EFPIA

Date: 10/05/2016

Location: DG SANTE offices

Participants

Representatives of EFPIA: E. Frénoy (Brussels'office), Petra Keil (EFPIA President Team, Novartis)

SANTE: F. Giorgio, O. Nagy (DG SANTE)

Purpose of the meeting

EFPIA had made a request on 27 April to have a meeting on the following two topics

1. The EFPIA- EUnetHTA event `joint REA at time of launch involving Member States' HTA authorities and company representatives` (scheduled for 7/6/216 in Paris)

2. The potential of EU cooperation in early dialogues

Discussion

Agenda item 1. EFPIA- EUnetHTA event on joint REA

EFPIA informed the EC on agenda items for the meeting, which is foreseen for 7th June. A short discussion followed on how to make most of the event. EFPIA position was that one of the key topics, the national implementation of the EUnetHTA Relative Effectiveness Assessment (REA) report in national HTA activities shall be given sufficient time for discussion. There was a concern that the meeting may repeat previous ones and devote too much time to the description of current activities, the objective, in the views of EFPIA was to provide time for discussion on next steps. The list of participants is not yet finalised, but it will include EFPIA member companies interested to explore the opportunity of joint REA, HTA bodies, EUnetHTA Joint Action, European Medicines Agency, and European Commission representatives. The participation of MS and in particular individuals from HTA bodies responsible for national pharma assessments as part of the reimbursement process is a key success factor of the meeting.

EFPIA pointed out that industry has an interest in making the joint REA a useful exercise; otherwise there is a risk of wasting resources, benefit to member states and loose the commitment of the

companies which so far are willing to take part. DG SANTE added that collaborating on a joint REA is a learning process; the willingness and the capacities of Member States (MS) to participate may vary, but all can benefit, in particular smaller MS. EFPIA is committed to engage into discussions and pilot the joint REA with interested MS.

EFPIA concluded that EFPIA hopes that the technical discussion during this meeting will evolve into a political commitment to integrate joint REA reports in national access pathways, potentially through discussions on EU level, under one of the following EU presidencies or other Member State leadership.

EFPIA mentioned that the Dutch Minister of Health is organising an informal roundtable on the 19th May for MS and executives of pharmaceutical companies to discuss various relevant issues and the possibility of future dialogue.

Agenda item 2. Early Dialogues

DG SANTE explained how the early dialogue efforts in EMA and the EUnetHTA JA complement each other. For the early dialogue to be useful, it is important that the two processes which are currently in place to provide HTA-Regulatory scientific advice both have the same objective and both are testing different modalities. The common objective is to build the necessary synergies between the HTA and the regulatory requirements, when possible and streamline the process in the best interest of HTA Bodies and company. Avoiding duplication with national HTA scientific advices shall also be considered and aimed for.

It was added that the draft report from the SEED project (Shaping European Early Dialogues for health technologies, funded by the EU Health Programme) will be shortly published, and feedback from EFPIA on the proposed recommendations for a way forward will be welcome.

Follow up

DG SANTE thanked the representatives for the meeting and informed EFPIA that EC will join the meeting on the 7th June.