PPRI Medical Devices Brief:
Country 2022 - Template

PPRI Medical Devices Briefs Series

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

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Country 2022

Template

PPRI Medical Devices Briefs Series

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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 the PPRI Medical Devices Briefs

This Brief presents the pricing and reimbursement policy framework for medical devices in country. It was produced as part of the activities of the PPRI subgroup on medical devices. The PPRI Medical Devices Briefs Series complements the medicines-related series of the PPRI Pharma Briefs launched in 2019 and [**PPRI Posters**](https://ppri.goeg.at/ppri_posters) on medicines and medical devices.

**PPRI network**

The Pharmaceutical Pricing and Reimbursement Information (PPRI) network is a collaboration of **pharmaceutical pricing and reimbursement authorities** of approximately 50 - mostly European - countries as well as international and European institutions (e.g. European Commission, OECD, World Health Organization). The aim of PPRI is to support the participating public institutions by facilitating exchange between their experts, providing scientific evidence, and developing a common understanding of health and pharmaceutical policy issues. The network is coordinated by the PPRI Secretariat which is hosted at the Pharmacoeconomics Department of the Austrian National Public Health Institute (Gesundheit Österreich / GÖG).

PPRI contributes to the international scientific evidence base in the areas of (comparative) health **systems research** and **policy analysis** related to medicines and further health products, by providing country information that is usually not published in the literature. This information supports policy-makers who want to benchmark their own work and learn about policies and experiences in other countries, and is used by researchers who perform policy analyses and require contextual information on national policy frameworks for pricing and reimbursement of health products.

**PPRI Subgroup on Medial Devices**

At request of PPRI network members, a Subgroup on Medical Devices (PPRI MD) was established in 2017. PPRI MD is focused on **exchanging information on pricing and reimbursement policies for medical devices** with a view to increasing transparency in the field.

Over the last 20 years, PPRI has developed a range of tools, including a glossary, a set of indicators for pharmaceutical system comparison, and templates for reporting country policy information. In PPRI MD, these tools are being gradually adapted to the specificities of medical devices, such as the high heterogeneity of products.

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

Provide any **specifications** (e.g. if the data only relate to a specific sub-group, which components are, for instance, included in expenditure data on medical devices, and if the data relate to the outpatient, inpatient or both sectors or the public, private or both sectors).

General and economic data

|  |  |
| --- | --- |
| **Population** (year)  |  million  |
| **Country size** (year)  |  km2  |
| **Gross domestic product** / GDP (year)  | GDP per capita: € PPP and/or USD PPP k  |
| **Health expenditure** / HE (year)  | HE per capita: € and/or USD PPP \_\_\_\_\_HE in % of GDP: %Public HE as % of total HE: % |
| **Expenditure on medical devices** / MD expenditure (year)  | MD expenditure per capita: €  and/or USD PPP  MD expenditure in % of HE: % Public MD expenditure as % of total PE: %  |

GDP = gross domestic product, HE = health expenditure, MD = medical devices, PPP = Purchasing Power Parties,

USD = United States dollars
Indicate specifications: e.g. data relate to the outpatient sector only or to the public sector only

Sources: a

Medical devices market

|  |  |
| --- | --- |
| **Medical devices market in value** (year) | € Indicate sub-markets (e.g. implantable MD) if applicable.If known, indicate the price level (e.g. ex-factory price, retail price) to which the market data refer. |
| **Number of medical devices on the market** (year)  | xxx medical devices on the country’s marketIndicate also the number for sub-markets (e.g. implantable MD) if applicable |
| **Number of suppliers of medical devices** (year)  | Number of companiesAny specifications |

