#### **Newsletter Pharmacoeconomics**

#### Edition 01/2021





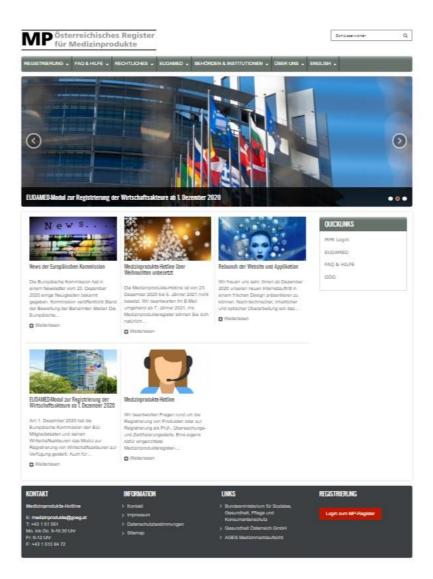


#### Re-launch of the Austrian Medical Devices Register

The Austrian Register for Medical Devices website was re-launched in December 2020. A comprehensive revision was done in technical set-up, contents and layout. The website is informative, up-to-date and responsive for all end devices.

Registration is obligatory for all persons and companies (manufacturers, importers, authorised representatives, sterilising companies, system(s) manufacturers) based in Austria and those responsible for placing medical devices (including in-vitro diagnostics and custom-made medical devices) on the market for the first time in the European Economic Area (and Switzerland) as well as for certifiers, testing laboratories and inspection bodies of medical devices based in Austria.

PPRI: https://ppri.goeg.at/



Read more: <u>https://medizinprodukteregister.at/</u>

### Mandatory discount and reimbursement information provided by the Pharma Price Information (PPI) service

Surveying pharmaceutical prices across countries is challenging and time-consuming. Our PPI Service offers fast, reliable and independent price information on medicine prices. We provide, upon request, up-to-date and comparable price information for single products and carry out comprehensive price comparisons customised for your individual requirements.

The PPI service covers all EU countries plus Norway, Switzerland and the UK.

Our service includes, as standard, information on the manufacturer price (ex -factory price), pharmacy purchasing price (wholesale price) and the pharmacy retail price, including and excluding VAT. We are proud to announce a valuable addition: The PPI service can also provide information on mandatory manufacturer discounts and the reimbursement status.

Contact ppi@goeg.at - we are pleased to discuss and prepare an offer.

More information: <u>https://goeg.at/Pharma\_Price\_Information</u>



### Pharma Price Information

The unique and comprehensive service for pharmaceutical prices in Europe

### Russian corner added to the website

Adding to the German and Spanish of the PPRI website that had been launched earlier in 2020, a Russian corner went live in autumn 2020. It offers information on pharmaceutical pricing and reimbursement policies and provides an overview of the activities of the Pharmacoeconomics Department, including their work with the PPRI EECA (Eastern Europe and Central Asian) network.

Read more: https://ppri.goeg.at/index.php/russian

# Start of the Actor registration module of the European Database of Medical Devices (EUDAMED)

The European Database of Medical Devices (EUDAMED) is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices. EUDAMED will provide a living picture of the lifecycle of medical devices that are made available in the European Union. It will integrate different electronic systems to collate and process information about medical devices and related companies.

The European Commission has made available the Actor registration module which is the first of six EUDAMED modules on December 1, 2020. The Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG) has been commissioned by the Austrian Ministry of Social Affairs, Health, Care and Consumer Protection to validate the entries in the Actor registration module.

Read more: https://ec.europa.eu/tools/eudamed/#/screen/home

## CONFERENCES / TRAININGS

### Save-the-date: Online Summer School, 5-9 July 2021

The WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies is pleased to announce the first Online Summer School on Pharmaceutical Pricing and Reimbursement Policies.

