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APPROVED MINUTES OF THE 6th HTA NETWORK MEETING

FRIDAY 20 MAY 2016

1. INTRODUCTION

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

Austria, Czech Republic Malta, and Iceland were excused; all other Member States (MS) and Norway, EUnetHTA, and EMA were present. In addition, nine stakeholders' representatives (BEUC, EPF, EURORDIS, ESMO, ESC, AIM, ESIP, EFPIA, EUCOMED) attended the whole meeting as observers. Centre of Innovation in Regulatory Science (CIRS) was invited as speaker and was present for the agenda item on Mapping of HTA in Europe (Topic 7). 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. Special welcome was addressed to the representative of Portugal as the new member of the Network. The Chair presented the agenda of the day which was accepted by HTA Network participants.

Xavier Prats Monne, Director General of DG SANTE made a welcome speech. He thanked the partners of Joint Action 2 for the work done and emphasized the importance of the knowledge shared and the joint reports produced. Today at EU level there is a greater knowledge of health systems, and HTA is clearly a priority for the EU and Member States. He underlined that EU shall focus on areas where added value can be demonstrated. HTA is the important field on which the Commission is reflecting in terms of added value of such cooperation. The Commission has to make sure that support is given to the national efforts in developing HTA and health care systems. During the discussion, it was suggested that the topic of using HTA for disinvestment decisions would be a useful addition to EU cooperation.

[1] http://ec.europa.eu/health/technology_assessment/events/ev_20160520_en.htm

Dominik Schnichels, Head of Unit: "Medical products, quality, safety and innovation" DG SANTE presented himself to the HTA Network and introduced the new HTA team.

3. STAKEHOLDERS' INVOLVEMENT IN THE HTA NETWORK AND EUnetHTA 3

Flora Giorgio made a presentation on the proposal from the Secretariat to stakeholders' involvement in the EU HTA cooperation (*see the presentation*[2]). It was explained that the Joint Action EUnetHTA 2 had set up a Stakeholders' Forum involving representatives of four categories of stakeholders identified as essential for the HTA cooperation, namely: patients, providers, payers and industry. Since the stakeholders' involvement in the new Joint Action 3 has changed and the Stakeholders' Forum will not exist anymore, the HTA Network needs to update its own process to associate stakeholders as foreseen by the Article 15 of the Directive 2011/24/EU and its Implementing Decision of 2013.

To avoid duplication, the HTA Network applied the same approach and decided to rely on the Stakeholder Forum of EUnetHTA 2 to appoint stakeholders' representatives as observers to the HTA Network[3]. Currently in the HTA Network, stakeholders are represented by one participant per category (patients, providers, payers, industry) plus the Stakeholders' co-chair of the EUnetHTA 2 Stakeholder Forum[4]. It was proposed that the number of representatives is increased to two representatives per each of the four groups. In addition it was proposed that ad hoc meetings on specific topics will be organised in order to have a targeted input. A call of expression of interest will need to be launched to create a new "pool" of Stakeholders' representatives' organisations with an interest and demonstrated added value in HTA activities, following the model of EUnetHTA2. The "pool" will serve as basis for the stakeholders to identify their representatives per category and propose them as observer to the HTA Network.

Discussion

During the discussion it was clarified that according to the proposal from the Secretariat the number of stakeholders representatives which could be invited to the HTA Network meetings (to the full or parts of the discussions) would increase from current 5 to 8. It was also underlined that according to the current Rules of Procedure and working methods additional representatives may be invited to take part to the discussion on a specific agenda item relevant to a specific constituency.

In addition, the following points were made:

- stakeholders should become more involved in the HTA cooperation, however some of them don't have enough resources to engage in all topics,
- it is important to gather input from stakeholders on concrete items/topics,
- healthcare professionals should be able to contribute and be informed about the work and decisions of the HTA Network,

[2] http://ec.europa.eu/health/technology_assessment/docs/ev_20160520_co011_en.pdf
[3] Art.8;4.c HTA Network Rules of Procedure.
[4] The EUnetHTA2 Stakeholder Forum is co-chaired by a stakeholder representative