Indicate specifications, e.g. if the data also include IVD

Sources: a

Pricing policies for medical devices (2022)

|  |  |
| --- | --- |
| **Price regulation**  | Is it applied? If yes, for which medical devices (MD) (e.g. MD of specific classes, reimbursable MD) and in which sectors (outpatient/inpatient)? |
| **Pricing authorities** | **Outpatient**: Which authority is responsible to set the price (if applicable)?**Inpatient**: Which authority is responsible to set the price (if applicable)? |
| Key pricing policies | **External price referencing**: In place? If yes, for which MD (e.g. MD of specific classes, reimbursable MD) and in which sectors (outpatient/inpatient)?**Internal price referencing**: In place? If yes, for which MD (e.g. MD of specific classes, reimbursable MD) and in which sectors (outpatient/inpatient)?**Value-based pricing**: In place?**Price negotiations**: Are they performed? If yes, for which MD (e.g. MD of specific classes, reimbursable MD) and in which sectors (outpatient/inpatient)?**Tendering and further procurement policies**: If in place, for which MD (e.g. MD of specific classes, reimbursable MD) and in which sectors (outpatient/inpatient)?**Any other pricing policy:** Any other pricing policy in place, for which medical devices (e.g. MD of specific classes, reimbursable MD) and in which sectors (outpatient/inpatient)? |
| **Pricing in the supply chain** | Wholesale / further distributors: Is remuneration for wholesale and any further distributors regulated, and if yes, for which MD and sectors, and how (e.g. regressive mark-up scheme)?Pharmacy / retailer: Is the retail remuneration regulated, and if yes, for which MD and sectors, and how (e.g. regressive mark-up scheme, dispensing fee)?Value-added tax: % for MD (and standard VAT and VAT for medicines) |

Source: a

Reimbursement policies for medical devices (2022)

|  |  |
| --- | --- |
| **Reimbursement authorities** | **Outpatient:** Which authority is responsible to decide on reimbursement (if applicable)?**Inpatient:** Which authority is responsible to decide on reimbursement (if appl.)?**HTA body:** Is there a specific HTA body to support the (outpatient/inpatient) reimbursement authority? |
| **Reimbursement lists**  | **Outpatient:** e.g. positive list / negative list**Inpatient:** e.g. hospital pharmaceutical formulary |
| HTA and reimbursement criteria | Outpatient: On which criteria is the reimbursement decision based (e.g. pharmacological, medical/therapeutic or health-economic evaluations)? Is there mandatory use of health technology assessment (HTA) for defined MD, e.g. for specific risk classes?Inpatient: On which criteria is the reimbursement decision based? Is there a mandatory use of HTA for defined MD, e.g. for specific risk classes? |
| **Co-payments for reimbursable medical devices** | **Outpatient:** e.g. prescription fee, percentage co-payments, deductible**Inpatient:** Do patient co-payment apply for reimbursable MD used in hospitals? |

Source: a

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

**Abbreviations** – Guide for authors:

The PPRI MD 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 use of abbreviations in the Executive Summary.

Exception: In case of tables and figures, abbreviations should be explained in the notes below (but not necessarily for the two tables on pricing / reimbursement policies in this “Key data at a glance” section.

Summary

At maximum 1-2 pages. This chapter summarises the key information on the pricing and reimbursement policy framework for medical devices presented in this PPRI MD Brief.

**Keywords**

Pricing, reimbursement, policies for medical devices, country

Please use “Summary” in local language as heading

Provide a translation of the English summary, including the keywords, in your national language(s).

**Keywords**:

Graphical summary

Kindly provide a visual overview (e.g. flowchart) of the policy framework for a MD in your country.

See an example of a graphical summary here: <https://ppri.goeg.at/system/files/inline-files/PPRI_MP_Brief_FR_final%20-%20Monika_barrierefrei.pdf> (page 5)



# **Framework**

This section covers the policy framework from a legal and institutional perspective. Information refers to the year 2022, unless indicated otherwise. Please write full coherent sentences and delete the instructions below when the text is ready. The final PPRI MD Brief should not be longer than 20 pages in total (incl. executive summary, annexes, etc.), with the main body of the text comprising around 5 pages.

Provide the national legal definition for medical devices and describe briefly the legal framework (list key legal provisions).

Introduce key competent authorities in the field: authorities to regulate / be notified about market entry, medical device vigilance, market surveillance as well as institutions related to HTA, CE marks, pricing and reimbursement.

Comment on possible differences between the outpatient and inpatient sectors.