Addressing a global audience of policy-makers and technical experts in public authorities who work on pricing and reimbursement of medicines, the Summer School offers opportunities to gain insight into latest evidence and policy experience in different countries, to discuss practical examples and to interact with experts and peers confronted with similar challenges.

Save-the-date: 5-9 July 2021

Registration opens mid-February 2021.

Read more: https://ppri.goeg.at/summerschool2021

### THE TEAM

### Russian-speaking research assistant

Yuliya Pashkevych has begun supporting the team working for the PPRI EECA (Pharmaceutical Pricing and Reimbursement Information Eastern Europe and Central Asia) network.

Yuliya is a Russian and Ukrainian native speaker and has been trained as a translator and interpreter for Russian, Ukrainian, English and German.



### INTERNATIONAL COOPERATION

### PPRI network for Eastern Europe and Central Asia

The regional subgroup of the Pharmaceutical Pricing and Reimbursement Information (PPRI) network for Eastern Europe and Central Asia was re-launched in 2020 under its new name of PPRI EECA. Members are public authorities for pricing, procurement and funding of medicines from Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, the Russian Federation, Tajikistan, Turkmenistan, Ukraine and Uzbekistan. The network is coordinated by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies at the Pharmacoeconomics Department (acting as PPRI EECA Secretariat) and the WHO Regional Office for Europe. Some members of the PPRI EECA network are also members of the large PPRI network.

On 16 November 2020, the fourth PPRI EECA network meeting took place online. Among others, challenges of the countries in the region, including the COVID-19 pandemic management, were discussed.

Information on pharmaceutical pricing and reimbursement policies in the PPRI EECA countries is available in the report:

Pharmaceutical Pricing and Reimbursement Systems in Eastern Europe and Central Asia (English version):

https://www.euro.who.int/ data/assets/pdf\_file/0007/455938/Pharmaceutical-pricingeng.pdf

Pharmaceutical Pricing and Reimbursement Systems in Eastern Europe and Central Asia (Russian version):

https://www.euro.who.int/ data/assets/pdf file/0008/455939/Pharmaceutical-pricingrus.pdf

Read more on the PPRI EECA network: <u>https://ppri.goeg.at/Regional\_PPRI\_networks</u>

### 2<sup>nd</sup> Euripid Webinar took place on 18 January 2021

On occasion of the planned launch of the new public website, the Euripid Secretariat at GÖG organized a webinar for their participants. Around 30 delegates from 20 countries and international institutes learned about recent developments in the undertaking, for example the start of a formal cooperation with WHO Headquarters and OECD. Both institutions will receive cost-free access to the comprehensive Euripid database that contains information on prices of mainly outpatient medicinal products in currently 28 countries. The database also provides volume information from eleven countries and shares information on whether Managed Entry Agreements (or similar) are in place for some products.

Based on a recent survey among members, participants discussed in which direction the database should develop. Options are to include system-relevant medical devices or to increase the database with further medicinal products.

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### PPRI continues growing

In October 2020, Singapore joined the Pharmaceutical Pricing and Reimbursement Information (PPRI) network of competent authorities for pharmaceutical pricing and reimbursement. The network has now expanded to 52 member countries.

Read more: <a href="https://ppri.goeg.at/PPRI\_network\_members">https://ppri.goeg.at/PPRI\_network\_members</a>

### PUBLICATIONS

### PPRI Pharma Briefs on France and Spain published

The PPRI Secretariat produced an up-to-date concise report of the French and Spain pharmaceutical systems: These PPRI Pharma Briefs describe, on a few pages, the institutional policy framework related to pricing, procurement and reimbursement of medicines and recent developments. The Briefs (in English) also include a summary in the local language and a graphic visualisation.

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The series of PPRI Pharma Briefs were launched by the PPRI Secretariat in 2019, in response to the interests and needs expressed by policy-makers and experts to have concise country reports. It started with the Austrian PPRI Pharma Brief\_published in 2019. Further PPRI Pharma Briefs based on the expertise and input of PPRI network members are planned to be produced in the months and years to come.

