EURIPID COLLABORATION
Stakeholder Dialogue Platform

10 April 2019 at DG SANTE, Brussels, Belgium

Minutes

Note: All presentations are available in the EURIPID Stakeholder Network of the EU Health Policy Platform https://webgate.ec.europa.eu/hpf/network/home/79

Setting the Scene

Welcome by Sylvain Giraud (European Commission) with an overview on EC activities in the field of pharmaceuticals and how the work of the EURIPID Collaboration fits into it.

Welcome by the Chair of the EURIPID Collaboration, Helga Festøy (Norwegian Medicines Agency, NOMA. She thanks the EC for hosting the meeting and also for supporting the further development of the EURIPID database in the frame of the Health Programme.

The General Secretary of the Euripid Board of Participants (BoP); Claudia Habl (Austrian Public Health Institute, GÖG) outlines the background of the Stakeholder Dialogue Platform: As an objective of the current GA No. 826652 between EU and Euripid and following the joint decision at the last stakeholder meeting on 28 June 2018 in Vienna, the Euripid Collaboration intends to establish a sustainable cooperation on information exchange in the field of pricing of medicinal products in Europe with the stakeholders of the pharmaceutical sector and supranational organisations.

Participants are then invited to outline their expectations to the meeting and the future Platform in an extended tour the table. Participants decide on Chatham House Rules and agree – in line with the GDPR – to information sharing (incl. names of delegates) in an electronic format. Claudia explains that delegates may revoke this right any time by informing the Euripid Secretariat.

The documents of the meeting shall be disseminated through the EU Health Policy Platform, in a group managed by Euripid. The delegates agree that only stakeholders, countries and EU services will be granted access for the time being (already 2 journalists have requested access, but we did not accept them). Discussions in the group will be rather technical and it is doubted if media could contribute to the discussion.

Euripid Collaboration – State of play – Gergely Németh

Project Manager Gergely Németh (NEAK, Hungary) presents the development of the EURIPID Collaboration since its beginning in 2010, the deliverables of the previous grant and gives overview of the tasks of the new grant. EURIPID is voluntary collaboration of several pricing and reimbursement authorities that are represented by a consortium in terms of the Grant

Agreement. It is an undertaking based on mutual sharing of pricing information of medicinal products. One of the means of the Collaboration is a database that offers regularly updated and maintained information on pharmaceutical prices provided by the members of Collaboration. During the grant period the launch of a public website is foreseen.

Q: Purpose of the planned public website of the EURIPID Collaboration. Will it be used for Information dissemination or will it also have restricted access as the database?

A: A public website is an obligatory deliverable for any grant in the health programme. At the moment, no access restriction to the website is considered, and the Euripid Terms of Use allows for sharing of data with the purpose of scientific research. The BoP of Euripid needs to approve such requests (submitted together with a study protocol), data can be provided on an aggregated level. Researchers are required to share the results with the Collaboration.

Main elements of the Technical Guidance Document ERP – Peter Schneider

Peter Schneider (GÖG, Austria) presents the main contents of the Guidance Document on External Reference Pricing (ERP) which has been jointly developed from 2015 till 2018 by BoP members and stakeholders. The document is based on (1) a scientific analysis of literature, (2) surveys among BoP-members and stakeholders on information needs when doing price comparisons, (3) the experience of authors and co-authors which are involved in national pharmaceutical pricing procedures, and (4) face to face meetings with stakeholders. Each of the twelve principles is structured into Background Information ("Setting the frame"), Links to other principles or areas ("Interdependencies") and conclusions on the debated aspect ("Recommendations"). The extended executive summary and the Laymen version are publicly available[1]. The needs assessment report and the technical report – both were deliverables of the previous grant – are available for BoP members and EU services.

Q: Does the principle #07 regarding the applied pricing formula include considerations on the economic strength of a country expressed by GDP.
A: Yes. There is no concrete recommendation but the principle asks for a "fair approach", stating: "*If the average GDP per capita of countries in the basket is above the domestic GDP per capita, the lowest price approach (or a modified method) could be used, while the average price approach (or a modified method) could be applied if countries with lower GDP are in the basket (i.e. average GDP per capita is below domestic GDP per capita)"* Although many discussions have focussed on that principle, it is only one part of the picture, as the interplay with other aspects is equally important.