*Kindly note:* The work (including assessment criteria) of the HTA institution(s) shall be described in the respective sections of pricing and reimbursement. If applicable for both pricing and reimbursement, the assessment of MD can also be presented in this introductory section.

# **Pricing**

This section describes pricing of medical devices, first in the outpatient and then in the inpatient sector. Information refers to the year 2022, unless indicated differently. If there are differences for different types / groups / classes of MD, kindly specify accordingly. If needed, you may change the order and place the reimbursement chapter before pricing.

Pricing in the outpatient sector

Explain if prices of MD used in the outpatient sector are regulated. If yes, for which types of MD (e.g. different groups / (risk) classes / reimbursable vs. non-reimbursable MD)?

Are pricing decisions for MD based on prior HTA? If yes, under which conditions?

Briefly describe the HTA process for MD. Kindly elaborate which dimensions (effectiveness, safety, budget impact) are covered, and which criteria / indicators are applied.

Which price type(s) (e.g. ex-factory price, wholesale price, retail price, reimbursement price) of MD used in the outpatient sector are price-regulated?

Which pricing policies are applied for (which) MD used in the outpatient sector? Describe the most common ones, e.g. external price referencing, internal price referencing, value-based pricing, tendering and other procurement policies and cost-plus pricing. Kindly comment on possible specifications (e.g. only applicable for certain MD).

Which criteria (e.g. added therapeutic value, cost-effectiveness) are applied for pricing outpatient MD? Under which conditions may a higher price be granted?

Are wholesale / distributor and retail mark-ups / margins regulated for outpatient MD? (How) are community pharmacies remunerated for supplying diagnostic tests or other MD?

Are sales taxes, e.g. VAT, charged on MD? Any lower rate and exemptions? for specific MD?

Pricing in the inpatient sector

Explain if prices of MD used in the inpatient sector are regulated. If yes, for which types of MD (e.g. different groups / (risk) classes / reimbursable vs. non-reimbursable MD)? Is the same procedure applied as for outpatient MD?

Kindly inform whether, or not, the following pricing policies are applied for inpatient MD: external price referencing, internal price referencing, value-based pricing, tendering / further procurement policies and cost-plus pricing. Kindly comment on possible specifications (e.g. only applicable for certain MD).

What role does procurement play for MD used in the inpatient sector? Inform if hospitals carry out their own procurement or if a group of hospitals performs joint procurement? Is procurement done at regional and/or central levels, and if yes, for which MD? In case of centralised procurement for (defined) MD, is it mandatory or voluntary? In case of cross-country joint procurement for some MD (such as under the Joint Procurement Agreement (JPA) of the European Commission), could you mention it as well.

Describe the main purchasing policies (open procedure, negotiations, framework agreements, ...) used in the inpatient sector.

Describe the procurement process. Who is involved, and how (advisory functions and decision-taking role)? Which are the most relevant criteria for deciding whether, or not, a MD will be procured (price as sole criterion or any other criteria)? What is the role of hospital pharmacists in procurement, and how do they coordinate with procurement units at hospital level, or with a central procurement agency?

Which role does HTA play for decisions on prices of MD used in hospitals and for procurement decisions?

Inform which price types are price-regulated / targeted by procurement for MD used in hospitals (only the ex-factory price and/or tender price?). Are wholesale / distributor or pharmacy / retail mark-ups / margins applied for MD used in hospitals, and if yes, are they price-regulated?

Are sales taxes, e.g. VAT, charged on MD used in hospitals?

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# **Reimbursement**

This section describes the processes, including criteria, for reimbursement of outpatient and inpatient MD. Information refers to the year 2022, unless indicated otherwise. The chapter includes two sections (heading in bold), feel free to include further sub-chapters (e.g. on Health Technology Assessment, specific funding schemes, co-payments), if needed (with headings in italic).

Reimbursement for outpatient medical devices

Are MD used in the outpatient sector reimbursed? Which types / groups / classes of MD are reimbursed?

Does reimbursement/funding relate solely on the MD itself (individual product-specific reimbursement) or is it part of the provider’s remuneration for to the application of the service?

