Minutes of
the 3rd Meeting of the Stakeholder Dialogue Platform on Pricing of Medicinal Products
under the Grant Agreement No. 826652 — EURIPID — HP-PJ-2018 Monday,

21 September 2020, 10:00-12:00 am

Venue: online

Moderation:
Claudia Habl (Euripid General Secretary,
Austrian National Public Health Institute GÖG)

Note: All presentations may be obtained from the Euripid Stakeholder Network site on the European Health Policy Platform: https://webgate.ec.europa.eu/hpf/network/home/79
Please contact euripid@neak.gov.hu if you have troubles in accessing.

AGENDA

10:00-10:30 Welcome and Setting the Scene

Helga Festøy (NOMA, NO) welcomed the participants and explained that due to the COVID-19 crisis the planned in-person meeting of the Stakeholder Dialogue Platform must take place online. She shared the housekeeping rules: Chatham House Rules apply.

Dirk Van den Steen (DG SANTÉ, EC) shared the latest developments of the EU Pharma Strategy discussions.

Reasons for the EU Pharma Strategy: Challenges of access, affordability, financial sustainability, research and development of medicinal products and the competitiveness of the European Pharma industry. He stressed that there is a long-standing policy debate on this issue and that these activities culminated in the mission statement of the new Commissioner and in the Pharma Strategy making.

The pillars of the strategy:

1. access, availability and addressing shortages.
2. affordability and sustainability of health system
3. enabling sustainable innovation (also in environmental terms)
4. succeeding the global level (industrial policy).

Dirk presented the milestones of the roadmap of the strategy making and the statistics of the feedbacks received in the consultation phase by 15 September

Claudia Habl (EURIPID-GÖG, AT) gave an update on the most important developments since the last Stakeholder Dialogue Platform meeting and the current issues. She pointed out that EURIPID celebrates its 10th anniversary in 2020 and introduced EURIPID in a nutshell (mutual collaboration of the pricing and reimbursement authorities in Europe, a database and technical tool and a platform to share pricing information of pharmaceutical products). She presented

- the brief history,
- the participants and applicants of the EURIPID Collaboration
- the recent achievements (graphic and quality control improvements, the technical Guidance Document on External Reference Pricing, the inclusion the information on the existence of managed entry agreements and volume information, the founding the of the Stakeholder Dialogue Platform and the process to allow access to data for researchers),
- the current activities (integration of non-reimbursed products, feasibility study on the inclusion of medical devices, launch of public sites and the cooperation with EUROSTAST on the calculation of price indices and PPPs)
- past and future challenges (database maintenances, transparency, and capacity building).

Question: how are researchers defined?
Answer: We define research in line with the Frascati-criteria as outlined in the OECD Manual (https://www.oecd.org/sti/inno/frascati-manual.htm). Each application of will be assessed by the Secretariat and, if applicable, put forward to voting by the Board of Participants.

10:30-11:30 Working Group on Price Transparency

Results of a Price Transparency Survey among Euripid members (Pierluigi Russo - Angelica Carletto, AIFA, IT)

The Executive Committee of EURIPID launched a survey within the EURIPID members to explore feasible options to foster information exchange and cross country collaboration on high cost and on-patent medicines by focusing on use of MEAs, transparency of prices and MEA, countries' interest in sharing information with confidentiality, legal constraints for the information exchange, general information on MEAs in place and exchange of information on MEAs through EURIPID.

A very good coverage levels was achieved (above 70% of EURIPID member countries). The survey confirmed the OECD survey funding that there is a general interest in sharing information with confidentiality. The most important barrier in the exchange of information is the non-disclosure clauses in the contractual agreements.

The survey also tried to identify the barriers for sharing information on the existence of MEAs with EURIPID. Confidentiality clauses and data ownership issues are the most important ones.

- The conclusions of the survey:
- the sharing of information on MEAS and /or net prices seems hardly feasible at the moment
- the main obstacles to the information exchange are the inclusion of non-disclosure clauses in contractual arrangements and national legislation in a few cases
- the current EURIPID solution (information on the existence of MEAs on a product level) is the first attempt to improve transparency
- further actions are necessary to overcome the current legal barriers.

Comment: *The goal should be to improve access to medicines and not to increase transparency of MEAs.*

Question: *Do these conclusions apply to all medicines or just products operating in monopolistic situation?*

Answer: *The survey was focusing on products in a monopolistic situation.*

Comment: *Not sure that cooperation theory works well in the case of net price transparency. We already see that impact of ERO and parallel trade on the flattening of prices which means that countries with lower GDP per capita will end up paying more and rich countries pay less than they should. See: "The case for transparecy in pricing"*
https://www.dropbox.com/s/xk7c39sa0egd2aa/Glynn_2015_The%20case%20for%20transparency%20in%20pricing_Comp%20Law.pdf?dl=0

and see:
https://www.kangaroogroup.de/app/download/22473255/20160316_Glynn_Kangaroo_Breakfast_Handout+Dermot+Glynn-3.pdf
Comment: *Currently prices across countries are not aligned with GDP/capita or ability to pay. Poorer countries sometimes pay higher price than rich ones.*

EURIPID's input to the EU Pharma Strategy discussion (Gergely Németh, EURIPID-NEAK, HU)

Gergely drew the attention that the basis of his presentation, EURIPID's input to the Pharma strategy discussion was shared as a background document to the invitation. There is a widespread desire for more transparency. The EU Parliamentary Report called EURIPID in 2017 to include real prices. The WHA adopted a resolution in 2019 and several stakeholder and governments expressed their need for transparency. It must not be forgotten that transparency is only a mean, the goal is to improve patients' access to medicines. Transparency can help this via two ways: by promoting best practices e.g., more rational use of medicines and supported by differential pricing the access to medicines in less-developed countries could be improved. Three facts that must be considered were highlighted: price is only one factor for accessing medicines, pricing is a national competence and there are legal barriers. EURIPID suggested that a working group could be set up with the participation of governments, the Commission, and stakeholders on a voluntary basis to elaborate a framework for pricing information sharing. The suggestion is that the following four principles must be considered at least:

- All important information on pricing of medicinal products subject of the co-operation should be transparent for the participants
- All important information on pricing of medicinal products subject of the co-operation should be transparent
- the products concerned must be exempted from the national legislation on external reference pricing
- the principles of price differentiation in an international context have to be agreed.