- all interests should be taken into account, each group has a specific way of contributing and participating in this HTA process,
- it should be considered by the Network the possibility to appoint in each Working Group one MS as responsible for facilitating the stakeholders' involvement,
- specific workshops can be dedicated to make the cooperation more effective,
- Multiannual Work Programme 2016-2020 provides that a Discussion Paper on stakeholders' involvement is planned in spring 2017, one MS asked for clarifications on the discussion point and the scope of the planned Discussion Paper.
- Involvement of stakeholders in EUnetHTA 2 was an important topic which was given a lot of attention and the Stakeholder Forum was a very constructive exercise, now with EUnetHTA3 the involvement of stakeholders will be more at work packages' level, therefore it is considered necessary to reflect such change at the HTA Network level.
- The importance of stakeholders' involvement in the HTA Network activities' was underlined by several members, however it was also considered important to maintain the possibility for HTA Network members to have part of the meeting reserved to Members only.

It was clarified that the Multiannual Work Programme 2016-2020 foresees a Discussion Paper on stakeholders' involvement, planned for early 2017; and this Discussion Paper was meant to have a broader scope of activities than the representation of stakeholders to the HTA Network meetings.

Conclusion

The Secretariat thanked all participants for the valuable points made and concluded that the meetings of the HTA Network will be open to two representatives (instead of one) of each of the four groups (patients, providers, payers, industry) - however parts of the meeting could be reserved to HTA Network members only, as foreseen by current Rules of Procedure.

The Secretariat of the HTA Network will launch the call for expression of interest to select the Stakeholders' representatives (20-30 stakeholders maximum to keep the group manageable) which should then propose their representatives. The "pool" will be regularly consulted on HTA related issues (according to the decision and the modalities which will be decided by the HTA Network). For that purpose, the EUnetHTA 2 "Call of expression of interest" criteria will be used as a model.

Any necessary changes to the Rules of procedure will be proposed to the HTA Network in November to reflect the new scenario.

HTA Network agreed with the conclusions.

4. HTA NETWORK MULTIANNUAL WORK PROGRAMME 2016-2020

Mirjana Huic, from the Croatian Agency for Quality and Accreditation in Health Care and Social Welfare and the Rapporteur/Chair of the HTA Network Working Group on

Multiannual Work Programme (MWP) made the presentation of the MWP 2016-2020[5] (*see the presentation*[6]).

The overall objective of the MWP is to contribute to the implementation of the Strategy for EU cooperation on HTA. The MWP proposes a vision for cooperation and specific calls and actions to implement the proposed vision.

Discussion and conclusion

It was suggested to foresee a mechanism for monitoring of the implementation of the MWP.
The Multiannual Work Programme 2016-2020 was unanimously adopted by the HTA Network.

5. THE INTERACTION BETWEEN REGULATORY AND HTA ISSUES

Agnese Cangini, from the Italian Medicines' Agency (AIFA) on behalf of the Italian HTA Network member was appointed Rapporteur of the HTA Network Working Group on "Interaction between regulatory and HTA issues". The Rapporteur made the presentation of the HTA Network Reflection Paper on "The interaction between Regulatory and HTA issues on pharmaceuticals" (*see the presentation*[7]*).*

Discussion and conclusion

The following points were raised during the discussion:

- importance of sustainability and predictability in the HTA process should be referred to in the paper,
- decision-makers, payers and registry holders should be considered,
- possible conflict of interest of involved parties shall be stressed (in the definition of therapeutic innovation),
- a reference to coordination of timelines (how much time the different phases will take, days/weeks/months) between the market authorisation procedure and HTA process would be beneficial,
- the need for a permanent structure for Early Dialogues, including both Regulatory and HTA, building on EMA and SEED experiences and taking into account the specificities of the two processes,
- the document would benefit from more specific action points,
- it was also clarified that when the document refers to handling the different positions between HTA and regulatory bodies it does not imply that there needs to be an alignment,
- One MS asked to reflect better their contributions on real world data.

