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APPROVED MINUTES OF THE 8th HTA NETWORK MEETING

WEDNESDAY 29 MARCH 2017

1. INTRODUCTION

These minutes are prepared by the Secretariat of the Health Technology Assessment Network ("HTA Network") in accordance with the rules of procedure.

Iceland, Slovakia were 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. AIM was excused. Were also present as speakers The contractors for the studies (Gesundheit Österreich GmbH, London School of Economics, Science&Policy, Stellalliance AB) supporting the European Commission in the Impact Assessment process for the strengthened EU cooperation on HTA were present for part of the meeting. Representatives of several European Commission services were also present.

No interests were declared for the assessment of a potential conflict. The meeting was chaired by Andrzej Ryś, Director, "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, ***Andrzej Ryś***, welcomed participants. The Chair presented the agenda of the day which was accepted by HTA Network participants and announced this meeting's minutes would 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 results of the ***online public consultation*** and the preliminary results of the ***study on the impact analysis of the policy options for strengthened EU cooperation on HTA***. Both of which have been carried out in preparation for the Impact Assessment (IA) (see website for more details).

Ioana Siska of DG SANTE provided an overview of the results of the online public consultation and the varying stances of the main stakeholders' groups on the policy options. She highlighted the reasons behind the differences in the preferred policy options for EU cooperation beyond 2020. A timeline of the upcoming steps in the preparation of the IA was put to the fore. It was clarified that the publication of the results is expected to come in the first quarter of 2017 (post meeting note: European Commission published the Report on 15 May 2017).

Following the presentation, Members raised questions on the topics included in the public consultations (such as governance of HTA cooperation, uptake of the results and duplication of work). Clarification was provided by DG SANTE.

The next part devoted to the exchange of views with the HTA Network Members was based on the questions on the scope, funding and governance of the EU cooperation on HTA. Flora Giorgio recalled the questions which were shared with the Members before the meeting.

Due to the time constraints only the questions related to the scope and funding of the initiative were addressed, the ones on governance were not discussed.

DG SANTE welcomed the constructive input received during the discussion and committed to continue the dialogue with Member States.

Following the discussion with the HTA Network Members, ***Claudia Habl*** and ***Anja Laschkolnig*** from Gesundheit Österreich GmbH, and ***Erica Visintin*** from the London School of Economics (LSE) presented the results of two (case study and online survey) of the three parts of the Study on impact analysis of policy options for strengthened EU cooperation on HTA. Firstly, the observations and result of analysing case studies of 40 health technologies were underlined. Secondly, the results from the survey process, which includes online survey and interviews, were presented.

Next steps:

- It was clarified by the Commission that the publication of the study will in all likelihood take place at the same time as the publication of impact assessment and the Commission proposal on the future of HTA beyond 2020 (publication foreseen for the last quarter of the year). Meanwhile, consultation meetings with the HTA Network Members, Ministries of Health, EUnetHTA partners and other stakeholders will continue.

4. INCEPTION HTA NETWORK STAKEHOLDER POOL (Topic 2)

Karolina Hanslik of DG SANTE presented the process of setting up of the HTA Network Stakeholder Pool. Following the Call for expression of interest (launched in December 2016), the Commission received a total of 39 applications. The Commission analysed the submitted applications in February 2017. Having verified that the Call's eligibility and added value

criteria were met, 30 organisations were selected for the HTA Network Stakeholders Pool. In accordance with the Call's provisions the organisations were divided into four categories, namely: (1) patients/consumers, (2) healthcare providers, (3) payers and (4) industry. Following the decision of the HTA Network in May 2016 to extend the representation of stakeholders to the HTA Network from one to two representatives per category, two nominations for each of the four categories (eight in total) were received by the Secretariat.

The list of eight nominations was shared with the HTA Network members and it was further explained that the organisations representing healthcare providers and medical technology industry proposed that one of their representative(s) would be on a rotational basis. It was also explained that the stakeholders participating in the HTA Network are tasked to consult the other members of the stakeholder categories before and after the actual meeting of the HTA Network (see website for more details).

Discussion and decision:

- Some Members asked how to handle new applications to become member of the HTA Network Stakeholder Pool. It was agreed that as the objective of the Stakeholders' Pool is to facilitate interaction with European umbrella organisations which are interested and relevant to the HTA scenario. The Pool will remain open to new applicants; however the new applications need to meet the Call's eligibility and added value criteria. The "late" applicants can not apply for the observer status to the HTA Network, until a renewal of the appointed observers will be initiated.

