE per capita: € USD PPP \_\_\_\_\_HE in % of GDP: %Public HE as % of total HE: % |
| **Pharmaceutical expenditure** / PE (year)  | PE per capita: €  USD PPP 63 4 PE in % of HE: % Public PE as % of total PE: %  |

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: a

Provision of pharmaceuticals

|  |  |
| --- | --- |
| **Community pharmacies** (DD.MM.YY)  | Number of community pharmacies |
| **Dispensing doctors** (DD.MM.YY)  | Number of dispensing doctors |
| **Wholesale** (year)  | Number of wholesale companies:Number of outlets (if available): |
| **Pharmaceutical industry** | Number of companies, thereof how many research-based companies |

Sources: a

Pharmaceutical market

|  |  |
| --- | --- |
| **Pharmaceutical market** (year) | €  |
| **Medicines** (year)  | xxx medicines authorised (counted including different pharmaceutical forms and dosages)xxx medicines (counted including different pharmaceutical forms and dosages) included in the outpatient reimbursement list (month, year) |
| **Generic market shares** (year)  |  % in value (reimbursement segment) % in volume (reimbursement segment) |

Sources: a

Pharmaceutical pricing (2021)

|  |  |
| --- | --- |
| **Price regulation**  | In place? If yes, for which medicines (e.g. reimbursable) and in which sectors (outpatient/inpatient)? |
| **Pricing authorities** | **Outpatient**: Which authority is responsible?**Inpatient**: Which authority is responsible? |
| Key pricing policies | **External price referencing**: In place? If in place, for which medicines (e.g. reimbursable) and in which sectors (outpatient/inpatient)?**Value-based pricing**: In place?**Price negotiations**: Are they performed? If yes, for which medicines (e.g. reimbursable) and in which sectors (outpatient/inpatient)?**Managed-entry agreements**: In place? If yes, for which medicines (e.g. high-priced medicines) and in which sectors (outpatient/inpatient)? What type of MEA (financial based, outcome based, etc.)?**Tendering**: If in place, for which medicines (e.g. reimbursable) and in which sectors (outpatient/inpatient)?**Cost-plus pricing**: In place? If in place, for which medicines (e.g. reimbursable) and in which sectors (outpatient/inpatient)?**Generic price link**: If In place? If in place, for which medicines (e.g. reimbursable) and in which sectors (outpatient/inpatient)?**Biosimilar price link**: If In place? If in place, for which medicines (e.g. reimbursable) and in which sectors (outpatient/inpatient)? |
| **Pricing in the supply chain** | Wholesale: Is wholesale remuneration regulated, and if yes, for which medicines and sectors, and how (e.g. regressive mark-up scheme)?Pharmacy: Is pharmacy remuneration regulated, and if yes, for which medicines and sectors, and how (e.g. regressive mark-up scheme, dispensing fee)?Value-added tax: % for medicines (and standard VAT) |

Source: a

Pharmaceutical reimbursement (2021)

|  |  |
| --- | --- |
| **Reimbursement authorities** | **Outpatient:** which authority is in charge?**Inpatient:** which authority is in charge? |
| **Reimbursement lists**  | **Outpatient:** e.g. positive list / negative list**Inpatient:** e.g. hospital pharmaceutical formularies |
| Reimbursement criteria | Outpatient: reimbursement decision is based on which criteria? (e.g. pharmacological, medical-therapeutic, health-economic evaluations, etc.)**Inpatient:** reimbursement decision is based on which criteria? (e.g. health technology assessment?) |
| **Co-payments for medicines** | **Outpatient:** e.g. prescription fee, percentage co-payments, deductible**Inpatient:** In place? |
| **Demand-side measures** to enhance the uptake of off-patent medicines | **Reference price system:** In place?**Prescribing by International Non-Proprietary Name (INN):** mandatory/allowed/not allowed?**Generic substitution:** mandatory/allowed/not allowed? |

Source: a

Key technical terms are defined in the glossary in Annex 3.