It was considered that the essential elements are in the document (open format). For additional comments, it was agreed that the HTA Network members will send written comments to the Rapporteur and HTA Network Secretariat by 3 June. The revised version will be circulated to the HTA Network by week 20 June. After comments from HTA Network, the Secretariat will

[5] http://ec.europa.eu/health/technology_assessment/docs/2016_2020_pgmnetwork_en.pdf
[6] http://ec.europa.eu/health/technology_assessment/docs/ev_20160520_co02_en.pdf
[7] http://ec.europa.eu/health/technology_assessment/docs/ev_20160520_co03_en.pdf

share the revised draft with the Regulatory side (Heads of Medicines Agencies and the STAMP – the Commission Expert Group of the Pharmaceutical Committee) for comments[8]. Before the meeting in November a revised draft will be shared with HTA Network who will decide on the new comments. Stakeholders will be associated to the process.

The Reflection paper is planned for adoption by the HTA Network in November 2016. At that stage an implementation plan will need to be developed to identify who takes lead on proposed actions.

6. UPDATE ON OTHER EU INITIATIVES RELATED TO HTA

A) EMA: Update on current initiatives relevant to HTA

Hans-Georg Eichler, from EMA, presented current EMA initiatives on HTA which demonstrated there are many domains where HTA-Regulatory synergies could be realised to mutual benefit (*see the presentation*[9]).

B) STAMP update

Helen Lee from DG SANTE outlined the main topics discussed by the Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) meeting of 10 March 2016 (*see the presentation*[10]). All the presentations of the last STAMP meeting are published[11].

Discussion and conclusion

During the discussion the following points were made:

- EUnetHTA3 welcomed the plans of EMA and informed that Joint Action 3 will continue to follow closely the EMA work plan. Structural involvement of EUnetHTA3 or individual bodies can be implemented in EMA activities.
- The point was made that PRIME should be approached with caution considering the difficulties to establish the therapeutic added value in the process.
- EMA informed that to facilitate the EUnetHTA3 pilot projects on rapid REA of pharmaceuticals, the Data Sharing Agreement would be soon established between EMA and individual HTA bodies. It was clarified such agreement cannot be done with EUnetHTA as the Joint Action is not a "legal person".
- Members welcomed the Data Sharing Agreement between EMA and HTA bodies as a positive development for the purpose of joint assessment.
- It was also stated that similar information sharing will be useful between national bodies for enabling timely national assessments.
- On the pilot on Adaptive Pathways, EMA informed the Network that a report on the Early Dialogues pilot will be published by EMA in the course of 2016.

[8] *Post meeting note*: as the deadline for sending documents to STAMP for its June meeting was set before June 20, the Secretariat in agreement with the Rapporteur and co-rapporteur decided to share with STAMP the current draft (dd April 22).
[9] http://ec.europa.eu/health/technology_assessment/docs/ev_20160520_co04_en.pdf
[10] http://ec.europa.eu/health/technology_assessment/docs/ev_20160520_co041_en.pdf
[11] http://ec.europa.eu/health/documents/pharmaceutical-committee/stamp/index_en.htm

- The issue of cooperation of HTA bodies with STAMP was raised, it was concluded that to maintain the close cooperation with the HTA bodies, EUnetHTA3 representatives will be invited to STAMP meetings when appropriate.

C) SANTE NEXT STEPS IN THE EU COOPERATION ON HTA

Dominik Schnichels presented SANTE next steps in the EU cooperation on HTA (*see the presentation*[12])

He underlined that the following questions need to be reflected upon: "How can we address the duplication of efforts?", "How can we reduce diverging outcomes of HTA processes?", "Why is the current joint work (EUnetHTA) is not sufficiently used?", "How we can make sure that the production of joint work and the overall cooperation is sustainable beyond 2020"?

The discussion was opened with two additional questions circulated in advance to the HTA Network: "What are the outputs of EU cooperation with the highest added value for HTA bodies and stakeholders in their national HTA activities?" and "How can EU support MSs and other stakeholders in increasing usefulness and uptake of Joint Actions in national/regional activities"?

Discussion and conclusion

It was clarified that the Joint Action 3 through its results would provide part of the answer to the questions raised. Some proposed that Commission could facilitate the "mutual recognition procedures" for the assessment reports and for that reason an agreed methodology is needed.

It was clarified the pricing and reimbursement processes will remain within the national competence. A concern was expressed that for some people not close to this subject, pricing and reimbursement could be seen as outcome of HTA processes, thereby it should be clarified.

