



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Brussels, 30th January 2019

SUMMARY RECORDS OF THE 1st STAKEHOLDER POOL MEETING OF THE HTA NETWORK

Wednesday 16th January 2019

1. INTRODUCTION

These records were prepared by the Secretariat of the Health Technology Assessment Network ("HTA Network") in accordance with its rules of procedure.¹

The meeting aimed to contribute to the HTA Network Multiannual Work Programme – specifically to point 3.3. on how to "facilitate appropriate involvement of all interested stakeholders in the European collaboration in HTA, notably patients, health professionals, healthcare industry, and payers".²

The discussion was chaired by Mr Andrzej Ryś, Director, Health systems, medical products and innovation DG Health and Food Safety, European Commission (EC).

With the agreement of all participants to the Stakeholder Pool, this meeting was recorded and the list of participants will be circulated.

The PowerPoint presentations are available on the HTA Network website.³

2. WELCOME AND OPENING

The Chair, *Andrzej Ryś*, welcomed participants at the first face to face meeting of the HTA Network's Stakeholder Pool and highlighted that this is an important milestone in the ongoing process of the stakeholder involvement. The two new members, EORTC – European Organisation for Research and Treatment of Cancer and ARM - Alliance for Regenerative Medicine, were introduced. Currently the Stakeholder Pool gathers 33 European umbrella organizations which have been selected through an open call for expression of interest. The member organizations are grouped in four pillars representing: (1) patient/consumers; (2)

¹ https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/ev_20161110_co03_en.pdf

² https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2016_2020_pgmnetwork_en.pdf

³ https://ec.europa.eu/health/technology_assessment/events/ev_20190116_en

providers (e.g. health care professionals and academia); (3) payers; (4) industry (both pharmaceutical and medical technologies sectors).

The Chair recalled the strategic objectives of the Stakeholder Pool: (1) to contribute to the development related to HTA at EU level; (2) to ensure that the views of different stakeholders are reflected in the policy development in a balanced way; and (3) to create synergies between different stakeholders. He thanked the members of the Stakeholder Pool for their continued interest, support, constructive and critical contributions to the European cooperation on HTA: the HTA Network, the Joint Action as well as the proposal of the EC.

The Chair presented the agenda of the day and announced that, following the participants' agreement, this meeting's summary records, presentations and list of participants would be circulated among the participants for approval; the final records and presentations would subsequently be published on DG SANTE website.

3. UPDATE ON EU COOPERATION ON HTA

The first topic discussed was devoted to the engagement of stakeholders in the EU cooperation on HTA.

Flora Giorgio, Head of Sector, DG SANTE provided an overview of EC commitment to stakeholders' involvement in HTA cooperation in all its different components (i.e. the HTA Network, EUnetHTA and the preparation and ongoing discussion on the EC proposal). She also gave a factual update on the status of the inter-institutional negotiations of the EC proposal for EU cooperation on HTA and the next steps (see presentation for details).

In the discussion that followed, the following points were made:

- The stakeholders called for the continuity of the EU HTA cooperation post 2020 to be ensured;
- The importance of the involvement of all stakeholder groups was highlighted; the participation should be inclusive with a view to gender and age to provide relevant input;
- The development of transparent and solid conflict of interest policies vis-à-vis industry and all stakeholders is a pre-requisite in order to ensure trust from stakeholders as well as Member States; the EUnetHTA Joint Action will shortly publish their Conflict of Interest Policies.

4. EUNETHTA UPDATE ON CURRENT AND FUTURE STAKEHOLDER INVOLVEMENT

The representative of EUnetHTA Joint Action and the work package leaders presented an update on current and future stakeholder involvement. In particular, they reported on the stakeholder engagement in the joint work: early dialogues and joint assessments (see presentation for details).

Following the presentation, there was a discussion on the overall stakeholder engagement policy of the EUnetHTA Joint Action. The specific contribution that the different stakeholder groups could bring to the joint work (with a focus on early dialogues and joint assessments) was explored; however, a challenge is to ensure stakeholder involvement in a way that it provides high quality input within the tight timeframe of the joint work – the timely

availability of the joint reports is key to allow Member States to use the reports in national healthcare decision-making (uptake).