**Abbreviations** – Guide for authors:

The PPRI Pharma Brief does not include a list of abbreviations. The abbreviations are thus to be written in full the first time when they are mentioned – in the “Key data at the glance” chapter, the “Executive Summary” and the main body of the text (thus, up to three times). If possible, avoid the use of abbreviations at all in the Executive Summary.

Exception: In case of tables and figures, abbreviations may also be explained below in the notes.

Summary

On maximum 1-2 pages, this section summarizes the key information on the pharmaceutical system presented in this PPRI Pharma Brief.

Please list the entities responsible for the overall regulatory framework; those responsible for pricing of medicines and deciding on the inclusion of medicines into the reimbursement lists.

Please state whether, or not, price regulation is in place and which policies (e.g. external price referencing, price link policy) are applied in the outpatient and inpatient sectors. Inform, if applicable, about the application of managed-entry agreements (MEA) in the outpatient / inpatient sectors, and the type of MEA (e.g. outcome-based, financial-based etc.).

Briefly explain whether, or not, wholesale and pharmacy remuneration is regulated and, if applicable, what schemes (e.g. regressive mark-up system) are in place? What is the value-added tax on medicines, compared to the standard rate?

Describe in a paragraph the design of the reimbursement system: inform on the existence of positive/negative lists (outpatient/inpatient sectors) and the criteria for inclusion into reimbursement. Briefly state the percentage rate(s) for reimbursed medicines (outpatient/inpatient sectors). In addition, state what co-payments are applied for patients (e.g. prescription fee, percentage co-payment or deductible).

Inform about key demand-side measures to enhance the uptake of generic or biosimilar medicines (e.g. prescribing by International Non-Proprietary Name, generic / biosimilar substitution).

The summary may conclude by a brief summary of on-going and planned developments.

Keywords

Pricing, reimbursement, pharmaceutical policies, pharmaceutical system, country

Summary in local language

Provide here a translation of the English summary in your national language(s).

Graphical summary

Kindly provide a graphical overview chart of the pricing and reimbursement system in your country. Consult the PPRI website at <https://ppri.goeg.at/methodology_documents> for Poster Templates.

# **Framework**

This section covers the pharmaceutical policy framework from a legal and institutional perspective. Information refers to the year 2021, unless indicated differently. Please write full coherent sentences and delete the questions afterwards. The final PPRI Pharma Brief should not be more than 20-30 pages in total (incl. executive summary, annexes, etc.).

Please list the key legal documents (laws, decrees, further regulations) of pharmaceutical policy, in particular related to pricing and reimbursement in your country.

Introduce the key competent authorities in the field: for marketing authorisation and pharmacovigilance as well as for pricing and reimbursement.

Comment on possible differences between the outpatient and inpatient sectors.

Relevant work (and assessment criteria) of an HTA institution shall be described in the relevant sections of pricing, or reimbursement, respectively. If applicable for both pricing and reimbursement, the assessment of medicines can also be presented in this introductory section.

# **Pricing**

This section describes pricing at manufacturer price level, procurement, and pricing in the supply chain. Information refers to the year 2021, unless indicated differently.

Pricing at manufacturer price level

Kindly present major pricing policies at the manufacturer price level (ex-factory), or, if applicable, at wholesale price level (in case that you set medicines prices at the wholesale level). List the key policies, and indicate for which types of medicines (e.g. reimbursable medicines, prescription-only medicines, originator medicines) and in which sectors (inpatient / outpatient) they apply.

External price referencing: State if it is applied, and if yes, for which medicines and in which sectors. Provide further information on specificities: reference countries, required minimum number of countries with available price data, calculation method for the reference price (e.g. average price), data sources, frequency of update. If applicable, state the committee/authority that is tasked to determine the benchmark price and describe its composition (e.g. which actors/stakeholders). Comment on the relevance of external price referencing: Does the determined price serve as a basis for further negotiations on the reimbursement price of the medicine? Are the prices in other countries one criterion among others in the pricing procedure, or is external price referencing the key policy?