How (i.e. through which reimbursement / funding mechanisms, such as fee-for-service, pay-for-performance, product-based funding?) are MD funded in the outpatient setting, or how is their service / application remunerated? If applicable: How is the remuneration of those health care providers (e.g. general practitioners or community pharmacists) for point-of-care testing (e.g. separate funding for the service/fee-for-service, capitation fee, fixed salary)?

Are funding (reimbursement) decisions for MD based on prior Health Technology Assessment (HTA)? If yes, under which conditions and for which MD?

Describe the (decision) processes regarding the inclusion of MD into reimbursement and involved institutions. If there are different procedures for different MD, kindly describe the most common ones.

Consider in particular the following issues:

Are there reimbursement lists? If yes, are these positive or negative lists? Which MD are included in these lists? Do these lists only address the outpatient sector or also the inpatient sector? How many MD are included? Are the reimbursement lists publicly accessible? If so, kindly provide the link.

Who decides on the inclusion of MD into the reimbursement list(s) and other funding systems (e.g. performance-based funding), and on which criteria?

Which MD / services applying MD are not reimbursed by the public payer, so that patients have to fully pay out-of-pocket for purchasing / applying these MD?

Are there any co-payments for outpatients using reimbursable MD? (e.g. a prescription fee, percentage co-payments per product or service, a deductible). If yes, how high is the co-payment for different MD (in the year 2022)? Think of a practical example: If a rapid diagnostic test is provided at a GP’s practice to determine whether, or not, an antibiotic is indicated, who pays for this test, and how is it supplied to the GP (e.g. patients first purchasing it in a pharmacy and bringing it to the GP)?

Are there reduced co-payments (for defined MD, for certain patient groups)? Are there exemptions from co-payments?

Reimbursement for inpatient medical devices

Describe major funding sources for inpatient MD (e.g. National Health Service/ Social Health Insurance, federal state, hospitals through their owners), and the type of reimbursement. E.g. are all MD included in the diagnosis-related groups (DRG) funding of hospitals and is there (also) product-specific reimbursement for some MD?

Specify if and which MD used in hospitals are included in a national positive list (which is also applicable for the outpatient sector). Inform if hospitals have (additionally?) their own formularies for MD, similar to a hospital pharmaceutical formulary? If applicable, who decides on the inclusion of MD in such formularies and on what criteria (e.g. (added) therapeutic benefit, cost-effectiveness)?

Inform whether, or not, a systematic HTA process is applied in the inpatient sector. Is this process done at a central level (for MD for both outpatient and inpatient use)? Do hospitals (or hospital (purchasing) groups and/or regions) do their own HTA or other type of assessments?

Inform if patients have to co-pay for MD in the inpatient sector? If yes, for which MD or which procedures (in which MD or IVD are used) and how much? Are there any exemptions?

Have specific agreements (e.g. asking for discounts, capping, pay-for-performance), similar to the managed-entry agreements for medicines, been negotiated for some MD? If yes, for which (types of) MD? By whom (procuring hospitals, regions, central procurement body, public payer)?

Optional: Are early access schemes in place for MD? Is Early Scientific Advice offered?

# **Developments**

This section describes the information on recent and planned developments in the policy framework and market for medical devices during 2022 and beyond. Briefly explain the most important changes in recent times in the outpatient and inpatient sectors. Which reforms related to policies are in an implementation phase, and which are being discussed?

# References

Kindly use a homogenous reference (output) style (e.g. Vancouver)