Q: Are the effects of ERP discussed in the Guidance Document.
A: No, as this was not the aim of the undertaking as benefits and limitations of regulating

[1] https://jasmin.goeg.at/432/

prices by the means of ERP have been widely discussed in literature. Still, the document suggests a reflection process on potential negative aspects of ERP (availability, accessibility, etc.) and encourages competent authorities and stakeholders to collect evidence and shared it with each other.

Q: How is "Reward for innovation" defined in the document.
A: The document does not define the term, but refers, e.g. to the findings of the WG on Pricing as part of the DG GROW (prev. DG ENTR) corporate social responsibility process.

Q: Delegate comment that some countries have formulas that go beyond the lowest price when calculating the reference price.
A: The guidance document does not recommend such approaches and states that "*The ERP formula should not aim for a price below the basket's minimum price*". However, "Exceptional deviations from the chosen ERP formula due to special conditions" are possible, but are to be taken in a transparent manner."

Thematic Inputs

Transparency and Role of Patient Organisations

Kaisa Immonen from European Patients' Forum (EPF) explain that transparency of information, particularly prices of medicines, is a complex issue and difficult for patient organisations. On the one hand are national authorities which often claim that procedures are hampered by a lack of prices. On the other hand is the pharmaceutical industry stating that confidential agreements ensure access to medicines. In principal, EPF supports the move towards transparency as long as it does not have a negative impact on patients. EPF considers medicines not as an ordinary good, but acknowledges that the existing imbalance of information usually provides an advantages to those who possess information. These information asymmetry result in inefficiencies when it comes to signal medical needs and therefore they should be addressed.

Another issue of transparency is related to the transparency of pricing procedures. In this are patients show large educational gaps i.e. they do not know how national pricing procedures work, and they need to be informed about pricing procedures. One possibility would be further involvement in the entire process of decision making, as this increases health literature. Only a few countries consider the position of patients (e.g. Germany) but this can only be a starting point in order to ensure the acceptance;

Sustainability of the off-patent industry

Diogo Piedade of Medicines for Europe (MfE) talks about the sustainability of the off-patent industry. Generic and biosimilars medicines represent a cornerstone of healthcare sustainability, as the sustainability of healthcare systems is related to the sustainability of the off-patent industry from the perspective of MfE. He compares the price evolution of a cup of coffee with those of generics, which is in unfavour of medicines. If this trend continued prices will not cover the production cost and exceptional events like shortages or non-availability will

become more and more common. In future, new funding models are necessary to ensure the sustainability of the off-patent industry. One approach are dedicated P&R models which aim to (partially) delink costs from prices. In such models there will be a fixed fee up to an agreed volume and after the threshold is reached, pharmaceutical pricing follows usual procedures. Sweden is currently piloting this model and assess its effects.

Q: Why does the Guidance Document not recommend ERP for generic medicines.
A: In principal, ERP can be applied to all medicines, but the large the scope, the more challenging it become to develop sound methods for price comparison. Other policy tools seem to me more adequate when it comes to regulate prices of generic medicines.

International price comparison 2018

Niklas Stridsberg (Swedish Dental and Pharmaceutical Benefits Agency, TLV) presents the results of an analysis of Swedish pharmaceutical prices and volumes relative to 19 other European countries. In the last four years pharmaceutical prices for medicines not exposed to competition have increased. One of the reasons is that Sweden has – compared to other countries – a strong focus on out-patient care. As a result, a larger number of medicines are administered in the out-patient setting in comparison to other countries. Therefore volume weighted indices are more sensitive towards price differentials among European countries. Another factor that has contributed to perceived increase of relative prices are currency fluctuations. A new feature compared to previous price studies of TLV is the analysis of life-cycle price developments of pharmaceuticals.

Comment: The term "*products not exposed to competition*" in the report and the graph could be misleading as also the on-patent market is subject to competitive forces however, they work differently.

