

WHO Fair Pricing Forum 2024

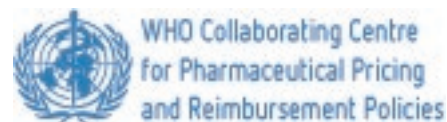
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Slide set reviewed by: Nina Zimmermann

Parallel Session 5: Advancing accessibility and affordability of medical devices
and in vitro diagnostics by bridging the information gap and complexity

7 February 2024, UTC 13.00-14.30



What is the PPRI network? (<https://ppri.goeg.at/>)

PPRI = Pharmaceutical Pricing and Reimbursement Information

PPRI network



- A **collaboration** of pharmaceutical pricing and reimbursement authorities
- **50** mostly European countries and European/international institutions
- **Aim:** to facilitate information exchange between public officials (including personal networking meetings), supported by scientific evidence and a common understanding of pharmaceutical policy issues

PPRI MD network



- In 2018, a **subgroup on medical devices** was established including public authorities dealing with medical devices
- **30** countries and European and international institutions
- **Aim:** to exchange information on pricing and reimbursement policies of medical devices and **to increase transparency in the field**

PPRI tools to increase transparency on accessibility and affordability of medical devices (including diagnostics)

Aim: Exchange information and knowledge on pricing and reimbursement of medical devices and diagnostics



Connect and meet
Network meetings/webinars



Annual network meetings
Webinars (e.g., on the German Digital Health Care Act (DVG) and apps on prescription – *information not publicly available*)



Understand each other
Definitions, glossary



Link: Medical Devices Glossary (German/English)
217 abbreviations, 751 technical terms, 140 symbols



Exchange of information
PPRI website/intranet
(country briefs, network queries)



Link: PPRI MD Country Briefs (France, Sweden)
Network queries (e.g., pricing and reimbursement of insulin pumps, hearing aids, pacemaker, remote patient monitoring systems – *information not publicly available*)

increase transparency

PPRI Secretariat: Austrian National Public Health Institute (ppri@goeg.at)

Pricing and reimbursement of medical devices

Key points

- **Different policies** for pricing and reimbursement are applied for different types of medical devices and across countries → diverse picture
- **Price regulations**
 - Few price regulations in the outpatient sector (only few public price lists are available)
 - Bilateral price control policies are in place (public procurement, price negotiations etc.) → often confidential
- **Different price components:** product (e.g. instrument, implant, software, reagent for in vitro use) and service (e.g. conducting a test) and maintenance of equipment (e.g. calibration)

Conclusions

- **Further research is needed** to understand specific pricing and reimbursement policies for specific groups of medical devices → measures to improve accessibility and affordability of medical devices
- Price comparisons of medical devices are currently difficult to conduct due to the different product names and nomenclatures used → European Medical Devices Nomenclature (EMDN)

European Medical Device Nomenclature (EMDN)

Website: <https://webgate.ec.europa.eu/dyna2/emdn/>

Download of full list (Excel file) is possible!

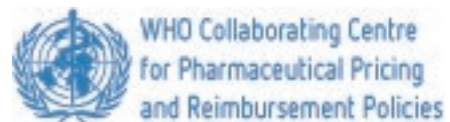
The screenshot shows the EMDN website interface. At the top, there is the European Commission logo and a search bar. Below that, the title "European Medical Device Nomenclature (EMDN)" is displayed. A text box explains that the page shows the most up-to-date version (1.1) and provides a link to download the full list. It also mentions that the platform is a submission platform for linguistic and syntax feedback. A section titled "1. What is the European Medical Device Nomenclature (EMDN)?" provides background information on the regulation and the purpose of the EMDN. At the bottom, there is a search function for EMDN term descriptions, with a search input field and a list of categories including Gastrointestinal Devices, Suture Devices, Active-Implantable Devices, and Endotherapy and Electrosurgical Devices.

- ⊞ A - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
- ⊞ B - HAEMATOLOGY AND HAEMOTRANSFUSION DEVICES
- ⊞ C - CARDIOCIRCULATORY SYSTEM DEVICES
- ⊞ D - DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES
- ⊞ F - DIALYSIS DEVICES
- ⊞ G - GASTROINTESTINAL DEVICES
- ⊞ H - SUTURE DEVICES
- ⊞ J - ACTIVE-IMPLANTABLE DEVICES
- ⊞ K - ENDOTHERAPY AND ELECTROSURGICAL DEVICES
- ⊞ L - REUSABLE SURGICAL INSTRUMENTS
- ⊞ M - DEVICES FOR GENERAL AND SPECIALIST DRESSINGS
- ⊞ N - NERVOUS AND MEDULLARY SYSTEMS DEVICES
- ⊞ P - IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES
- ⊞ Q - DENTAL, OPHTHALMOLOGIC AND ENT DEVICES
- ⊞ R - RESPIRATORY AND ANAESTHESIA DEVICES
- ⊞ S - STERILISATION DEVICES (EXCLUDING CAT. D - Z)
- ⊞ T - PATIENT PROTECTIVE EQUIPMENT AND INCONTINENCE AIDS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)
- ⊞ U - DEVICES FOR UROGENITAL SYSTEM
- ⊞ V - VARIOUS MEDICAL DEVICES
- ⊞ W - IN VITRO DIAGNOSTIC MEDICAL DEVICES
- ⊞ Y - DEVICES FOR PERSONS WITH DISABILITIES NOT INCLUDED IN OTHER CATEGORIES
- ⊞ Z - MEDICAL EQUIPMENT AND RELATED ACCESSORIES, SOFTWARE AND CONSUMABLES