- The HTA Network Members unanimously agreed to accept as Observers to the HTA Network, the eight proposed nominations, including the two rotating seats, as representatives of the Stakeholders' Pool.

5. MAPPING STUDIES (Topic 3)

The afternoon part of the meeting was open to the HTA Network Members and Observers.

Julia Chamova from Stellalliance AB highlighted an excerpt of the results of the ongoing study aiming at mapping HTA national organisations and processes. Ms Chamova described the study – its objectives and scope, the utilised methods, and the expected limitations – and then underlined some preliminary results focusing on the different forms and structures of HTAs across Europe, including the different role HTA plays in the decision making process in the different Member States (i.e. informative, advisory or mandatory).

Following Ms Chamova's presentation, ***Prof. Finn Børlum Kristensen*** from Science & Policy presented the results of the other ongoing study aiming at mapping HTA methodologies in the EU. Prof. Børlum Kristensen pinpointed that the European HTA agencies assess a significant range of health technologies. Additionally, all MS and Norway include the four clinical domains in the assessments they do. Moreover, most of them include also non-clinical domains in their assessments depending on the question at hand. According to Prof. Kristensen the future in which following scientific and technical solutions and using best available evidence for valid and reliable comparison of technology options is near. Therefore, aiming at joint guidelines that are used at both national and EU level is a realistic goal. In support of this idea, he pointed out that a large majority of HTA institutions use reports from

other countries. In addition to that, most European HTA institutions have already written guidelines for assessments (see website for more details).

***Discussion*:**

Wim Goettsch (EUnetHTA) expressed appreciation for the results of the studies. UK asked whether a question on the average time it takes to perform a REA, had been asked. As the answer was negative, DG SANTE proposed to send a question to the HTA Network Members on the timing of REA (post-meeting note: the Secretariat was made aware that EUnetHTA WP7-National Implementation and Impact- has already collected this information from HTA Bodies. Therefore, the Secretariat decided not to ask these additional questions and the HTA Network).

6. SYNERGIES BETWEEN REGULATORY AND HTA ISSUES ON PHARMACEUTICALS (Topic 4)

Flora Giorgio of DG SANTE elaborated on the follow-up mechanism after the adoption of the Reflection Paper on synergies by the HTA Network in November 2016, namely *the Ad-hoc Synergy Group* that has been set up. The group contains an equal number of HTA representatives and regulators, gathered through STAMP (Commission Expert Group on Safe and Timely Access to Medicines for Patients) and HMA (Heads of Medicines Agencies). European Medicines Agency (EMA) is also part of the group as it was also in the HTA Network Working Group drafting the Reflection Paper.

Among its aims is to map the actions identified in the Reflection Paper, identify which network/body is doing what in specific areas/activities to support synergies and to avoid duplication of efforts. The idea of the synergy ad hoc group was shared with and supported by both HMA and STAMP. Both groups are also working on HTA related issues and plan to address the topic identified in the Reflection Paper. The *Ad-hoc Synergy Group* will include appointed representatives of each group, plus EMA, to make sure that the activities of the different networks/groups/body in such domains are complementary and do not duplicate.

Upcoming steps in the formation of the group include the election of rapporteurs, who will coordinate the mapping of the activities and have the responsibility to report to their respective organizations, thus ensuring that the output of the Synergy Group are reflected in the on-going activities of each organization (see website for more details).

Discussion and conclusion

During the discussion a concern was raised on the potential overlap between the joint activities of EUnetHTA and EMA, on the one hand, and the Synergy Group, on the other hand. An informal request was expressed to set up formal timelines within which the Synergy Group should be ready with its deliverables.

Ms Giorgio clarified that the Synergy Group is a follow-up mechanism, which sole purpose is to build upon the work carried out by EUnetHTA and EMA and extended to other networks/groups which are also developing similar topics. By following-up on their activities, the Group would avoid duplication – it would map the main actors and their activities; where the synergies lie.

7. NATIONAL DEVELOPMENTS ON HTA (Topic 5)

Kamila Malinowska from the Polish Ministry of Health presented the HTA system of the Health Policy Programmes (HPP) done by the Polish Agency for Health Technology Assessment and Tariff (AOTMiT). She described the rationale, the subject matter and purpose, along with their local/regional characters. The AOTMiT assesses among others the clinical effectiveness and safety of the HPP. Ms Malinowska clarified that while there is one systematic rule for carrying out HPPs, there often are specific local differences. In 2016 there were 202 opinions delivered on HPP and since 2009 around 2050 HPP were evaluated in the country, however most of them were done by the local governments. As an example of opinions, Ms Malinowska presented the case of the evaluation of vaccine programmes in Poland (such as HPV, influenza, pneumococcal, meningitis), (see website for more details).