### Measures to address medicines shortages in 24 countries

Experts of the Pharmacoeconomics Department conducted a survey in 24 countries on measures that governments have implemented to address medicines shortages. Common policies include a notification obligation for marketing authorisation holders to report upcoming and existing shortages which are then recorded in a register, a regular dialogue with stakeholders, including actors in the supply chain, and simplified regulatory procedures (for the import of alternative medicines, for instance). Further measures by some countries included supply reserves and export bans for some medicines.

Information was surveyed from public authorities that are members of the Pharmaceutical Pricing and Reimbursement Information (PPRI) network. The research findings were published in an article in the journal "Health Policy".

Vogler S, Fischer S. How to address medicines shortages: Findings from a cross-sectional study of 24 countries. Health Policy. 2020.

LINK: https://doi.org/10.1016/j.healthpol.2020.09.001



How to address medicines shortages: Findings from a cross-sectional study of 24 countries

Sabine Vogler<sup>\*,1</sup>, Stefan Fischer

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Pharmacoeconomics Department, Gesundheit Österreich (GÖG / Austrian National Public Health Institute), 1010 Vienna, Austria

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#### ABSTRACT

Shortages of medicines have become a major public health challenge. The aim of this study was to survey national measures to manage and combat these shortages. A questionnaire survey was conducted with public authorities involved in the Pharmaceutical Pricing and Reimbursement Information (PPRI) network. Reponses relating to measures as of March / April 2020 were received from 24 countries (22 European countries, Canada and Israel). In 20 countries, manufacturers are requested to notify – usually on an obligatory basis – upcoming and existing shortages, which are recorded in a register. Further measures include a regular dialogue with relevant stakeholders (18 countries), financial sanctions for manufacturers in cases of non-supply and/or non-compliance with reporting or stocking requirements (15 countries) and simplified regulatory procedures (20 countries). For defined medicines, supply reserves have been established (14 countries), and legal provisions allow the issuing of export bans (10 countries). Some measures have been introduced since the end of 2019 and countries are planning and discussing further action. While governments reacted by taking national measures, the COVID-19 crisis might serve as an opportunity to join forces in cross-country collaboration and develop joint (e.g. European) solutions to address the shortage issue in a sustainable manner. A practical first step could be to work on a harmonisation of the national registers.

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### Further publications: a book chapter and articles

Vogler S, Schneider P, Panteli D, Busse R. Biosimilars in Deutschland und im europäischen Vergleich – Marktsteuerungsmechanismen und Einsparpotenziale. In: Schwabe U, Ludwig W-D, Eds. Arzneiverordnungs-Report 2020. Berlin, Heidelberg: Springer; 2020.LINK: <u>https://link.springer.com/chapter/10.1007/978-3-662-62168-4\_5</u>

Gombocz, M., Vogler, S. Public spending on orphan medicines: a review of the literature. J of Pharm Policy and Pract 13, 66 (2020). https://doi.org/10.1186/s40545-020-00260-0 LINK: <u>https://joppp.biomedcentral.com/articles/10.1186/s40545-020-00260-0</u>

Vogler, S., Schneider, P. & Lepuschütz, L. Impact of changes in the methodology of external price referencing on medicine prices: discrete-event simulation. Cost Eff Resour Alloc 18, 51 (2020). https://doi.org/10.1186/s12962-020-00247-3

Cost Effectiveness and Resource Allocation

LINK: https://resource-allocation.biomedcentral.com/track/pdf/10.1186/s12962-020-00247-3.pdf

Vogler, S., Zimmermann, N., Babar, ZUD. et al. Addressing the medicines access challenge through balance, evidence, collaboration and transparency: key take-away lessons of the 4th PPRI Conference. J of Pharm Policy and Pract 14, 18 (2021). https://joppp.biomedcentral.com/articles/10.1186/s40545-021-00300-3

Read more: <u>https://ppri.goeg.at/publications</u>