Document 25

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Sent: Thursday, June 27, 2019 2:44 PM
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Subject: FW: efpia meeting 25/6/2019

Dear All,
Please find below a report from a meeting with EFPIA that took place this Tuesday, prepared by [redacted] and [redacted]
Best,
[redacted]

Meeting between DG Anne Bucher and EFPIA DG
25/06/2019

Participants
SANTE: A. Bucher; A. Rys; [redacted]
EFPIA : [redacted]

Health Systems
EFPIA recalled the European Health Summit recommendations and the follow up that is now developing through a multistakeholder process involving 28 organisations; another summit is planned Q1 2020 which will focus on measuring outcome; they highlighted the importance of such an approach and called for formalising this into a " high level forum" modelled on the pharmaceutical forum that existed a few years ago. They were not really able to describe the type of susbjects that could be discussed there and the actual format and nature of the work. They would expect the Commisison to define these. Their interest is in access to innovative treatments for the patients (and not so much in access to health care as such)
Anne Bucher highlighted the references to health systems and access to healthcare made in recent strategic documents (Sibiu paper, Council strategic agenda, EP)
EFPIA felt that this also resulted from their own advocating; they would welcome more cooperative actions between MSs but not in the format of the regional voluntary collaborations that have developed in the last few years. They are also unhappy with some of the rhetoric and provocative action taken by some MS (NL in particular) which they feel are questioning the stability of the regulatory environment.

HTA
EFPIA stressed that they continue to be supportive of the HTA proposal and that joint work on scientific advice and clinical assessments makes a lot of sense and can contribute to patient access. EFPIA underlined, however, that a future legislation needs to be predictable, remove duplications and ensure a level playing field. EFPIA companies contributes to the current project based Joint Action (EUNetHTA), but see clear shortcomings with such a project based system that is fully

voluntary. Anne Bucher referred to the need for some flexibility and , in that context mentioned the amended text voted by the European Parliament , but confirmed that the Commission sticks to the key principles of non-duplication and use by Member States.

Incentives

EFPIA thanked the Commission for bringing together the different stakeholders for open dialogue at the Conference on Medicines for Rare Diseases and Children. The complained though that the report presented to the plenary from the break out session on incentives did not fully reflect the discussions at the session and did not accurately presented the current incentives for innovative products e.g. market exclusivity being presented as a monopoly tool without taking into account possible competition from products that demonstrate superiority. EFPIA complained for not having the opportunity to comment further during the open space. DG SANTE explained the principles of the method of participatory leadership where the rapporteur's role is to present three main takeaways due to time restrictions, but not reopen the discussion at the plenary. DG SANTE reassured EFPIA that we will keep track of all the ideas raised in both the breakouts and the Open Space. It was clarified that the views harvested at the conference will be only one of the inputs to the Commission evaluation report which is mainly based on the evaluation study carried out by Technopolis.

On development of new antibiotics, EFPIA highlighted the need for pull incentives that take into account requirements for prudent use. They are carrying out a study on this topic and will come back with the results and proposals in Autumn.

Regulatory framework

EFPIA expressed concerns about opening the regulatory framework on pharmaceuticals. They informed that the REVEAL study on real world evidence and complex clinical trials, carried out by Technopolis is completed. EFPIA will not publish their own report but Technopolis will make a publication in Autumn. One of the concerns raised in the study relate to the limitations for sponsors to submit multiple substantial modifications to ongoing trials in parallel, where EFPIA questions the Commission's strict interpretation and has concerns with the IT Portal which is currently under construction. EFPIA also informed about a legal analysis carried out by a legal firm on behalf of EFPIA about the fit for purpose of the legal framework in light of new developments. EFPIA noted that the study concludes that such developments can be accommodated in the current framework and commented that it is a matter of interpretation of law.

Anne Bucher asked EFPIA to share the conclusions of the two studies, especially those of the Technopolis study since the contractor was the same as for the Commission study on the orphan regulation; this is an issue which was examined by DG SANTE for CoI and previously discussed both with EFPIA and Technopolis.

EFPIA committed to come back to SANTE with the results of the studies the week of 1st July following their board meeting.

Use of compound preparations in the NL: **EFPIA** brought up the issue of the NL policy to allow the use of compound preparations instead of authorised orphan medicines for economic reasons. They claimed that this is in breach of the EU legislation. They will send a letter with more details on this topic.