Briefly state if managed-entry agreements (MEA) may be concluded (details about MEA will be covered at a later section – see “Agreements”).

Does your country have a price link policy for “follower medicines” (generics and biosimilar medicines) in place, and if yes, for which medicines and in which sectors? How much is the percentage price reduction for follower medicines (generics and biosimilars) and the originator medicine / reference medicine which went off-patent? Are there different rates for the price reduction of the first generic / biosimilar medicine, second generic / biosimilar medicine, third generic / biosimilar medicine, etc.

Comment on the use of further pricing policies, e.g. value-based pricing or cost-plus pricing, if applicable.

List which medicines and in which sectors are not covered by government pricing policies, so that marketing authorisation holders apply free pricing.

**Procurement**

Inform if hospitals carry out their own procurement or if a group of hospitals performs joint procurement? Is there a national / regional procurement agency in your country? How often does procurement take place?

Describe the procurement process for medicines used in the inpatient setting. Is there centralised procurement for defined medicines (mandatory / voluntary)? If yes, present briefly the national procurement agency and their major procedures applied (e.g. framework agreements, dynamic purchasing system, open procedure)? Which are the most relevant criteria for deciding if a medicine will be purchased (price as sole award criterion or any other criteria)?

For direct procurements at hospital level, briefly describe the process. What is the role of the hospital pharmacists in procurement, and how are their coordination with procurement units?

Describe the main purchasing policies (tendering, negotiations, etc.) used in the inpatient sector. Under which conditions and for which medicines are they applied? Which legal provisions on national and EU level need to be complied with?

State if there are further purchasing policies (besides tendering and negotiations) that play a role in the inpatient sector? What are the legal provisions for them? Who is involved and which are the most relevant criteria for decision-making?

Pricing in the supply chain

Is the wholesale/pharmacy remuneration regulated, and if yes, for which medicines (e.g. reimbursable medicines). Is it only valid for the outpatient sector, or also for the inpatient sector?

Which remuneration type (e.g. linear mark-up, regressive margin scheme, dispensing fee, fee-for-service) is applied to remunerate pharmaceutical wholesale and community pharmacies?

What is the value-added tax (VAT) on medicines, and what is it to the standard VAT?

If applicable: Which price type does the hospital price correspond to (ex-factory, pharmacy purchasing price, pharmacy retail price)? Is there an official price calculation scheme for medicines used in hospitals? Are medicines sold to hospitals subject to VAT and at which rate?

# **Reimbursement**

This section describes the processes, including criteria, for reimbursement of outpatient and inpatient medicines. Sub-sections present agreements concluded the new high-priced medicines and demand-side measures to enhance the update of off-patent medicines. Information refers to the year 2021, unless indicated differently.

**Reimbursement for outpatient medicines**

Indicate the main third party payer for outpatient medicines, and mention the role of complementary insurance, if applicable. Is coverage by the state covered as “in-kind” service (no payment of patients), or do patients have to ask for refunding?

Indicate the reimbursement lists that are applied in the outpatient sector. Are they positive/negative list(s)? If so, are they also relevant for the inpatient sector?

Explain which authority is responsible for deciding whether or not a medicine is included in outpatient reimbursement. Which criteria is the decision based on? Can the marketing authorization holder appeal against the decision?

Describe the co-payments that (specific) patients have to pay for (defined) outpatient medicines (e.g. prescription fee, percentage co-payment, deductible). If applicable, kindly specify the amount of co-payment as of 2021. If applicable, indicate percentage rate(s) at which medicines are covered and explain the underlying reasons for the differences in percentage rates coverage.

Please identify if reductions or exemptions (100% coverage, exemption from prescription fee, lower deductible) are in place (what determines eligibility for reductions/exemptions: e.g. specific medicines / indications / population groups)? Is co-payment capped, e.g. if a certain percentage of the net annual family income is spent on co-payments?

