EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical products: quality, safety, innovation

SANTE MEETING WITH EFPIA

Date: 16/06/2016

Location: DG SANTE office, Brussels

Participants

EFPIA: E. Frénoy (EFPIA Brussels'office), Jakob Riis (Novo Nordisk), Troels Rye Andersen (Novo Nordisk), Morten Frank Pedersen (Novo Nordisk)

SANTE: D. Schnichels, F. Giorgio, I. Siska, C. Larsson Lindqvist

Purpose of the meeting

EFPIA with their member Novo-Nordisk (NN) requested a follow up meeting to the conference at the Danish Permanent Representation on 16 March 2016. In particular NN wanted to explain in more detail its views on EU cooperation on clinical assessment (REA).

Presentations

EFPIA submitted that there is a need to find new models as regards market access of pharmaceuticals where outcome based assessments and value based pricing should be explored. Business predictability is an important element for deciding whether a new product should be developed. Also for the national health systems it would be important to assess how the products perform in real life. The main challenge is how to implement the concepts and more specifically how data could be collected in real life.

In terms of HTA, EFPIA called for a strengthened EU cooperation on clinical assessment. A big concern for industry are the different procedures and methodologies applied by national HTA agencies. Multiple requests for evidence were also a reason causing delays in patients' access, as well as increasing costs. Therefore EFPIA advocated that the cooperation on REA should be strengthened at European level, in particular by harmonising the clinical parts of the assessments. EFPIA also underlined that for economic considerations/domains, the assessments should remain national.

Discussion

DG SANTE acknowledged the ongoing research and debate on outcome based assessment/value based pricing but reiterated that pricing and reimbursement is a Member State competence and will remain so.

In reply to a question from DG SANTE EFPIA argued that there is a need to establish a sustainable mechanism of the EU cooperation - after the EUnetHTA Joint Action 3 ends in 2020. EFPIA does not have a fixed position whether the permanent structure should be attached to EMA or another sustainable solution should be found.

Follow up

SANTE asked EFPIA to share data, case studies and experiences on how health technology developers experience HTA in the EU and how the EU cooperation may address these issues.