- ⊞ A - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
 - ⊞ A01 - NEEDLES
 - ⊞ A0101 - NEEDLES FOR INFUSION AND SAMPLING
 - ⊞ A010101 - HYPODERMIC NEEDLES
 - ⊞ A01010101 - HYPODERMIC SYRINGE NEEDLES
 - ⊞ A0101010101 - HYPODERMIC SYRINGE NEEDLES, WITH SAFETY SYSTEMS
 - ⊞ A0101010102 - HYPODERMIC SYRINGE NEEDLES, W/O SAFETY SYSTEMS
 - ⊞ A01010102 - HYPODERMIC PEN NEEDLES
 - ⊞ A01010199 - HYPODERMIC NEEDLES - OTHER
 - ⊞ A010102 - BUTTERFLY NEEDLES
 - ⊞ A010103 - NEEDLES AND KITS FOR IMPLANTABLE SYSTEMS (PORT)
 - ⊞ A010104 - NEEDLES FOR VIAL COLLECTION
 - ⊞ A010105 - NEEDLES FOR COLLECTION UNDER VACUUM
 - ⊞ A010106 - NEEDLES AND KITS FOR RECONSTRUCTIVE FILLING
 - ⊞ A010180 - NEEDLES FOR INFUSION AND COLLECTION - ACCESSORIES
 - ⊞ A010199 - NEEDLES FOR INFUSION AND COLLECTION - OTHER
 - ⊞ A0102 - BIOPSY NEEDLES AND KITS
 - ⊞ A0103 - ANAESTHESIA NEEDLES AND KITS



Annex: Selected studies



Study supporting the monitoring of availability of medical devices on the EU market (EU4Health programme)

- **Duration:** 2 December 2022 – 1 December 2025 (36 months)
- **Aim:** To support monitoring and analyzing the availability of medical devices on the EU market in the context of the implementation of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices from the perspective of key stakeholders (e.g. notified bodies, manufacturers and authorized representatives of medical devices and in vitro diagnostic medical devices, health services providers, medical doctors and societies, patient representatives, competent authorities)
- **Study team:** Austrian National Public Health Institute, Areté, Civic Consulting (contact: medical.devices@goeg.at)
- **Dashboard:** Results are presented in aggregated form in a publicly available and regularly updated dashboard Available at: https://health.ec.europa.eu/study-supporting-monitoring-availability-medical-devices-eu-market_en

Monitoring the Availability of Medical Devices and In Vitro Diagnostic Medical Devices in the EU

Home About Process Indicators MDR Outcomes IVDR Outcomes Glossary/Links Contact/Help

Welcome to the dashboard
monitoring the availability of medical devices and in vitro diagnostic medical devices in the European Union

Medical devices (MDs) and in vitro diagnostic medical devices (IVDs) are essential for a working healthcare system and play a crucial role in the prevention, diagnosis, monitoring, prediction, prognosis and treatment of acute and chronic illnesses and diseases as well as rehabilitation. However, they require a strong regulatory framework to ensure safety and optimal performance.

Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) which replace the previous regulatory framework in the European Union (EU), aim to improve the safety, performance and effectiveness of medical devices as well as, strengthen transparency and provide information for patients while enhancing vigilance and market surveillance. In order to ensure a smooth transition from the previous regulatory framework, it is essential to regularly appraise the situation on the ground and gather concrete data on the activities currently performed by relevant stakeholders.

A study was commissioned by the European Commission (via its European Health and Digital Executive Agency / HaDEA) from *Gesundheit Österreich GmbH* (Austrian National Public Health Institute), *Civic Consulting* and *Areté* with the support of four regulatory experts to monitor the availability of medical devices on the EU market. Starting in December 2022 and lasting 36 months, the study aims to monitor and analyse the availability of medical devices on the EU market in the context of the implementation of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices. As part of the project, this dashboard was established.

The dashboard presents an overview of the data gathered from different stakeholders monitoring the availability of MDs and IVDs in the EU. In addition, comparable data from previous surveys of notified bodies conducted by the European Commission have been integrated in the dashboard and can be found on

MD Availability Dashboard 1.0

EURIPID - Feasibility study for the integration of medical devices into EURIPID

- EURIPID (The European Integrated Price Information Database) is a voluntary non-profit collaboration of the European pricing and reimbursement authorities for the mutual sharing of pricing information of medicinal products.
- The EURIPID Collaboration has considered including **medical devices** into the database. The feasibility study analysed whether or not **reimbursement and price lists for medical devices** exist in the EURIPID member countries and for which **price types**.
- Available at: https://euripid.eu/wp-content/uploads/2023/05/Feasibility-study-for-the-integration-of-MD-into-EURIPID_pricing-models_Publikation_bf.pdf
- Contact: euripid@goeg.at

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