Discussion:

The discussion engaged many Member States and stakeholders. One of the most discussed questions was the number of the regional assessments in Poland and it was clarified that there are many differences (population based) at regional level which require an assessment of all HPPs in Poland. Other part of the discussion was devoted to the assessment of vaccines (HPV) and divergent views on the effectiveness of the vaccines, it was therefore suggested that the vaccine assessments are shared with the HTA Network. Some HTA Network representatives suggested that Poland looks at the WHO recommendations as regards the positive opinions on vaccines HPV. It was further clarified by the speaker that Poland focuses its assessments not on the effectiveness of the vaccines but on the aspects related to the prevention and reduction of cervical cancer (including use of HPV vaccines). Those vaccination programmes are foreseen for the population of 11-12 years old girls and the duration of the programme is foreseen for 1-2 years. It was therefore concluded that the prevention of cervical cancer is difficult to achieve within this population and the proposed timeline. These programmes need to be coherent.

8. PROPOSAL FOR A REGULATION ON MEDICAL DEVICES (Topic 6)

Vincent Houdry of DG GROW gave an overview of the state of play of the revision of the regulation on medical devices, its key components, including derogations and mechanisms will be put in place to implement the new Regulation. The clinical evaluation, carried out by notified bodies, the scrutiny performed by an expert panel on some innovative high risks devices and the post market surveillance systems for medical devices were described in more details due to their potential relevance to the HTA activities. The conformity assessment by reference laboratories and expert panels for in-vitro diagnostics Class D devices were also described (see website for more details).

Discussion and conclusion:

One of the questions raised during the discussion regarded the statement in the Regulation about the information provided for end-users of medical devices. Mr Houdry reaffirmed that there are provisions in the Regulations regarding instruction for use. Yet, there are no

provisions on the organisation of healthcare in the Member States, as it is not an EU competence. Additionally, the scope of the cooperation between HTA and clinical scrutiny was elaborated on. The opinion of the expert panel on the medical device, which is delivered before its placement on the market, could be a valuable input for HTA decisions. Nevertheless, the scientific scrutiny is not expected to replace HTA processes, since their scope and purpose are considerably different. The number of medical devices that are concerned is expected to be limited, even if the estimations by Member States of the number of medical devices concerned vary widely. In addition to that, it was highlighted during the discussion that from a health system sustainability perspective, the effectiveness and efficacy of medical devices should also be assessed. As reiterated by the representative of medical technology industry, real-life data, which are obtained after the placing on the market of the device (and thus after the scrutiny) are crucial when assessing the effectiveness of medical devices. Programs that collect and analyse such data, like the ones carried out by EUnetHTA are important to assess the value of technology.

9. JOINT ACTION EUNETHTA3 (Topic 7)

Wim Goettsch 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).

Regarding the joint production, Mr Goettsch informed about the ongoing (2) joint assessment of pharmaceuticals and the 4 non-pharmaceuticals collaborative assessments. One assessment (on wearable cardiovererter defribilator therapy) has been finalised. On Early Dialogues, he recalled that the call for expression of interest on multi-HTA Early Dialogues was launched in January 2017 and that the WP has set up a dedicated HTA working party to perform Early Dialogues. The collaboration with EMA on one system for parallel early dialogues is ongoing. EUnetHTA is also working on the draft report on current barriers for national HTA implementation.

Additionally, Mr Goettsch highlighted the practical examples of the involvement of patient/consumers' associations, healthcare providers and technology producers in the EUnetHTA activities. Last, but not least he linked the work of EUnetHTA to the activities of the Commission in any of the post-2020 scenarios. Thus, the involvement of EUnetHTA Executive Board in the discussions of the scenarios was underlined (see website for more details).

10. CONCLUSIONS AND CLOSURE OF THE MEETING

The Chair thanked for the participation to the 8th HTA Network meeting and invited the HTA Network to the next 9th meeting on 6 November 2017 in Brussels and not 23 November as originally planned (post meeting note: the next meeting will be postponed to the first quarter of 2018).