# Annex

Glossary

|  |  |
| --- | --- |
| Authority | Government entity responsible for designing the regulatory framework and implementing policies (e.g. ministry, public agency). In the European context the term “competent authority” is frequently used. |
| Benefit catalogue / benefit package | A scheme which includes all goods and services provided by the health system and funded by a third party payer (such as a health insurance or the National Health Service). Co-payments are possible. A reimbursement list for medicines or medical devices is one example of (an element of) a benefit catalogue. |
| CE marking / CE marking of conformity | A marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the EU Regulation 2017/745 or EU Regulation 2017/746 and other applicable Union harmonisation legislation providing for its affixing. |
| 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. |
| Coverage | A measure of the extent to which the services rendered cover the potential need for those services in the community. |
| Diagnosis related groups (DRG) | A classification system of hospital cases used to pay hospital services, regardless of the cost to the hospital to provide services. The system is based not on the severity of the disease but on the amount of resources consumed. |
| Ex-factory price (manufacturer price) | The price at the level of industry, charged by a supplier; official ex-factory prices can be lowered by discounts or other arrangements offered by supplier (actual price). |
| External price referencing (EPR) | The practice of using the price(s) of a medical device or 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. Synonym: International price comparison (IPR), external reference pricing (ERP) |
| Free pricing | Pricing policy, in which governments allow medical devices companies to determine the price of the device they launch. |
| Funding | Funding is the act of providing resources to finance a good or commodity, a service, program, or project (in this case, a medical device). |
| Generic device group | A set of medical devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics. |
| Health technology assessment (HTA) | A multi-disciplinary 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. |
| Inpatient sector | Mainly hospitals and also in nursing and residential care facilities. |
| Internal price referencing | The practice of using the price(s) of similar medical devices (same category) with other medical devices in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country. |
| Margin | The percentage of the selling price that is profit. |
| Mark-up | The percentage of the purchasing price added on to get the selling price. A mark-up is added on to the total cost incurred by the producer of a good in order to create a profit. |
| Negative list | List of medical devices that cannot be prescribed at the expense of a third party payer. |
| Notified body | A conformity assessment body designated in accordance with EU Regulation 2017/745 or EU Regulation 2017/746. |
| Out-of-pocket payments | The expenses of a person for medical care, medicines and medical devices that are not covered by reimbursement of a third party payer – often for a defined period (e.g. a year).It includes expenses for non-reimbursable medical devices and any form of co-payment, e.g. prescription fee, percentage co-payment, deductible |
| Outpatient sector | The type of the health care setting in which ambulatory care is provided, in contrast to the hospital (inpatient) sector. |
| Performance | The ability of a medical device to achieve its intended purpose as stated by the supplier. |
| Placing on the market | The first making available of a medical device (other than an investigational device) in a national market. |
| Positive list | List of medical devices that may be prescribed at the expense of a third party payer. It is one form of a reimbursement list. |
| Price control (price regulation) | Action by a government authority to set the price of a medicine / medical device and/or indirectly influence it (e.g. through pricing policies) for different price types (e.g. ex-factory price, retail price) and to monitor and review and eventually adapt it. |
| Price negotiation | A pricing procedure, in which prices (of medical devices) are discussed and agreed (e.g. between supplier and third party payer). |
| Price type | The level (i.e. stage in the supply chain) at which the price of a medical device is set. Common price types include: ex-factory price, purchasing price at medical supply distributor and retail price. |
| Pricing (pricesetting) | Act of setting the price which is either taken by a medical device company (free pricing) or is the competence (responsibility) of a competent authority (price control). |
| Pricing policies | Regulations and actions taken by government authorities to set the price of a medical device as part of exercising price control. Strategies by private sector actors (e.g. medical devices industry and supply chain actors) to determine and set a price of a medical device are not subsumed under the term “policy”. |
| Procurement | A process to purchase goods and services (e.g. medical devices) that involves many steps and many stakeholders based on national, or supranational, regulation, policies, structures and procedures. |
| Reimbursablemedical device | Medical devices which are eligible for reimbursement. Costs of reimbursable medical devices 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 medical devices with regard to their reimbursement status. They may either include medical devices eligible for reimbursement (positive list) or those explicitly excluded from reimbursement (negative list). Reimbursement lists may target either the outpatient sector (usually positive lists or negative lists) or the inpatient sector (typically called hospital formulary), or both. |
| Reimbursement process | Decision-making procedure on the reimbursement status, reimbursement price and the reimbursement rate of medical devices that involves the roles and the composition of the responsible bodies and committees, the application process, the decision-making itself, the information process around the decision and the arbitration process after the decision. The outcome of the process is the decision whether or not the medical device will be included in reimbursement lists, and at which cost. |
| 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-added tax | A sales tax on products collected in stages by enterprises. |

Source: PPRI MD Glossary (in development)

**Any other heading for the Annex (optional)**