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 DG SANTE B4 and AIM

Date: 19/01/2017

Location: DG SANTE

Participants

Catarina Lopes Pereira, Isabel Klinnert (Teva), Erika Satterwhite (Mylan) representing Medicines for Europe

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Orsi Nagy, Carl Larsson Lindqvist, Flavia Testa (DG SANTE B4)

Anja Laschkolnig, (Austrian Public Health Institute GÖ FP)

Purpose of the meeting

Medicines for Europe has requested a meeting with DG SANTE to discuss the survey on the impacts of the Commission's initiative regarding EU cooperation on HTA post 2020.

Discussion

- Medicines for Europe gave a short introduction to the concept of value added medicines. It is a relatively new sector, covering medicines which are known molecules that bring an added value through for example a new indication (drug repositioning), finding a better formulation or dosage (drug reformulation), or developing a combined drug regimen, adding a new device or providing a new service (drug combination).
- The market access path and value proposition of value added medicines was discussed. Medicines for Europe explained that the added value of such medicines is often not recognised as typically these products are considered generic medicines and so they do not have a choice to undergo HTA. Moreover, certain attributes, such as improved quality of life or patient satisfaction, as well as, better patient adherence play only limited roles in HTAs across Europe.
- Medicines for Europe expressed an interest in a more active participation in the joint HTA at EU level (e.g. voluntary for pharmaceutical industries but mandatory uptake in Member States that opted-in; common template/tools) and highlighted the importance of the eligibility of Value Added Medicines in this process. They found industry fees also be acceptable – if the fees are linked to a technology undergoing a joint assessment and they are not a general fee for all pharmaceutical companies. Furthermore, Medicines for Europe believes that the economic aspects of HTA should be the responsibility of Member States.

- Medicines for Europe considered that a positive impact of the improved cooperation could be the improved predictability, especially if value added medicines are recognised for their attributes in EUnetHTA's common tools. Early dialogues are considered to have potential to determine the necessary level of evidence and support a better understanding for all parties if outcomes of early dialogue are honoured in the subsequent HTA process.
- DG SANTE set out shortly the main elements of the "Initiative on strengthening of the EU cooperation on HTA" as set out in the Inception Impact Assessment, published on the 14th September. DG SANTE explained the purpose of this document and its role in the subsequent process (i.e. initiating discussions to develop an impact assessment and inform subsequent decision on the type of initiative).
- DG SANTE summarised the aim of 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.
- The different sections of the survey were discussed; e.g. accessibility of medicinal products, costs for healthcare systems as well as innovation and research and the consequent importance of the recognition of the value of these medicines).

Follow up

DG SANTE thanked the participants for the meeting and encouraged them to submit a response to the survey despite the challenges of data availability. DG SANTE received further information on the market access path of the value added medicines after the meeting. Medicines for Europe and DG SANTE agreed to continue the dialogue.