5. PARALLEL SESSIONS

In the afternoon, the breakout sessions addressed two topics:

- A. The involvement of patients and clinical experts in joint work;
- B. Horizon scanning and prioritization of joint work – the second session was further broken down in two: one for the pharmaceutical and one for medical technologies sector.

In both topics, a number of rather concrete ideas were discussed and proposed to be further explored and possibly tested within EUnetHTA and possibly be used in any implementation of future cooperation.

Group A: Patient and health care professional experts' involvement in the joint HTA work

The session was co-chaired by DG SANTE and BEUC, the European Consumer Organisation. It started with a scene setter by EURORDIS, as a representative of patients in the Stakeholder Pool. The lively discussion confirmed that the stakeholder community considers important to have a systemic engagement of patients and health professionals; at the same time to leave enough flexibility on the detailed modalities of involvement of relevant experts, mainly patient and clinical/healthcare experts, in the different output (i.e. joint clinical assessment and joint scientific consultations). Stakeholder representatives called for ensuring that general key principles of stakeholder engagement are agreed at EU level and implemented consistently. The conflict of interest policy was referred as one concrete example in which such approach is essential to secure trust and acceptance of the cooperation.

Group B PHARMA: Cooperation on identification and prioritisation of health technologies for Joint work

The session was co-chaired by EUnetHTA Joint Action and EFPIA, European Federation of Pharmaceutical Industries. EFPIA gave a short presentation on the industry's views on horizon scanning and topic prioritisation. The Stakeholder representatives agreed on a common understanding on horizon scanning – such an information exchange needs to have a pragmatic approach to identify relevant technologies. The importance of using an agreed definition for unmet medical needs was considered essential if had to be used as a criterion. Regarding the timelines, horizon scanning should look at medicinal products 6-12 months prior to submission to the European Medicines Agency (“EMA”) for regulatory approval. Industry indicated an openness to exploring whether they could share with EUnetHTA information on medicinal products that they plan to submit to EMA (several months before the actual submission for marketing authorization). Currently this information is available to EMA as part of a pre-notification procedure - however EMA cannot share the information with third parties. This information would allow EUnetHTA a more timely planning and preparation for joint clinical assessments and give a longer term perspective to the work.

Group B MEDTECH: Cooperation on identification and prioritisation of health technologies for Joint work

The session was co-chaired by DG SANTE and MedTech Europe. It started with a scene setter by EUnetHTA Joint Action on their work in to develop and refine a system of horizon

scanning, topic selection and prioritization for medical technologies. The following discussion focused on the need to define common criteria for prioritizing technologies in particular for joint clinical assessments. Two approaches were proposed for identifying new technologies (1) to focus on the new technologies (2) to first identify health policy/disease areas of interest and then the relevant technologies. The concept of transformative technologies (addressing unmet needs; leading changes in the organization of care/patient pathways; potential to add value) was considered an important one; however, there needs to be a common understanding to its definition to be able to use it as a possible criteria for prioritization of joint work, both within EUnetHTA and in any possible future framework. Following the meeting, a schematic representation of the transformative technologies was presented by medical technologies industry representatives (see Annex 1. – *also open for comments*). From the perspective of the industry, it was noted that horizon scanning – and broader, topic prioritization - has the potential to improve predictability for industry and improve the relevance of joint clinical assessments for healthcare decision makers.

The common messages emerging from the three groups were that the ideas above and the several others which were raised during the discussion need further reflection. Therefore some follow up meetings would be extremely useful both for the short and longer term cooperation. Finally, the possibility to invite members of the HTA Network (Member States Authorities) for future discussions was suggested.

6. CONCLUSIONS AND CLOSURE OF THE MEETING

The Chair thanked for the participation to the 1st Stakeholder Pool Meeting of the HTA Network and expressed the commitment of the EC and the EUnetHTA Joint Action to continue the dialogue with the Stakeholders.