**Reimbursement for inpatient medicines**

Describe major funding sources for inpatient medicines (e.g. NHS/ SHI, federal state, hospitals through their owners), and the type of reimbursement (e.g. product-specific reimbursement or as part of a diagnosis-related groups funding).

Specify if and which medicines used in hospitals are included in a national positive list (which is also applicable for the outpatient sector). Inform if hospitals have their own hospital pharmaceutical formulary (HPF)? If applicable, who decides on the inclusion of medicines in the HPF and on what criteria (e.g. therapeutic value, cost-effectiveness)? How many medicines are included in the HPF on average, if known?

Inform if a systematic Health Technology Assessment (HTA) process is applied in the inpatient sector.

Inform if patients have to co-pay for medicines in the inpatient sector? If yes, for which medicines and how much?

**Agreements**

Inform about the managed entry agreements (MEA) in place: how many MEA have been concluded in the outpatient and/or inpatient sectors? Which type of MEA are used (e.g. financially-based such as flat discounts or price-volume agreements or performance-based agreements such as coverage with evidence, pay-for-performance).

**Demand-side measures**

Inform if your country has a reference price system. If yes, how is the reference price calculated? (e.g. average price of all the medicines clustered, How are the medicines clustered? Who decides on clustering/setting the referencing prices and the inclusion of medicines in the reference price system?

Inform if prescribing by Non-Proprietary Name (INN prescribing) is in place, and if yes, on a voluntary or obligatory basis? For which medicines (e.g. specific medicines such as biologicals excluded)?

Indicate whether, or not, generic substitution is in place, and if yes, on a voluntary or obligatory basis? Are any medicines excluded? Inform whether, or not, biosimilar substitution is in place, and if yes, on a voluntary or obligatory basis.

# **Developments**

This section describes the information on the current plans and foreseen developments in the pharmaceutical sector in the months to come in 2021 and beyond.

Briefly explain the most important changes in recent times in the outpatient and inpatient sectors. Which reforms related to pharmaceutical policy are in an implementation phase and which are being discussed?

# References

# Annex

Annex 1: Stakeholders (please complete)

|  |  |  |
| --- | --- | --- |
| Role | Name in local language (language) | Website(s) |
| Competent authority for marketing authorisation of medicines |  |  |
| Competent authority for pricing of medicines |  |  |
| Competent authority for reimbursement of medicines (outpatient) |  |  |
| Public payer(s) for outpatient medicines |  |  |
| Public payers for inpatient medicines |  |  |
| Patients organisations |  |  |
| Consumers organisations |  |  |
| Pharmacy associations |  |  |
| Industry associations |  |  |
| Wholesale association |  |  |

Source:

Annex 2: Regulation of wholesale and pharmacy remuneration (year) – optional

Annex 3: Glossary

We prefilled some terms. If you want to include more, kindly take the definitions from the “Glossary of Pharmaceutical Terms” available at: <https://ppri.goeg.at/ppri-glossary>.

|  |  |
| --- | --- |
| claw-back | A policy where funds already paid by public payers to pharmaceutical companies, wholesalers or pharmacists have to be paid back to the third party payers under certain conditions (e.g. if a certain threshold is exceeded). |
| 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 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’. |
| discount | A price reduction granted to specified purchasers under specific conditions prior to purchase. |
| dispensing fee | A fixed fee that pharmacies are allowed to charge per prescribed item instead of or in addition to a percentage mark-up. |
| 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. |
| free pricing | Pricing policy, in which governments allow pharmaceutical companies to determine the price of the medicine they launch. |
| 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). |
| price negotiation | A pricing procedure, in which medicine prices are discussed and agreed (e.g. between manufacturer and third party payer). |
| price regulation (price control) | Pricing policies where government authorities set the price of a medicine and/or indirectly influence it (e.g. statutory pricing, price negotiations, public procurement). |
| 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