Ensuring added value of EURIPID to the European Commission, Member States and European citizens

This document was prepared in March 2022 by the Executive Committee to demonstrate the achievements of the undertaking so far and gives an outlook on the future roadmap that is currently discussed with the EURIPID partners.

Policy Framework

Member States of the European Union are free to regulate the prices of pharmaceuticals and to determine the scope of their coverage by the national health insurance systems, provided that their decisions are made in a transparent manner and comply with the provisions of the EC Treaty (Article 164 of TFEU).

There is a shared understanding in the European Union that pricing and reimbursement policies need to balance (1) timely and equitable access to pharmaceuticals for patients all in the EU, (2) control of pharmaceutical expenditure for Member States, and (3) reward for valuable innovation within a competitive and dynamic market that also encourages Research & Development.[1]

Prices of reimbursable pharmaceuticals are regulated in all EU Member States (MS). MS have developed different sets of regulatory principles or requirements for managing the prices of pharmaceutical products. External Reference Pricing (ERP) is a very common tool, but also other approaches (e.g., Health Technology Assessments) have gained relevance in the pricing and reimbursement of pharmaceuticals. Due to these different national pricing policies that are consequently mirrored by country-specific strategies of the pharmaceutical industry prices of products vary between countries.

Despite regulatory differences, all approaches share one aspect**: Need for information**, and especially for trustworthy and meaningful price information to enable informed decision making. In principle, pharmaceuticals are subject to the provisions of the Transparency Directive (Council Directive 89/105/EEC)[2], which highlights the importance of transparency in the decision-making process of pricing and reimbursement as well as in its outcomes. The Directive requires Member States to publish and communicate to the European Commission, at least once a year, a complete list of pharmaceuticals covered by their reimbursement system, together with their prices fixed by the authorities.

The **Pharmaceutical Strategy for Europe**[3] mentions on 'to *make medicines more affordable*' that further engagement between MS and the Commission can foster transparency of price information, which can help countries to take better pricing and reimbursement decisions. Prices and pricing decisions influence access to cost-effective and affordable medicines. Moreover, pricing practices in the pharmaceutical sector can affect the functioning of internal market in the Union[4].

The **EU Pharmaceutical sector inquiry** yielded, whilst fully acknowledging national choices, that pricing regulations may create room for misuse and unintended behaviour (e.g. hidden discounts on published price lists used for reference pricing).[5] The growing number of contractual obligations in so-called Managed-Entry-Agreements (MEAs) which usually include provisions regarding the confidentiality of prices is an example of this.

[1] Final Conclusions and Recommendations of the High Level Pharmaceutical Forum (http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/pharmaforum_final_conclusions_en.pdf)
[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0105:EN:HTML
[3] https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2173
[4] https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/index.html
[5] https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf

EURIPID in a nutshell

In 2009, in response of the calls of Member States for an instrument to access comparable price information and following work done in the INFOPRICE initiative of the Transparency Committee, the European Commission (EC) launched a call for proposals to create and maintain an electronic price database of pharmaceuticals for the use of EU public administrations and, if appropriate, other relevant stakeholders. The grant was awarded to the EURIPID Collaboration. EURIPID was founded as a voluntary, non-profit collaboration of the European pricing and reimbursement authorities for the mutual sharing of information regarding pharmaceutical pricing policies and prices of medicinal products. The EURIPID Collaboration consists of founding members, partners i.e. members from 26 countries, associated partners and the EC[6].

Since its first launch the pharmaceutical database has been continuously online for already 12 years and provides more than 30 million data points.

EURIPID is recognized as an operational tool and is included in the work plan 2021-2023 of the Flagship initiative "National Competent Authorities on Pricing and Reimbursement (**NCAPR**)[7].

The **EU4Health Work Programme 2022** calls EURIPID for a proposal for an action that will contribute to the policy priority to implement the Pharmaceutical Strategy for Europe as it concerns the support Member States in national pricing and reimbursement policies. The EURIPID database, can support through exchanges of relevant information to identify and warn for market practices and to prevent unintended negative effects on access to medicines and healthcare.

EURIPID's mission

Our mission is to make pricing procedures and prices of pharmaceuticals more transparent in Europe and to improve collaboration and communication among its members. The members of the EURIPID collaboration are convinced that transparency is a way to ensure patients timely access to medicines.

