EUROPEAN COMMISSION
DIRECTORATE GENERAL FOR HEALTH AND FOOD SAFETY

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

Meeting with EuropaBio

Date: 19/05/2016

Location: EuropaBio office

Participants

EuropaBio: Thomas Bols, Emmanuel Chantelot, Douglas Gregory, Kåre Hansen, Angelika Joos, Stephanie Lane, Flaminia Macchia, Myriam Zylberman, Nathalie Moll, Miriam Gargesi, Riccardo Mezzasalma, Alex Gibbs

DG SANTE: Flora Giorgio, Ioana Siska

Purpose of the meeting

The meeting was convened at the request of EuropaBio and allowed the Commission to present the state of play regarding EU cooperation on HTA as well its plans for the future.

Discussion

The Commission presented the current state of play on the EU cooperation on HTA, which includes a strategic and an operational (scientific and technical) arm.

The strategic arm is represented by the HTA Network introduced by the Cross Border Health Care Directive[1] and the operational/technical arm corresponds to the EUnetHTA Joint Actions[2]. It was clarified that the EU cooperation on HTA started with EU-funded projects and was followed by Joint Actions (i.e. EUnetHTA 1 and 2 ran from 2010-2012 and 2012-2015 respectively), with a third Joint Actions to officially start in June 2016 and last until 2020. Overall participation in the Joint Actions was/is very high and the latest Joint Action 3 has more than 70 members and observers; industry and other stakeholders will be also involved.

Concerning the HTA Network, it was mentioned that the next of the bi-annual meeting will take place on 20 May and among the major points on the agenda are the adoption of the Multi Annual Work Programme for the period 2016-2020 and a discussion on the draft Reflection Paper on synergies between regulatory and HTA issues. The Reflection Paper aims

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF
[2] http://www.eunethta.eu/

at identifying activities along the life-cycle of health technologies in which cooperation between regulatory and HTA bodies can contribute to facilitating efficient access to effective, safe, innovative, and added value technologies and should be adopted by the HTA Network in November 2016. EuropaBio had the opportunity to provide feedback during a stakeholder meeting convened by DG SANTE on 20 April 2016.

The work-plan of the new Joint Action 3 was briefly introduced. The emphasis was put on the work-packages on joint production (WP4) and early dialogues and real world evidence generation (WP5) which could be of interest for EuropaBio members. The importance of the recommendations provided by the SEED (Shaping European Early Dialogues) project was also underlined, with the final report of the project to be made public by mid-2016. Following queries, it was clarified that the focus will be on Joint clinical assessments, but full assessments are also possible. In relation to early dialogues, the JA plans both parallel regulatory-HTA scientific advices as well as multi-HTA early dialogues (depending also on the demand from companies).

Finally it was mentioned that the Commission plans to launch a broad stakeholder consultation on the next steps for further strengthening EU cooperation on HTA and the participation of EuropaBio and its members was strongly encouraged.

During and after the Commission presentation, several issues were brought forward by the participants:

- Use of the joint work (e.g. joint REA) at national level, as an important factor for decreasing duplication of work for companies interested in entering on several EU markets, thus ensuring faster access for EU patients. The Commission expressed interest in receiving data on the costs of duplication from EuropaBio members.
- Stakeholders' involvement in HTA Network and EUnetHTA Joint Action 3 activities. It was clarified that even though the "stakeholders' forum" as organised by Joint Action 2 will disappear, during Joint Action 3 stakeholders will be asked to contribute to specific topics according to their interest and expertise. In addition, the Commission is planning to launch a call for expression to identify a pool of European umbrella organisation representing key stakeholders, with an interest in HTA. The pool will be asked to propose their representatives to become Observers to the meetings of the HTA Network, and it will be consulted on an ad hoc basis on HTA Network activities. It was explained that only 2 stakeholders per category (i.e. patients, health care providers, payers and industry) will be accepted.
- Sustainability of the current model of EU cooperation. In case of a "fee for service" mechanism, the companies would be interested to be able to choose the HTA bodies corresponding to the Member States where they plan entering first.
- The future of the two procedures for the parallel regulatory-HTA scientific advice, as developed by EMA and SEED respectively. Companies expressed concerns on two parallel procedures. It was clarified that one of the major recommendations from SEED was to merge the two procedures and this issue will be tackled by WP5 in EUnetHTA Joint Action 3. Probably a phase in will be implemented during the EUnetHTA Joint Action 3 activities.

Conclusions

EuropaBio will follow the HTA policy developments at EU level and expressed its willingness to contribute to stakeholders' consultations and EUnetHTA activities. The Commission also welcomes contributions from EuropaBio on concrete ideas on how the HTA cooperation at EU level could function to address some of the current identified limitations. Other bilateral meetings could be envisaged in the future.