



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD
SAFETY
Health systems, medical products and innovation
Medical products: quality, safety, innovation

SANTE meeting with Industry Stakeholders on study on `Impact analysis of policy options for strengthened EU cooperation on HTA`

Date: 07/11/2016

Location: DG SANTE, 4 Rue Breydel, Brussels

1. Introduction

The event was organised by the European Commission in relation to the upcoming study on `Impact analysis of policy options for strengthened EU cooperation on HTA` carried out by the Austrian Public Health Institute (GÖ FP), the London School of Economics (LSE Health) and Sogeti (contractors). Partially connected via telcom, representatives of the contractors, industry representatives of European Federation of Pharmaceutical Industries and Associations (EFPIA), the European Association for Bioindustries (EuropaBio), Association of the European Self-Medication Industry (AESGP), Medicines for Europe European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) and MedTech Europe (EDMA and Eucomed) as well as members of DG SANTE participated in the meeting. The meeting aimed at updating the industry representatives on details of the upcoming studies as well as to answer their questions in order to facilitate the data collection and to maintain a continuous dialogue between the contractor and the European Commission on one side and the stakeholders involved in the study on the other.

2. Introductory Update

After an introduction of all participants, the Contractor's representatives updated on the current phase of the study and the necessary steps referring to the two pager, circulated amongst the participants prior to the meeting(see annex). It was laid out that the study will consist of two different parts, firstly a case study on a sample of health technologies and secondly the survey on the impact of the policy options put forth in the Commission's [Inception Impact Assessment](#) .

The case study which will be led by LSE will target a number of selected medical products and examine primarily the role of HTA in market access. The products have mostly been selected already to create a representative sample of pharmaceuticals, medical devices and other products.

The survey will address the manufacturers of health technologies via direct questions on the probable impact of the different policy options; the questions are previewed to be sent out by the end of November and the responses are being expected by mid-January.

3. Discussion

During the discussion, the representatives of the EC and the contractors aimed to answer a number of questions submitted by industry prior to the meeting as well as to precise aspects of the study unclear to industry thus far.

- Details on the criteria which were used to select the products of the case study were given referring to the better regulation guidelines and it was stated that the list of products would not be published at this point. The case studies will focus on the technologies/process that have already undergone HTA. Additionally, it was specified that some products that underwent joint HTA through EUnetHTA JA during the past three years had been selected.
- SANTE stated that manufacturers refusing to participate in the case study would be replaced by others. At the same time, if there is a lower participation from certain sectors or sections in the case study as well as in the survey, it would be duly noted that these sectors have been given the opportunity to get involved in the current dialogue, but chose not to participate.
- It was stressed that the contractor's task would be limited to data collection as in collection of facts and figures. The actual assessment of the policy options, based on the study's results would be solely the responsibility of the EC. The methodology and the selection of the indicators will closely follow the recommendations in the Better Regulation Guidelines.
- Industry articulated concerns considering the short available timeframe of the study referring amongst other things to the busy period over Christmas and prior pilot experiences. SANTE acknowledged the concerns but pointed out the overall timeframe of the initiative, which needs to ensure that a mechanism is in place by the end of the EUnetHTA JA3 in 2020.
- Where possible hindrances due to the transmission of economically sensitive data were brought up, SANTE stated their awareness of necessary confidentiality and confirmed that the EC's statutory obligation of confidentiality is in place. Referring to antitrust considerations, it was suggested that industry transmits sensitive data directly to the contractor who is equally bound by confidentiality obligations.
- Industry asked if they could suggest products which from their point of view represent suitable objects to the case study. SANTE and the contractors replied that the earlier the suggestions would be received, the more they could be considered; an inclusion could however not be guaranteed.
- Considering the survey it was stated that the policy options/business models put forward in the Inception Impact Assessment might theoretically still be modified if new options emerge from the results of the open public consultation or discussions

with MS. So far, stakeholders consulted did not raise new policy options. The final options including the business models would be published in the upcoming Impact Assessment by the EC.

4. Follow up

- The companies participating in the **case studies** should be contacted in advance to facilitate the process. Industry representatives offered help in identifying the contact points in the companies. This would be done without disclosing the product list. Interviews with the companies will take place in the beginning of 2017.

- A draft questionnaire will be piloted. As soon as the survey is available, it will be sent to the industry association, who will assist in identifying the contact person within the company(ies), and assist in transferring the questionnaires for the companies. Companies will send their answers directly to the Contractor.

- Industry was also invited to participate in the **ongoing public consultation**.

5. Conclusion and closure of the meeting

SANTE concluded the meeting expressing that it had been a fruitful and constructive dialogue between the EC and the representatives of industry which would have to be continued during the ongoing process of assessing the future of European cooperation on HTA and thanked all participants for their respective contribution.