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The consortium acting on behalf of the EURIPID Collaboration under this grant consists of :

- NATIONAL HEALTH INSURANCE FUND ADMINISTRATION (NEAK), Hungary
- AUSTRIAN PUBLIC HEALTH INSTITUTE (GÖG), Austria
- STATE INSTITUTE FOR DRUG CONTROL (SÚKL), The Czech Republic
- DENTAL AND PHARMACEUTICAL BENEFITS AGENCY (TLV), Sweden
- PHARMECA a. s., The Czech Republic

EURIPID Collaboration is a voluntary and strictly non-profit cooperation between mostly European countries on building up and maintaining a database with information on national prices of medicinal products in a standardized format.

EURIPID database is currently exclusively available online for national competent authorities for pricing and reimbursement of medicinal products, who agreed on the rules of the collaboration and who participate actively.

EURIPID database contains data on **official prices of publicly reimbursed**, mainly **out-patient medicinal products** that are published by national authorities in line with the Transparency Directive 89\105\EC.

3 Years of Co-funding

26 European Countries participating
10 000 000+ Price References of medicinal products
24h online availability of database
8+ Years of close cooperation between project partners
2009 First financial contribution by EU

Besides regular **maintenance tasks,** activities under the Grant were to **identify and implement extra information** (e.g., on volumes or the existence of a special discount called MEA) allowing authorities to obtain price information in a more efficient way and lower the risk of making decisions based on incorrect or incomplete data. EURIPID database has been of great value to the authorities in the past years aiding them in their decision making duties. With the expanded funding opportunity from the EU Health Programme, the EURIPID consortium has achieved even more additional value for users.

The EURIPID collaboration in a cooperation with all relevant stakeholders has developed a **technical Guidance Document on a coordinated approach of Member States regarding External Reference Pricing** (**ERP** - using medicinal product prices from another countries). The document is available to authorities and partly to general public thus can help to **avoid or mitigate potential negative impact for patient access to medicines** in case of unskilled use of external reference pricing.

The **Guidance Document** was developed, based on a **scientific analysis**, by a study team of the Euripid Collaboration led by Gesundheit Österreich GmbH (AT), SUKL (CZ) and NEAK (HU) with input by the Board of Participants of the Euripid Collaboration.

The final document was prepared following a series of formal and informal consultations including Face-to-Face meetings between Euripid members, further national competent authorities on pricing and reimbursement of medicines, EC policy officers and stakeholders in the field.

Stakeholders at EU level that were involved in process are
National competent authorities for pricing and reimbursement of medicinal products, Pharmaceutical Industry Associations, Patients' Organizations, Third Party Payers, Doctor's Association and Association of Distributors.

The **Guidance Document** consists of:

(1) concise overview of the principles in form of an **Executive Summary** and
(2) a more detailed **technical background report** also ex-plaining the method how the principles were developed. The latter version including the references used is for internal use of the collaboration and EC Services only and will be published on the Euripid website.

All principles follow the structure:

'Framing the issue – Things to consider – Recommendations'.

Basic principles and some recommendations selected are mentioned further 

1) ERP is an important policy tool that should be used in a mix with other instruments and not as stand-alone policy tool

ERP can be successfully used as a supportive criterion or as a price limit but should always be complemented by other tools. Such other tools are for instance, comparisons with available therapeutic alternatives, value-based assessments, negotiations or managed entry agreements and other related non-pricing tools such as budget impact limitation.
(recommendation no. 1.4)

2) ERP should take place on single product basis rather than by indices

The necessary personal and technical capacity must be available to perform the task. If possible, Euripid partners should consult the Euripid database instead of 'manually' collecting data from reference countries on a case-by-case basis. **(recommendation no. 2.3)**

3) The aim of the national pharmaceutical policy should determine the selection of reference countries

A careful choice of reference countries takes into account considerations on economic indicators and indicators related to the performance of the health system as well as aspects of fairness. **(recommendation no. 3.2)**

Consider if the information needed for referencing / comparing is available in the necessary format and level of detail; preferably even from Euripid. **(recommendation no. 3.4)**

4) Evidence has shown that ERP is most effective when applied to pharmaceuticals without generic or therapeutic competition

