EUROPEAN COMMISSION
DIRECTORATE GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation
Unit B4 - Medical products: quality, safety, innovation

EFPIA Workshop for national associations

Date: 17.11.2016

Location: Thon Hotel, Rue de la Loi 75, 1040 Brussels

Participants

EFPIA: Member companies and national associations

DG SANTE: Ioana Siska, Orsi Nagy

Purpose of the meeting

The workshop was an internal workshop organised by EFPIA secretariat to discuss EU cooperation on HTA with its national associations, in particular to identify the barriers for using EU REA (European assessment on the added clinical value) at time of launch in national decision-making and ways to address these barriers. The EFPIA discussion was supported by a study conducted by Charles Rivers Associate (CRA) with the support of EFPIA national associations. In the morning before the EFPIA-internal workshop, DG SANTE was invited to update the group on the Commission initiative regarding EU cooperation on HTA post 2020, with focus on the European Commission HTA Roadmap and public consultation launched in October. After the presentation from DG SANTE, CRA presented the project scope and main findings.

Presentations

The event was chaired by Mr. Philippe Lamoureux (LEEM/EFPIA) who welcomed the delegation of DG SANTE and the opportunity for discussion.

DG SANTE gave a presentation on the main elements of the "Initiative on strengthening of the EU cooperation on HTA" as included in the IIA, explaining the purpose of this document and its role in the subsequent process (i.e. development of an impact assessment and subsequent decision on the type of Commission initiative). The focus was put on the shortcomings of the current EU cooperation on HTA which require validation, and on the policy options, which need to be further defined. The presentation also covered the study supporting the Inception Impact Assessment. It was clarified that, together with the information provided by the public consultation, the study will provide facts and figures to the European Commission for fine-tuning the policy options and assessing their possible impacts.

CRA gave an overview of the study conducted. Its main aim was to map common barriers and drivers for using EU REA in national settings. The study covers nine countries (France, Germany, Italy, Netherlands, Norway, Poland, Spain, Sweden, and England) presenting industry's perception on the position of stakeholders, the national processes and actions related to the potential use and acceptance of EU REA at national level.

Discussion

- DG SANTE thanked EFPIA and CRA for conducting the study and the presentation.

DG SANTE pointed out the importance of sharing the findings of the study with Work Package 7 of EUnetHTA, which works on the national uptake of joint reports, led by NICE UK (WP7). EFPIA and CRA confirmed that they have already been in contact with NICE, informed them about the study and will continue to keep them updated about the findings.

Timelines were also discussed. The timely availability of the EU REA report (close to the CHMP decision or EPAR publication) is necessary for adoption by national systems. The CRA study has identified “ideal” timelines of submission, assessment, and availability of national HTA reports in the 9 countries and compared it with “ideal” timelines set out by EUnetHTA. Under these “ideal” timelines, it was considered that having an EU REA report available at time of EPAR publication would be early enough to directly input into national processes by replacing some of the local assessment in the majority of countries (even if sometimes limited to certain sub-categories of products). Specific challenges related to systems with integrated cost-effectiveness assessments need to be addressed. DG SANTE added that there is a considerable effort from EUnetHTA to bring forward the time of EU REA availability by conducting the clinical assessment parallel to the authorisation process. EFPIA representatives also underlined that most of these “ideal” timelines are not realistic for all products and all countries, and that it would be interesting to compare them with average timelines. Differences in methodologies also remain, but most surveyed countries considered there were ways to address these differences.

DG SANTE answered to a number of questions to clarify the scope and timeline of the study supporting the future impact assessment. EFPIA highlighted the importance of sharing information (in particular on the products on the case studies) as early as possible.

Follow up

Once the findings of the study are finalised, EFPIA will share the conclusions with DG SANTE.

As agreed already in previous meetings, EFPIA and representatives of the pharmaceutical industry will provide their views on the Inception Impact Assessment and their input during the open public consultation. In addition, companies' representatives expressed interest to provide data to the consortium led by SOGETI.