EURIPID can offer its support via network of experts, its technical and conceptual knowledge and expertise in managing an international voluntary cooperation.
Question: *Does the proposed solution represent the views of the country representatives in EURIPID or the official position of those countries' member of the EURIPID Collaboration?*
Answer: *The proposal does not represent the official position of any member of the EURIPID Collaboration., it is suggestion for debate.*

Comment: *Transparency must be seen in a global context especially after the decision of the US to implement external reference pricing.*

Document: Euripid contribution paper (available from the European Health Policy Platform https://webgate.ec.europa.eu/hpf/item/item/29137

Activities of the European Observatory on Health Care Systems regarding Transparency (Dimitra Panteli, TU Berlin, DE)

Dimitra Panteli stressed that her presentation is rather an invitation to follow the work of the Observatory on Health Systems and Policy as their research is still ongoing.

There is resistance against the call for increased transparency not least due to fears that such measures would lead to price inflation. Consequences of the effect of more transparency could also affect countries beyond the one implementing the policy. So far there is no overview of existing empirical evidence on the impact of price transparency.

Idea: summarise existing evidence on the effect of price transparency policies on prices from the area of pharmaceuticals, other areas of health care and other industries.

Methodology:

- review of the published literature (pharmaceutical policy: rather theoretical work than empirical evidence; other health sectors: almost exclusively from the USA and focus on effect on price transparency on the consumer; other industries, limited transferability)
- development of scenarios based on identified empirical evidence
- expert consultation on draft brief scenarios
- development of methodology for group interviews with key stakeholders
- drafting of final insights for policy makers.

Round table question on the World Congress on Public Health 2020

- **SWOT Analysis of Euripid Collaboration** (Niclas Stridsberg, TLV, SE)

Niclas told that in recent years an increased interest has been experienced for the participation in EURIPID from countries outside the EU/EEA. EURIPID reflect-

ed on this phenomenon which led to a SWOT analysis. After the short introduction he highlighted the indentified

Strengths:

- most development international pricing database
- information content extended to volumes and information on MEAs
- Weaknesses
- not all EU members are members of EURIPID and as a consequence EURIPID cannot give the full European picture

Opportunities:

- participation of further countries could help EURIPID to be a standard
- participation of countries with similar developed welfare systems could help European countries to have a more global picture on pricing

Threats:

- participation of non-EU countries could undermine the cooperation with EU stakeholders
- EURIPID could end up in the focus of political debates

Comment: *Lovely to see that transparency is the favoured way forward while confidentiality is seen as a barrier and constraint. EURIPID has a lot more potential.*

11:30-11:55 Other Working Groups – State of Play

- **ERP Monitoring Working Group**

a. Follow up on the uptake of Euripid ERP Technical Guidance document (Claudia Habl, EURIPID-GÖG, AT)

Claudia) drew the attention on the principles of the ERP recommendations and shared the questions which were sent to the EURIPID members about the uptake of the recommendations of EURIPID on ERP.

National authorities and stakeholders are to a large extent aware of EURIPID but are less aware of the recommendations on ERP. No country went into a formal dialogue with the stakeholders to discuss the principles, but a few countries stated that in case they plan to change their national legislation on ERP, they will consider the EURIPID document.

b. Collection of topics and time slot for next meeting

e.g., potential proposal of an index measuring the conformity of national ERP practice with the recommendations of the Euripid guidance document.

Comment: *there is disappointment by stakeholder that countries are not implementing the principles despite of the thorough discussions that led to its compilation. The question is how the countries could be more influenced to consider the recommendations.*

Comment: *The proposed changes in the US on the introduction of ERP could increase the importance of confidential agreements otherwise European countries can experience price increases or non-launches of new products.*

Comment: *OECDs work on price transparency has been pushed by the US government.*

Comment: *a separate webinar on ERP could make sense enable a detailed and fruitful discussion.*

Comment: *Further discussion would be welcomed on ERP monitoring. And support developing an index as mentioned in the agenda.*

- **Patients' Access Working Group**

a. Collection of ideas for measuring patients' access to medicinal products in Europe

Potential topics of the next meeting and time slot e.g., W.A.I.T indicator (EFPIA), OECD Activities, Comparison by Consumption patterns (Euripid)

Comment: *Access is an objective that we all share fighting shortages and enabling access to medicines; this aspect is more important than transparency. There should be a discussion on patient access to medicines.*

Comment: *Several indicators should be listed, and the pros and cons assessed before supporting a specific method.*

Comment: *EURIPID is open to receive ideas to measure access which could be sent in email.*

11:55-12:00 Closing

The next EURIPID Stakeholder Dialogue Platform meeting is planned to take place in September 2021 in Oslo if the COVID situation allows the participation in person.

Note: There are plans to have perhaps a short meeting in spring 2021 as well.