Q: Is a main reason for the change that the Swedish crown has appreciated?
A: No, on the contrary: the Swedish crown has devaluated in comparison to other currencies (mainly Euro) of countries that have been included in the price comparisons.

Q: Different systems of European countries are difficult to compare. The Swedish report also demonstrate the necessity to extend the dataset in the EURIPID database with volume information from all countries as currently TLV had to purchase data from a commercial provider. The members of the EURIPID Collaboration are invited to share volume information which will facilitate future analyses.

Q: How many countries reference to Sweden, and does this have an impact on products.
A: Sweden is in the reference basket of 15 other countries, but so far no impact on prices in Sweden has been observed.

Q: The analysis shows patterns of life-cycle pricing in Sweden, is this the life-cycle authorities want?
A: TLV thinks that their pricing procedures for on-patent ("value based pricing") and off-patented medicines (Obligatory generic substitution combined with the "product of the

month"-system) has shaped this lifecycle. Higher prices during the on-patent phase constitute the Swedish contribution to a reward to innovation.

Patient W.A.I.T. Indicator 2018 survey

Francois Bouvy of EFPIA presents the survey which was commissioned by EFPIA and conducted by IQVIA for 30 countries. Patients W.A.I.T. stands for Patients Waiting to Access to Innovative Therapies and give a snapshot of two parameters: (1) rate of availability, and (2) average time between marketing authorisation and patient access. Sources of information which have been considered in the survey are published information of competent authorities, complemented by information provided by EFPIA member associations. IQVIA survey 121 products which have been approved by EMA between January 1st, 2015 and December 31st, 2018; the cut-off date on information was 19th December 2018. IQVIA defined a set of "rules" to determine market availability: (1) included in the reimbursement scheme, (2) other funding channel (e.g. hospitals), and (3) special reimbursement conditions (e.g. temporary reimbursable); E.g. in Austria, up to 29% of medicines are available through a restricted marketing authorisation in the Red Box of the Reimbursement system.

Q: Is it possible to look also at subsets of data, to check if differences between different indications groups exist.
A: Yes, the report also includes an analysis of subgroups but due to time constraints it was not included in the presentation.

Q: What are the reasons for delays?
A: EFPIA has focussed on quantitative and not on qualitative data.

Q: Does EFPIA plan a follow-up study in order to check if the rate of availability has improved and link it to policy decisions.
A: Yes, it is planned to survey this information on a regular basis. The long version of the presentation contains a slide on changes between the 2017 W.A.I.T. indicator study and the 2018 study. The indicator on the average time between marketing authorisation and patient access has improved for some South-Eastern European countries (e.g. Slovenia & Croatia) while it has deteriorated for some Central- and Eastern European Countries (Czech Republic, Slovakia, Hungary) and the Baltic Countries (Estonia, Latvia & Lithuania).

Pricing of medicines in the Netherlands

Ellen Koster (Dutch Ministry of Health, Welfare and Sport, MINVWS) presents their national pricing and reimbursement system. In the Netherlands there are two different reimbursement systems (1) inpatient, and (2) outpatient system, and ERP is applicable to both systems. In the inpatient sector the health care insurer and the hospital sign a contract on the basis of DRGs. Hospitals are considered as business entities and are responsible for their financial sustainability. External Reference Pricing (ERP) applies to all medicines on the market. The current reference basket is composed of BE, UK, DE, FR but in 2020 Germany will be out and Norway in. The formula applied to determine the benchmark is the average price of the reference countries. ERP determined prices will be re-calibrated (i.e. revision) twice a year.

Access to medicines and information asymmetries

Tim Reed from Health Action International (HAI) presents the work of HAI and their campaigns to increase affordability. He claims that prices charged for new on-patent medicines threat the financial sustainability of national health system even in Western European countries and constitute an insurmountable obstacle to access for low-income countries on a global scale. He argues that prices for new medicines do not reflect R&D costs, as basic research is often financed by the public through. He suggests to implement track and trace of public funding of R&D as approx. 30-40 % of research is financed by public universities. Governments are implementing new forms of cooperation like BENELUXA to overcome information asymmetry and there is a global push for transparency. A wide range of stakeholder demand greater transparency on R&D costs, pricing & reimbursement and is important to establish an effective dialogue between stakeholders.

