EURIPID COLLABORATION
Stakeholder Dialogue Platform

23 September 2019 at NEAK, Budapest, Hungary

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

The chair of the EURIPID Collaboration, Helga Festøy (HF, NOMA), and the General Secretary of the BoP Claudia Habl (CH, GÖG) welcome all participants of the workshops. The Chair thanks NEAK for hosting the meeting and the executive committee of the EURIPID Collaboration for preparing the meeting. HF emphasises the informal character of the meeting and that Chatham House rules apply. All documents are available on the HPP;

The EURIPID project manager Gergely Németh (GN, NEAK) gives a welcome and starts the tour the table in which participants are asked to describe their expectations.

Euripid Collaboration – State of play

GN explains the development of the EURIPID Collaboration, the deliverables of the previous grant and overview of the tasks of the new grant.

CH presents the updated draft concept note based on the discussion from the 1st dialogue platform in April and comments received after the meeting. She highlights the points discussed and explains the final wording. Since there are no further comments from the audience the concept note is considered as finalised and was uploaded at the Health Policy Platform of the European Commission. The delegates determine jointly the main points for debate in the Platform.

- **Pros and Cons of transparency efforts**: Some participants fear that the exchange of price information might have an impact on investments
- **"Real" Patient access**: Participants point out the need to find an adequate indicator that measures patient access to medicines and balances affordability and availability.
- **Medicine shortages**: Participants emphasise the increasing problem of medicine shortages in European countries and how the platform could contribute in mitigating this problem.
- **Role of Euripid and Uptake of ERP guidance document**: It would be important to monitor actions related to previous work in order to be coherent with the objectives stated in the concept note.

- **Causes of pre-launch patient access**: Patients do sometimes have access to medicines before the product is "officially" marketed which may have implications in later decision making procedures.

Input by Members of the Dialogue Platform

Pricing, transparency and parallel trade of pharmaceuticals

Esco Aguiar (EA, EAEPC) gives a brief presentation on pricing, transparency and parallel trade of pharmaceuticals. EAEPC has more than 120 member companies in 22 EU member states. Figures show stable turnover of parallel imports (PI) over the last eight years although the share of parallel imports on total pharmaceutical sales is steadily declining. Contrary to common beliefs, more than 50% of PIs are sourced in high income countries (UK and France). PI contribute to promote price competition among single-source products, lower prices and patient access. From EAEPC's perspective more transparency in prices would be desirable as parallel importers rely on accurate price data to assess the viability of the transaction. Esco answers on a question what Brexit would mean for the parallel traders that it will be very disrupting for their business but so it will be for all pharmaceutical enterprises.

Pricing of medicines in Belgium

Vinciane Knappenberg (VK) and Bertrand Dirie (BD) , both RIZIV/INAMI give a presentation on the Belgian situation. The legal basis for pricing and reimbursement has been established in 2013, and 1994 respectively, and has been continuously adapted since then e.g. a major change in the procedures was the introduction of pharmaco-economic evaluations. Belgium is one of the countries where pricing and reimbursement decisions are taken by different organisations, which may limit manoeuvring room for timely decisions as reimbursement evaluations start when prices have been decided. In recent years Belgium has concluded Managed Entry Agreements but the scope of medicines eligible for such agreements is limited. Within the BeNeLuxA collaboration the authorities have agreed on principles which ensures the confidentiality in joint negotiations.

Measuring patient access to healthcare

Kaisa Immonen (KI) from European Patients' Forum (EPF) gives a presentation on measuring patient access to healthcare. EPF was founded in 2003 and is an independent non-governmental umbrella association of Patient Organisations (74 national patient coalitions and EU diseases specific organisations). EPF defines access according to the 5As: Availability, Affordability Accessibility, Adequacy, and Appropriateness. In 2016 EPF conducted an online-survey which found delays in accessing different healthcare services (medicines, treatment, medical devices, diagnostic texts, primary care doctor, specialist appointment). Furthermore, 50% of the participants indicated that they experience sometimes or regularly financial difficulties as a result of spending on healthcare. There is a need to develop measures for access across the EU which goes beyond qualitative surveys.

WHA Resolution on Transparency on Pricing of Medicines

Andrew Rintoul (AR, WHO Geneva) introduces the WHA Resolution on Transparency of Pricing of Medicines ("Transparency Resolution") triggered by Italy among others, and puts the decision in some context. One main foundation of the Transparency Resolution was the technical report on "Pricing of cancer medicines and its impacts" which concluded with six major recommendations, each having further action points. Regarding Transparency the reported indicated as action point: "*Disclosing the net transaction prices of cancer medicines to relevant stakeholder*". Countries took up this idea on transparency of net transaction prices and at the World Health Assembly the Transparency Resolution was adopted, but three countries (Germany, Hungary and Switzerland) have disassociated themselves from the Resolution. WHO does not have means to enforce the implementation of the Transparency Resolution but the Director-General is requested to submit a report on progress made at the next WHA. AR points out that the resolution aims for implementation at a global scale, but the EURIPID database constitute a great opportunity at the regional level.

