



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

SANTE MEETING WITH MEDTECH EUROPE

Date: 17/02/2017

Location: DG SANTE offices, Brussels

Participants

Representatives of MedTech Europe: Yves Verboven, Victoria Wurcel, Lisa Boch-Andersen, Timea Rezi-Kato

DG SANTE: Dominik Schnichels, Orsi Nagy

London School of Economics (LSE): Panos Kanavos (for the agenda point on the study)

Discussion

The meeting was requested by MedTech Europe (MTE) to discuss the following issues

- MTE proposal for strengthening EU HTA cooperation
 - Progress on the Impact Assessment on the initiative for Strengthening of the EU cooperation on Health Technology Assessment (HTA)
 - Progress of the study on the impacts of strengthened HTA cooperation by the Austrian Public Health Institute, Sogesti and LSE (Panos Kanavos, leading the LSE team the joined for this part)
 - HTA Network Stakeholders Pool
 - HTA Network next initiatives
 - Stakeholder participation in EUnetHTA Joint Action 3
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- MTE presented their proposal for strengthening EU HTA cooperation, which emphasises the differences between the pharmaceutical and the medical technologies sector, in terms of the market access path, the country specific role of HTA in aiming to inform decision making (primarily not pricing and reimbursement decisions and at different times leading to little opportunity for cooperation) as well as specificities in effectiveness evidence generation. Therefore the planned cooperation model foreseen for pharma cannot be superimposed and the negative impact and unintended consequences were expressed. To obtain a valuable cooperation, MTE proposes a Modern HTA cooperation in Europe for MedTech. It proposes a voluntary, non-legislative collaboration of Member States, operating in several collaborative groups of Member States smaller than EU 28, driven by decision maker's demands on what to collaborate on. These collaborative groups can be dynamic, and should be based on the demands and common needs of specific countries at specific times, supporting decentralised decision-making. The coordination and funding is provided by the EU primarily, using existing funding streams (to be explored). The

cooperation should focus on the value of 'transformative technologies', which have the ability to address high unmet needs in clinical, social and/or health systems common to several Member States. Member States need to agree on predictable criteria for prioritising medical technologies. CE marking and HTA systems should remain distinct processes given the different objectives and taking into account the new legislations'. In the discussion, the concepts of transformative technologies, thematic clusters and funding were further clarified. DG SANTE asked whether – in the assessment of MTE – this particular form of voluntary cooperation would be sustainable. MTE shared several possibilities currently being explored in collaboration with different stakeholders to further support a voluntary sustainable HTA cooperation in Europe, and proposed to follow up on that discussion.

- DG SANTE gave a brief update on the Impact Assessment on the initiative for Strengthening of the EU cooperation on Health Technology Assessment (HTA). The public consultation has been closed; results are foreseen to be published in Q2 2017. The impact assessment is foreseen for Q4; it will be published with all the supporting documents (the large study on the impacts of policy options and the two small studies on methodology and processes).
- Panos Kanavos, leading the LSE team of the study, gave an update on the progress of the study on the impacts of strengthened HTA cooperation. The survey has been closed and there was a good response rate, in particular from medical technologies companies. Now, interviews are being conducted with selected companies to gather more in-depth information. Companies are interested in the interviews; contacts have been made to the responsible people in the companies and interviews are on the way. MTE offered to assist with finding the right contacts, if there the need emerges. Panos Kanavos indicated that the companies are reacting positively to the interview requests. He also offered to conduct an interview with MTE to get a better understanding of their views as a representative of the sector.
- HTA Network Stakeholders Pool. DG SANTE has assessed all the applications to the Call for expression of interest launched on 13 December 2016 and informed the applicants. Members are grouped into four categories (patients/consumers; healthcare providers, payers and industry and are now asked to nominate two representatives per category to be proposed to the HTA Network as observers. MTE inquired if DG SANTE has any preference with regards to the allocation of the representatives. DG SANTE confirmed that it is up to the stakeholders to agree on the two representatives, but representatives are expected to coordinate the input of all participants in their category in advance, represent it during the meeting and provide feedback afterwards.
- HTA Network - next initiatives. MTE was particularly interested in the Reflection paper on efficient joint cooperation on HTA of Medical Technologies and the reuse of assessments at national/regional levels. DG SANTE confirmed that the priority for the Network is currently to continue working on the Synergies paper on pharmaceuticals and support the development of the strengthened cooperation on HTA post 2020.
- Stakeholder participation in EUnetHTA Joint Action 3 was very briefly touched upon; DG SANTE informed MTE that the work packages of the Joint Action are progressing. Nonetheless the last year has proved that launching and coordinating a project of 80 partners requires substantial resources.

Follow up

DG SANTE and MedTech Europe agreed to continue the discussion.