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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Brussels,

DRAFT MINUTES OF THE 9th HTA NETWORK MEETING

FRIDAY 9 FEBRUARY 2018

1. INTRODUCTION

The Secretariat of the Health Technology Assessment Network ("HTA Network"), in accordance with the rules of procedure, prepared these minutes.

Austria was excused. All other Member States (MS), Norway and EUnetHTA were present. In addition, EMA and the following stakeholders' representatives from the HTA Network Stakeholder Pool (BEUC, EFPIA, ESIP, EURORDIS, MedTech Europe, PGEU and UEMO) attended the afternoon session as observers.

For the assessment of a potential conflict, no interests were declared. The meeting was chaired by the Director of "Health systems, medical products and innovation" DG Health and Food Safety. The meeting was recorded.

Presentations are available on the HTA Network website.[1]

2. WELCOME AND OPENING

The Chair welcomed participants. The Chair presented the agenda of the day, which was accepted by HTA Network participants and announced this meeting's minutes will be circulated among the participants for approval and subsequently be published on the DG SANTE website.

The morning part of the meeting was for HTA Network members only. The Chair recalled that the Chattenham house rules apply to the morning session.

[1] https://ec.europa.eu/health/technology_assessment/events/ev_20170329_en

3. EU INITIATIVE STRENGTHENING COOPERATION ON HTA (Topic 1)

The first topic discussed was devoted to presentation of the recently published EC legal proposal for strengthening cooperation on HTA.

The Director General DG SANTE, introduced the topic. He highlighted the reasons behind the published Commission legal proposal to carry out the HTA cooperation in Europe after 2020 and the relevant role of the HTA Network in steering the cooperation process. He gave some examples on how this proposal covers the needs of the HTA underlining the vision of a joint work on clinical aspects, leaving decision-making to Member States, and meets the specificities of different technologies, giving priority to the ones with in which EU cooperation can bring the greater added value.

The Head of Unit B4, DG SANTE, presented the Commission proposal, giving details regarding objectives, outcomes and key elements of the general provisions of the proposal a Q&A session followed the presentation.

4. HTA NETWORK SYNERGY GROUP (Topic 2)

The representative from the Italian Medicines Agency (AIFA) gave an update of the work of the HTA Network Synergy Group actives since mid-2017. The Synergy Group is mapping EU activities relevant for the cooperation, Mr Tafuri, provided an overview of the work carried out aiming at avoiding duplication and facilitating synergies between networks and/or Institutions dealing with HTA related topics (e.g. STAMP, HMA, EUnetHTA, EMA) . Preliminary results of the exercise were presented; areas of possible collaboration have been identified, such as definition of unmet therapeutic innovation, real world data and collaboration with EMA, EUnetHTA and HMA.

5. QUERY ON NUSINERSEN (SPINRAZA) IN SPEINAL MUSCULAR ATROPHY (SMA) (Topic 3)

The representative from the Croatian Agency for Quality and Accreditation in Health Care and Social Welfare, presented the results of a query concerning a recently approved (May 2017) orphan drug for 5q spinal muscular atrophy (SMA) under accelerated assessment due a significant unmet medical need. The query' questions were asked to the Member State authorities concerning the HTA process in each country, and some update on reimbursement status is available. Twenty-two Member States replied, and most of them had still the decision process ongoing. The Secretariat inform participants that the company contacted the Commission asking clarifications on the rationale for the agenda to be discussed and raising concerns on the confidentiality of the information on pricing negotiation. The company also offered to provide additional update on the status of the product in the different Member States. The point was noted, it was agreed to it is useful to receive update but the information shared between HTA Network members shall remain within the members. Some reply updates were given during the meeting and considerations about the interactions between HTA stakeholders, sharing of information and post approval evidence generation were discussed. In conclusion, it was highlighted that such requests are a good example of the usefulness of EU cooperation for national/regional level activities on HTA..

6. EU INITIATIVE STRENGTHENING COOPERATION ON HTA (Topic 4)

The afternoon session of the meeting was opened by a speech of the Deputy Director General DG SANTE, giving an overview of the Commission legal proposal on the HTA cooperation in Europe after 2020 in relation to the involvement of stakeholders and their participation in the process. He emphasised the constructive input received from all stakeholders, from the results of the open public consultation, which showed a broad support to the EU cooperation beyond 2020. The public consultation helped the Commission to understand better the challenges and the difficulties for implementing joint work. These challenges were addressed during many bilateral or multilateral meetings with Member States and stakeholders.

The Head of Unit B4, DG SANTE, presented the Commission proposal, giving details regarding objectives, outcomes and key elements of the general provisions of the proposal.

7. PATIENTS/CONSUMERS' ORGANISATIONS CONTRIBUTION TO THE HTA COOPERATION (Topic 5)

Representative from European Organisation for Rare Diseases, as representative of the patients and consumers in the Stakeholder Pool, gave a presentation on the principles of patients and consumers engagement in the HTA and on the criteria for prioritisation of technologies for joint HTA. A list of relevant principles for engagement, such as inclusion, visibility, relevance and responsibility, were introduced and defined. Regarding the prioritisation of technologies, the listed criteria for pharmaceuticals and non-pharmaceuticals were selected, and covered aspects such as complexity, benefit, prevention and costs.

8. JOINT ACTION EUNETHTA JA3 (Topic 6)

The Director of EUnetHTA provided an update on the work carried out under EUnetHTA Joint Action 3. He summarised some of the activities of the Joint Action, e.g. WP4 (Joint Production), WP5 (Evidence Generation), WP6 (Quality Management) and WP7 (National implementation and impact) (PPT available on HTA Network website).

10. CONCLUSIONS AND CLOSURE OF THE MEETING

The Chair thanked for the participation to the 9th HTA Network meeting and invited the HTA Network to the next 10th meeting in Brussels – date to be confirmed.