It was concluded that once the first ideas of this reflection process on the future initiative (legislative or non -legislative) are identified, they will be shared with the HTA Network. The open public consultation is envisaged to be launched during the summer time 2016; the consultation and any following steps will need to follow the Better Regulation process. HTA Network will be informed about its launch.

7. EUnetHTA JOINT ACTION 3

Wim Goettsch, the coordinator of the Join Action 3 from the Dutch National Health Care Institute (ZIN) made a presentation on the EUnetHTA3 and its progress made so far (*see the presentation*[13]).

[12] http://ec.europa.eu/health/technology_assessment/docs/ev_20160520_co042_en.pdf
[13] http://ec.europa.eu/health/technology_assessment/docs/ev_20160520_co05_en.pdf

Discussion and conclusion

During the discussion the question on topic selection was raised (avoidance of competing proposals) and the role of Liaison Committee in this regard. It was explained that EUnetHTA still needs a reflection on this and the Liaison Committee will start after 9 months, leaving necessary time for the reflection on its role.

It was also suggested that it is more appropriate to refer to "use" of joint production (and not re-use) by national authorities. This was identified as a key objective that the Joint Action aims at facilitating (i.e. WP7 "National Implementation and impact").

Regarding the organisation issues, it was said that the kick off meeting was organised in March 2016. The first Executive Board will take place on 14 June and will be hosted by ZIN in Diemen.

8. EARLY DIALOGUES: REPORTS FROM EMA AND SEED

Jane Moseley, from EMA, presented the report[14] of the pilot on parallel regulatory – HTA advice (*see the presentation*[15]).

Francois Meyer from HAS and the coordinator of SEED project[16], made a presentation of the SEED Final Report (*see the presentation*[17]). His presentation was focused on the SEED recommendations for the future which includes:

- The issue of potential conflict of interest.
- The need to maintain consistency and avoid contradictions in advice when it was provided in both international multi HTA and national single HTA advice settings (transparency of the code of conducts, rules of procedures).
- On participation to ED: adequate expertise is essential, a coordination at national level is needed to decide which body shall participate (if more than one national agency), regulators, health professionals and patients (a transparent process shall be developed) shall be also involved.
- On the funding of the early dialogues: in SEED the early dialogues were publicly funded, alternative sources of funding have to be put in place.

Discussion and conclusion

The importance of early dialogues has been stressed by HTA Network members. There was consensus that two procedures for HTA-Regulatory early dialogues (EMA, SEED) need to merge in a single procedure, during the Joint Action. The operational details and the steps to achieve it will need to be defined and discussed with the JA and the key players involved. The Commission declared support this process.

[14] http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/03/WC500203945.pdf
[15] http://ec.europa.eu/health/technology_assessment/docs/ev_20160520_co06_en.pdf
[16] http://www.earlydialogues.eu/has/
[17] http://ec.europa.eu/health/technology_assessment/docs/ev_20160520_co061_en.pdf

9. MAPPING OF HTA IN EUROPE: "HTA REGULATORY AND REIMBURSEMENT ATLAS" (CIRS)

Tina Wang from the Centre for Innovation in Regulator Science (CIRS) presented the Mapping of HTA in Europe "HTA Regulatory and Reimbursement Atlas" initiated 5 years ago. The presentation focused on a comparative process mapping project, methodology used, outputs (case studies) (*see the presentation*[18]).

Discussion and conclusion

During the discussion the question on the availability of the mapping to the general public was made. It was explained that the results of the Atlas are shared with the collaborating companies and HTA bodies. It was also stressed that greater collaboration with HTA agencies is foreseen in the future. The information provided in the Atlas is of interest also to the HTA Network (update of available information) and to Commission's services.

10. AOB

No update on the national HTA developments was reported.

11. CONCLUSIONS AND CLOSURE OF THE MEETING

The Chair thanked for the participation to the 6th HTA Network meeting and invited the HTA Network to the next meeting on **10 November 2016** in Brussels. He also informed about the official start of the EUnetHTA JA3 foreseen for June 2016. Currently the work will continue on the Reflection Paper on Regulatory/HTA issues and the consultation process. On the EU future initiative, the Commission will inform HTA Network as soon as a concept is available.

[18] http://ec.europa.eu/health/technology_assessment/docs/ev_20160520_co07_en.pdf