Q: The discussion on pharmaceutical prices seems to be exaggerated as OECD data show that pharmaceutical expenditures per capita did not change much over the last couple of years; also spending on cancer medicines is flat. The presented figures on expenditures on research in health do not include the costs of bringing a medicine to market, as they only focus on successful launches and do not include the research of medicines that did not make it to market.
A: This argument has been highly debated in the past, and some authors like Donald Light or Jack Scannell have a different view on this issue. Scannell argued that R&D costs are sunk cost and the argument of high prices to recoup the costs is not valid.

Q: Is there any conflict of interest as the European Commission is supporting HAI's attendance of the Platform?
A: No. One major goal of the health programme funding is to address Health inequalities and HAI is a patient advocacy. Bringing the public, represented by HAI or other organisations, to such a dialogue is one way to address inequalities.

Discussion on the framework of the Stakeholder Dialogue Platform

Claudia outlines the draft concept note ("2-pager") for the EURIPID Stakeholder Dialogue Platform shared prior to the meeting and invites the participants for comments. Comments that had reached the team in advance were incorporated already. Points raised were:

- The concept note might also include non-objectives.
- The concept note should clearly state the intention/purpose of the Platform, as several participants expressed resentment to a mere "debate club" without specific objectives.
- The stakeholder see steps for a better understanding what EURIPID is doing ("Information dissemination") as an important objective, because in the last years communication with stakeholders was no high priority of the Collaboration.
- Discussions on the objectives followed. The 2-pager should be more specific regarding the scope of transparency. Transparency can have more dimensions which either relate to the inputs and outputs (prices) or the procedures (pricing). The transparency of

prices (in terms of real prices) goes along with transparency in the procedures of pricing, but we have to be careful not to interfere with legislation as pricing is a national domain.

Gergely explained that in the beginning, the EURIPID databases aimed to reduce the administrative burden by providing fast and reliable price information in one database. However, in the last couple of years the database has already gone beyond price information, as it also includes validated information on the pharmaceutical systems and pricing procedures. The Chair of the EURIPID BoP, Helga Festoy, concludes that the success story of EURIPID is related to a policy of small steps, and therefore the Collaboration should focus on the dataset optimisation.

Discussion on mandate

The Platform could be used to feed in topics / ideas in the beginning of drafting reports or documents. Stakeholders complained that they were involved at a rather late stage of the project when the guidance document was already drafted. Claudia reminds delegates on the stakeholder kick-off meeting at RIZIV/INAMI already in Nov. 2015 were the planned methodology was presented by the team.

Delegates agree that the activities of the Dialogue Platform shall be connected to the work of EURIPID. The interplay between the Platform and the Collaboration will be considered, and Claudia emphasises that the Stakeholder Dialogue Platform will have no voice in deciding on new participants in the EURIPID Collaboration nor membership of the Platform will grant access to the database. A change in the current access policy would require a modification of the contractual framework of the Collaboration. Some delegates then request access to all legal documents, this needs to be discussed in the Executive Committee of Euripid. Due to the lack of time participants did not consider it possible to define concrete outputs (e.g. “joint statement” or consensus document), nor were concrete parameters to monitor the impact of Euripid discussed however tangible outcomes should be defined for the Platform.

Discussion on working structure

The group did no object that the Euripid Secretariat will prepare and document meetings, but due to the lack of time participants did not consider it possible to finalise the working structure, particularly as the outcome of such a Platform is not fully defined.

Despite, stakeholders expressed their interest to participate in a follow-up meeting and also showed willingness to host a meeting in time. Also Helga of NoMA announced the willingness to host a meeting in parallel to the planned Euripid BoP Meeting in Norway in 2020 or 2021. Delegates asked the team to explore options in piggy-backing with the upcoming PPRI conference in Vienna (23-24.10.2019), preferably 25.10. morning.