In a first instance pricing information was made available for the experts of those European national competent authorities who share the same understanding on the main issues of pricing of pharmaceuticals and who are formal members of the EURIPID collaboration and share their pricing information in exchange to get access to the information of the others. In 2019 the decision-making entity of EURIPID, the Board of Participants, ruled that actual membership to EURIPID shall be restricted to European countries solely but that international exchange and capacity building is explicitly endorsed, e.g. via close cooperation with OECD and WHO.

Achievements by EURIPID

- **Easy to use 24-hour available database** with constantly updated price information. The price information for pharmaceuticals is made comparable across countries, even if products are not centrally authorised. Until Art. 57 database becomes fully functional or another publicly available "standardised" data core for pharmaceutical products is available to P+R authorities, this standardisation of products in relation to the IDMP standard[8] is one of the most demanding and resource-intense tasks of the collaboration.

[6] Under the Grant Agreement Nr. 664317 the European Commission was invited to delegate a member to the Executive committee, who takes part in the Collaboration during the duration of the Grant Agreement and has voting rights in the Board of Participants.
[7] The group has been relaunched in 2021 as a flagship initiative of the Pharmaceutical Strategy for Europe (see section 2.3)
[8] https://www.ema.europa.eu/en/human-regulatory/overview/data-medicines-iso-idmp-standards-overview

- **Most comprehensive source on publicly available price records (~30 Mio.)** which is readily accessible to national authorities for pricing and reimbursement. The robustness and validity of the included information was confirmed and is regularly evaluated and has been gradually expanded over years (e.g., volume information, partly non reimbursed products).
- **More than a database**: It provides targeted services to the users, like background information about the pricing systems and the type of data delivered and allows e.g., trend analysis.
- **Technical Guidance on External Reference Pricing**: The EURIPID collaboration jointly developed with NCAPR representatives and stakeholders 12 "Guiding Principles" which are meant to guide a coordinated approach of national competent authorities regarding the use of ERP to avoid/mitigate negative impact for patient access to medicines
- **Standard operating procedures (SOP) on data standardisation:** The national practice of publishing price information is different in each participant country in terms of data structure, way of data provision and the frequency of adjustments. The Founders developed SOP for the inclusion of their products and price information in the database for each participant.
- **Quality assurance**: EURIPID ensures continuous data validation through different means to ensure the quality of data in the database (e.g. an online error reporting system and random cross-checks against national sources). Also, the Secretariat checks and authorises country background information and aims to identify relevant changes in national systems.
- **Channelling discussions on pricing and reimbursement**: Representatives in the Board of Participants of the EURIPID collaboration are technical experts in the field of pharmaceutical pricing and reimbursement. EURIPID contributes regularly to discussions and brings in its expertise in public debates and strategy development. Furthermore, participants of the EURIPID collaboration participates in EU-wide discussions and developments within the remit of their national responsibilities.
- **Transparency** is a key pillar of EURIPID's work. A public website www.euripid.eu was deployed in spring 2021 and complements the network on the EU Health Policy Platform[9]. One highlight of the current EC grant period was the establishment of a **Stakeholder Dialogue Platform** that aims "*to strengthen the cross-functional cooperation in the field of pricing of medicinal products within the EU/EEA/EFTA as a component in order to enhance patient's access to medicines*."[10]
- **Scientific work:** The EURIPID team is engaged in various research activities like data analysis for partners (e.g., quick analysis on infliximab) or in exploring alternative methods for the calculation of Purchasing Power Parities for medicinal products together with Eurostat. The Secretariat regularly presents on scientific events like the European Public Health Conference or PPRI. Also, researcher may receive access to EURIPID information on aggregate level[11] free of charge.
- **Knowledge broker and capacity builder:** In 2021, the EURIPID collaboration signed a cooperation agreement with OECD to explore potential future avenues in sharing information on pharmaceutical prices. A formal cooperation with the World Health Organisation in Geneva is under development. Despite database access is restricted to European countries, EURIPID supports all countries by promoting EU best practices (e.g., via the Guidance Document on External reference pricing of

[9] https://webgate.ec.europa.eu/hpf/network/home/79

[10] Quote from the joint Concept note https://euripid.eu/activities

[11] See https://euripid.eu/researchers/ for application

medicinal products) to help in avoiding any potential negative aspects of ERP on patients' access to medicines worldwide.

Voices on EURIPID

„A database of pharmaceutical prices is a practical example of voluntary co-operation between EU/EEA countries and the European Commission. It is a useful tool for competent authorities, and ultimately benefits payers and patients in increasing price transparency in this field."