There are other, better, policies (e.g., internal price referencing) to steer or monitor the prices of generics and biosimilars, which should be taken into account. **(recommendation no. 4.2)**

5) The comparison of prices of medicinal products should be done on the first price type in the pharmaceutical distribution chain

ERP should preferably be applied at the first possible price type, i.e. ex-factory prices. Margins and taxes are different in the various countries, resulting in varying price differentials along the pharmaceutical distribution chain. Those differences cannot be attributed to the MAH, but to national distributors and to national policies – or in some cases the absence of the latter. **(recommendation no. 5.1)**

6) Competent authorities should apply clear and transparent procedures to determine which pharmaceuticals are considered as comparable

Differences in pharmaceutical forms for the same active ingredient should be taken into account during pricing and reimbursement procedures if those differences provide additional/different outcomes/health effects or are deemed as therapeutically useful (e.g. pediatric forms). **(recommendation no. 6.4)**

7) The pricing formula applied for ERP should reflect the national pricing policy objective

The ERP formula should not aim for a price below the basket's minimum price. **(recommendation no. 7.3)**

However, the ERP formula is only one part of the picture. Decisions on the calculation method should be taken in conjunction with other – equally important – factors and ERP should be used in mixture with other tools to ensure access to medicines. **(recommendation no. 7.7)**

8) ERP procedures should be performed with the highest possible accuracy and completeness of data sources

Information sharing instruments that have been established by public authorities in the field of pharmaceutical pricing and reimbursement, e.g., Euripid database or the PPRI network, should be used to double-check prices. **(recommendation no. 8.3)**

9) If price information is adjusted to national requirements, it should be done in a transparent and sustainable manner

An average exchange rate of a longer period should be used in order to avoid the effects of exchange rate fluctuation. The average exchange rate of the last twelve months as published by the European Central Bank should preferably be used. Countries are not encouraged to adjust their referenced prices only because of currency fluctuations.
(recommendation no. 9.2)

10) ERP activities need careful planning and should also be considered as a policy tool for price revisions and monitoring

ERP's potential for being an effective and predictable pricing method depends on time parameters chosen . Indicate clearly the validity of price information, and make planned revision timelines transparent. **(recommendations no. 10. 1 and 10.4)**

11) The procedures and price inputs to ERP should be transparent to ensure predictability and effectiveness

Stakeholders and competent authorities in the field of pharmaceuticals should commit to transparency as it increases accountability and could contribute to an improved coordination of ERP activities on European level. Countries and stakeholders should jointly establish a Dialogue Platform for these topics. **(recommendation no. 11.1)**

12) Policy-makers should consider strengthening their cooperation, in particular through the contribution and benefits of existing policies

Maintaining and deepening cooperation between countries in platforms like the CAPR Network, Pharma Policy Directors' Meetings, PPRI etc. is helpful to obtain general information on other countries. It should be complemented by a Dialogue Platform with stakeholders - such as established in Euripid – for exchange of information. **(recommendation no. 12.1)**

Further information, tools and utilities that were implemented as part of the EU grant include:

New **database interface, predefined queries, improved search function, user reported errors,** and several other functionalities that boost users comfort and make database management easier.

Information on **presence of a special discount** (so called Managed Entry Agreement) was added to the database and filled with information for several countries. This information was highly demanded from authorities – it will help them to understand price better and improve informed decision-making.

Information on **volume** (packages delivered) was added to the database and filled with information for several countries. This information was highly demanded from authorities – it will help them exclude unrealistic price references or even deal with shortages of medicinal products better.

New **Country Background Information** system which contributes to the correct interpretation of the price information available and management that ensures that the information is always up-to-date and valid.

Planned activities for the coming years

Continuous information provision related to pricing of medicinal products

- extension of the data scope to non-reimbursed but regulated priced products

Service improvement of the EURIPID Collaboration

- newsletter, helpdesk, webdesign and ergonomics
- training sessions
- improved documentation of data processing

Strengthening the cooperation within the EU in the field of pricing of medicinal products

- establishment of a platform with the stakeholders
- establishement of a cooperation with EMA, Eurostat and EMVO
- inclusion of medical aids and devices to the dataset

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