Break up in 3 Working Groups

Transparency Working Group: Increasing transparency of pricing

HF/GN Short intro to the WG by HF/GN; Questions aiming to support a structured discussion:

- **Would access to the EURIPID database be useful to your organisation? Why would you like to get access?**
  - National competent authorities on pricing and reimbursement which have already access to the database consider it as a very useful tool and regularly consult the database during pricing and reimbursement procedures. However, they express concerns about presumed discrepancies between prices included in the database and "real" prices, which undermines the validity of information.
  - While there are stakeholders which do not deem it as necessary to get access to the EURIPID data – on condition that the competent authorities have access to the information – some stakeholders express their interest in accessing the information, as it could be helpful for their work. However, some have concerns on the quality of price information and the implemented quality control measures. By granting stakeholders access to the database they could perform some sort of quality control.
  - The interest and support of stakeholders is appreciated, but there are three crucial points: (1) It has been a long process to achieve a joint understanding among the members of the EURIPID Collaboration and to establish standards in data presentation; (2) the administrative workload (user management) would be too high to deal with every single national stakeholder group; and (3) The main working principle of the EURIPID Collaboration is mutuality i.e. all members of the Collaboration share the information with each other. Extending the access to other groups requires

changes in the Terms of Reference of the EURIPID Collaboration and the approval of the board of participants.

- The development of a governance framework which regulates procedures (e.g. what is defined as error and how will it be corrected) and defines which groups are eligible for access, may provide a tangible solution to the three points described above. Until then stakeholders are urged to use prices published by the national competent authorities as those are included in the EURIPID database.

- **EURPID's answer to the EU Parliament call on the inclusion on real prices**
  - The EURIPID Collaboration was highlighted by Commissioner Vytenis Andriukaitis as best practice example for collaboration among EU Member States. Furthermore the EURIPID database was mentioned in the report of the European Parliament on EU options for improving access to medicines to which the EURIPID Collaboration gave a formal reply (available on the HPP).
  - In the last project grant a specific objective was to extend the dataset of the EURIPID database. In previous BoP meetings, members of the Collaboration had indicated that information on Managed Entry Agreements (MEAs) would be the most desired extension as this would enable them to better interpret available price information in the database.
  - Some stakeholders oppose the call for more transparency in the report to of the EU Parliament on EU options to improving access to medicine. Transparency would undermine the possibility to determine willingness-to-pay of each national public payer and as a results its implications on pricing.
  - Participants pointed out that transparency can be the mean, not the goal. The goal is to improve patients' access to medicines.
  - If transparency is implemented on a step-by-step approach it should also be considered how intended and unintended effects of transparency are measured (e.g. patient access). During such an evaluation other aspects than only prices should be taken into account.
- **The WHA resolution (presented earlier in the agenda); which opportunities and threats does the WHA resolution represent? What could be the EURIPID's potential role in the implementation of the WHA resolution?**
  - Stakeholders prefer to define what a "real price" is. If it relates to a price that is actually paid by public payers there could be real prices within a country e.g. in Germany it depends on the contracts each company has with the sickness fund.
  - Each policy will create winners and losers; while some fear that there will be an economic net loss for payers as full transparency could negatively impact discounts offered by companies, others expect that it would not have an impact at all (e.g. the transparency of the vaccines market did not have negative results). However, the main driving factor for more transparency could be political support.

ERP Monitoring Working Group: Monitoring the uptake of the recommendations of the EURIPID guidance document on external reference pricing

CH and Jindrich Kotrba (JK, Pharmeca) give a brief introduction about the rationale of the working group and present questions which aim to support a structured discussion

- **Has EURIPID had an impact on your national resp. company policy concerning pricing and reimbursement of pharmaceuticals? If yes, in formal or informal way? And how?**
  - The EURIPID database had a major impact on countries especially in countries where legislation requires competent authorities to search for price information. With regard to materials provided by the EURIPID Collaboration (i.e. background information or technical guidance documents), competent authorities seem less eager to consider them during pricing and reimbursement procedures.
  - Some stakeholders are – for various reasons – not in favour of including non-European countries into the reference basket. However, across EU Member States only a few reference to countries outside the EU like Iceland, Norway, Liechtenstein and Switzerland
- **Problems related to ERP**
  - National databases/datasets may contain "virtual" prices or outdated price information is found when they are searched for in the internet. It has been suggested that both problems could be addressed by introducing some sort of "appeal" process in the EURIPID database. However, EURIPID only uses published information and therefore the appeal process is already covered in national procedures. The project team is working ad adding more information to better assess the prices contained (e.g., existence of MEA, volume information).
- **What are the principles from the ERP Guidance document that you find useful for implementing**
  - Recommendations on transparency of pricing procedures are considered as useful for implementation. In Canada for instance, the calculations on how competent authorities have calculated respective benchmark prices are published.
- **How probable will these principles be implemented?**
  - Competent authorities cannot commit to one-to-one implementation of the principles as national characteristics need to be considered.
  - Stakeholders appreciate an even stronger commitment as this would generate more predictability of the outcomes.
- **Can you describe barriers for their implementation**
  - Some EURIPID members have already brought the technical guidance document to a national dialogue. However, the implementation of any policy is a long and cumbersome process, and this also holds for the recommendations of the technical guidance document.