– Helga Festøy, NoMA, Norway, Chair of the Board of Participants

"Safeguarding affordable and sustainable asses to high quality medicines forces payers – buyers – to engage in a societal dialogue to set preferences, make choices and decide on willingness to pay/invest in therapies. Comprehensive, comparable, correct and up to date information on the cost and price of medicines – the kind EURIPID delivers – is crucial for this task."

– Francis Aricks, RIZIV/INAMI, Belgium, Chair of Euripid Executive Board since 9/2021

Problem analysis

Though EURIPID is a very successful project three obstacles hamper the exploitation of the full potential of the undertaking.

Gaps in information

EURIPID's goal is to be a comprehensive database in terms of geographic coverage, product scope and price types. Despite huge efforts of the team information gaps continue to exist in the subsequent areas:

Geographic aspect: Participation in EURIPID is restricted to the European region as defined by the United Nations. The primary target countries are the EU Members States. EURIPID was very successful in the recruitment, since almost all EU Member States joined voluntarily and additional countries as well. However, EURIPID still misses Germany, Luxembourg, Malta and Croatia.

Information type aspect: EURIPID focuses on collecting information on prices; on volumes and on the existence of MEA. Though price information is available from 29 countries, volume information is only available for 12 countries and information on the existence of MEA for 11 countries.

Product type aspect: Out-patient pharmaceuticals are the core focus of EURIPID. Several countries share official prices of hospital products and a few countries also share prices of non-reimbursed products which are price-regulated. The differences in the delivery of various product types impact the analytical tools of EURIPID.

Price type aspect: Members of EURIPID have committed to deliver at least one price type out of the four price types recorded in EURIPID (manufacturer price, wholesale price, net, and gross retail price). There is no price type which is available from all members which limits the usability of EURIPID data.

Timely access to information: national competent authorities need the information on time to make informed decisions. In average price and related information is available within the same month, but sometimes there are delays in data delivery or back-logs in the information processing procedure (data standardisation and upload).

Solution: The project team works hard in keeping the motivation of the participating country on timely delivery and description of the respective data sets. Also, efforts are put into adding additional information from more countries whilst acknowledging national information barriers.

Underuse

Some national competent authorities lack the capacity to explore the full potential of the EURIPID database. Moreover, EURIPID has not explored all the potentials to provide target analytics and the potential use of IT developments like AI and machine learning. More features can be explored from the use of the current or future data, like sequence launching, 'gaming' of the market, price increases etc. that could help flagging unintended effects.

Solution: The Secretariat recently organised a series of capacity webinars to show users the potential of the database. Also, factsheets on concrete questions have been and will be produced.

Voluntary nature

EURIPID started and still is a voluntary, MS-driven, initiative, building on mutual trust among the members of the collaboration. This voluntary nature of data sharing demands high administrative efforts as e.g., data delivery rules (completeness, deadlines) are sometimes not respected. On the other side, incomplete our out-dated information limits the usability of EURIPID for decision making. Also, the database misses some sort of pricing information which would be of interest for P+R authorities, such as the reimbursement conditions of a product.

Solution: To keep the voluntary nature of the collaboration, EURIPID may explore other mechanisms (peer control, incentives for data sharing, etc.) to reap benefits from a 'network buddy effect'. Another option could be to make the publication of price regulated pharmaceuticals in the EURIPID database legally binding.

Scenarios for the future

We are proud that EURIPID is a flagship project for cross-country collaboration in Europe and beyond, a role which has been acknowledged explicitly in written or oral comments by high-level executives[12], The efforts of the collaboration culminated in the 2020 '*Pharmaceutical strategy for Europe*' in which EURIPID is listed under pillar '*making medicines more affordable'*.

But, in our 13th year, EURIPID might have reached its limits in the collection of information on a solely voluntary collaborative basis, still involving a lot of manual work. The momentum is here for EURIPID to explore news ways of operation to overcome the above identified problems and better serve the NCAPR in facing the challenges of pricing of pharmaceuticals at present and in the future.

The EURIPID collaboration will explore several possibilities for future development with its Board of Participants. To remain a central pillar of the European Pharmaceutical Strategy EURIPID will define a **Roadmap** with up to four scenarios, reaching from 'Baseline' (i.e. keeping everything like it is) to Euripid on complete 'New Ways'.

In parallel, the Secretariat will work on the **call for action**[13] in the current EU4Health workplan to e.g., develop early warning mechanisms and guidance in the area of pricing through the EURIPID database, based on lessons from competition cases, in particular on excessive pricing.

[12] One prominent example being former Commissioner for Health and Food Safety Vytenis Andriukaitis in his address to the European Council in December 2017

[13] EU4H-2022-PJ-08 HS-g-22-17.01