- A barrier for the implementation of recommendations is the growing number of MEA with confidentiality provisions on target population, sales volumes, prices, etc. Another challenge is related to tendering as tendered prices are also confidential and in some countries tendering is done at the hospital level.

- **Suitable parameters to monitor with the goal of tangible outcomes.**
  - One aim of the working group on monitoring is to think of suitable parameters for monitoring. During discussion the participants suggested to develop an indicator that measure availability aspects of one (or more) product(s).
- **Future working structure of the working group**
  - Although participants emphasize the importance of monitoring, they doubt whether an own working group is necessary. A brief report on the implementation status could be part of the next dialogue platform. Additionally, some stakeholders are reluctant to participate in the working group as participation could signal that they accept ERP although they are opposing it.

Patients' Access Working Group: Measuring patients' access to medicines with the help of EURIPID (methodology and integration of volume information).

Niclas Stridsberg (NS) of TLV and Dimitrios Florinis (DF) from EC DG SANTE introduce to the rationale of the group and present questions which aim to support a structured discussion

- **How to measure patient access?**
  - It would be beneficial and the right thing to measure actual access, but it is complicated. What do we want to measure? The WHO or the EPF access framework have defined different dimensions of access, suggesting a multi-component indicator. Past studies often focussed on single-components as approximation e.g. inclusion in a country's positive/reimbursement list or Units / doses of active substances. Although this may be a sufficient approximation for the availability of medicines, it might not capture the entire situation at the pharmaceutical market
  - Conclusion was that units is the preferred measurement and not value. Volume per patient based on the population could be a good comparison between countries. The definition of access could be the first sales of the product on an indication that is on the market or when the product reached a certain level of sales is to be discussed. Application date for reimbursement is useful but it was commented that this is not a good measure because the application may be rejected.
- **Methodological question**
  - Firstly, the medicine groups to be considered must be defined. Centrally authorised medicines? Only Orphan medicines? Basket of different medicines? The conclusion was that the first focus should be on originals and biosimilars and later add generics.
  - Together with scope of products it needs to be decided whether the selected medicines should be part of the reimbursed market or not? Although it would be easier

to focus on the reimbursed market, there is need to monitor non-reimbursed medicines as those are often highly-specialised medicines of the in-patient sector.
    - During the discussion the question of measuring outpatient and inpatient medicines was raised. The working group concluded that the point of service may vary between countries and medicines which are inpatient in one country can be outpatient in another. Maybe defining a basket of medicines to start with would be the most appropriate way. One suggestion was to start with TNF inhibitors to create a case study.
- **How can EURIPID play a meaningful role**
    - Stakeholders agree that there is a need for robust data to understand what is happening in the market and to construct indicators for patient access. The EURIPID Collaboration aims to contribute by providing such data and will therefore launch a survey.

Conclusions of the meeting and the Working Groups

The facilitators of each group briefly presented the outcomes of each group. The results will be discussed during the next meeting of the Executive Committee of the EURIPID Collaboration who will propose how to proceed. HF announces that NOMA might host one meeting next autumn. Also EFPIA has expressed interest in hosting a meeting, if biannual meetings are necessary.

It seems that the working groups are not necessary at the time being. There will be no parallel session in the future meetings so all delegates can take part in all working group activities.

Conclusions and next steps in the working groups

Transparency Working Group

- The EURIPID team will follow-up with those stakeholders who expressed their interested in getting access to the EURIPID database. The developments will be shared at the next meeting.
- Transparency can be the mean to improve patients' access to medicines, not the goal itself. There is no agreement among all participants if transparency can improve patients' access to medicines. This topic shall be further discussed, the criteria should be defined under which transparency could improve patients' access to medicines.

ERP Monitoring Working Group

- Continuous efforts and more time are needed for promoting the ERP Guidance Document and overcoming local barriers for its implementation in the countries. There is no need for the ERP monitoring working group to reconvene unless specific requirements arise.

- The Euripid database as such has currently more impact on the pharmaceutical systems than the ERP Guidance Document. GÖG will do an annual survey with members on the impact and will invite stakeholders to give input already once per year
- Pharmeca, together with GÖG will develop suitable parameters to monitor with the goal of tangible outcomes.

Patients' Access Working Group

- The group agreed to look into the option to assess actual access with the example of TNF inhibitors by measuring volume per patient based on the population. Preferred measurement is units. Euripid Collaboration will prepare a survey on this product group.
- The questionnaire will define a list for requirements, assess which information would be helpful to know, and also if countries are able to deliver the required information.