EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Brussels,

# APPROVED MINUTES OF THE 7th HTA NETWORK MEETING

# THURSDAY 10 NOVEMBER 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.

Malta, Slovenia and Iceland sent apologises. All other Member States (MS), Norway and EUnetHTA were present. In addition, EMA and eight stakeholders' representatives (AIM, BEUC, COCIR, EFPIA, EHC, ESIP, ESMO, EURORDIS) attended the afternoon session as observers. 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 Secretariat announced a change concerning the draft Reflection Paper on the "Synergies between the Regulatory and HTA issues on pharmaceuticals" (topic 5), tabled for adoption. France proposed some amendments aiming at clarifying certain sentences leaving the main message unchanged. While the changes were proposed very late in the process, the Secretariat proposed to circulate the revised version and then discuss under topic 5 if the proposed changes were acceptable to all.

The morning part of the meeting was for HTA Network members only.

[1] http://ec.europa.eu/health/technology_assessment/events_en#anchor0

## 3. HTA NETWORK RULES OF PROCEDURE (Topic 1)

***Karolina Hanslik*** of DG SANTE explained the proposed changes in the Rules of procedure. Since then the context has changed and the Rules shall reflect current working methods; it was therefore agreed that some adaptation were necessary.

The changes concern: the replacement of the former EUnetHTA Joint Action 2 (in place from 2012-2015) by the current Joint Action 3 (JA3) launched this year (Article 1.1), the possibility for HTA Network Members to attend the meeting in justified circumstances with more than one national expert. As in the past, the Secretariat will continue to reimburse the cost of one representative attending the meeting (Article 2.3). The third change concerns the involvement of stakeholders as observers to the Network which will not be based anymore on the technical mechanisms provided by the JA2 (Article 8.4.c)).

The proposed changes were unanimously adopted by the participants.

## 4. INCEPTION IMPACT ASSESSMENT ON "STRENGTHENING THE EU COOPERATION ON HTA" (Topic 2)

The Chair recalled that the Chattenham house rules apply to this session and informed that the Inception Impact Assessment (IIA) that was published in September 2016 proposes 5 options on the future EU cooperation on HTA. He stressed that the options still allow for fine-tuning, in particular when considering the "implementation mechanisms" (finance, organisational structure and gradual extension of the product scope). He also underlined that inputs from Member States and stakeholders are important to assess the impacts of possible EU action. He stated the IIA had been drafted according to the Better Regulation guidelines.

***Dominik Schnichels*** of DG SANTE explained the state of play of EU cooperation on HTA, its main achievements, but also its main challenges. In this respect he highlighted the lack of a sustainable financial model beyond 2020 and the need to improve uptake of joint work. He also presented the options set out in the IIA and the next steps. He reiterated the invitation to all Member States to actively participate in the discussions, either via the public consultation, bilateral meetings or submissions outside the public consultation.

The discussion following the presentation was constructive and open and showed engagement by HTA Network members to contribute to the development of the policy initiative.

## 5. JOINT ACTION EUnetHTA (Topic 3)

Observers were invited to attend the afternoon part of the meeting.

***Wim Goettsch,*** Director of EUnetHTA JA3, gave a presentation on the state of play of EUnetHTA. He briefly introduced JA3 specifying its objectives. He further summarised the selected activities and gave examples on the content of the Work Packages (WPs).

As issues up for further discussion he specified the future actions on horizon scanning, the interactions with national activities and the importance of alignment with DG SANTE activities on the post 2020 scenario.

The involvement of stakeholders was briefly explained and their role in JA3 stressed. Stakeholders will be involved directly in the specific EUnetHTA work packages and will contribute joint production. The rules of such involvement are currently being developed by the JA partners. Some examples of stakeholder's early involvement were then presented.

***Discussion*:**

- Some stakeholders asked further about the involvement in the EUnetHTA JA3 activities and Wim Goettsch explained that the preferable solution would be that the stakeholders approach directly the EUnetHTA WPs. On the issue of the interaction with stakeholders via EUneHTA intranet, he explained that EUnetHTA plans to set up an extra-net in addition to the existing intranet.

- The EC added that the Call of expression of interest to set up the HTA Network Stakeholder Pool will be launched and the stakeholders willing to collaborate could register to be part of the Pool. It was further clarified that the scope of activities of the Stakeholder Pool is to contribute to the strategic/policy development of the HTA Network and not directly in EUnetHTA JA3 work.

## 6. INCEPTION IMPACT ASSESSMENT ON "STRENGTHENING OF THE EU COOPERATION ON HTA (Topic 4)

The Chair informed about the publication of the IIA and the launch of the public consultation. He highlighted that stakeholder contributions are considered very important and pointed to several meetings with stakeholders that have already taken place or are currently planned. During these meetings the needs and challenges of the future EU HTA cooperation are discussed. He also made reference to the EC-EUnetHTA Forum of the 21st of October in which several of the present stakeholders' representatives had participated.

The discussion was divided into three sections (in line with the structure of the IIA): (1) the state of play, (2) the policy options and (3) the "implementation mechanisms", in particular the issues of financing and organisation (secretariat).

***1st part of the discussion:***

In the first section the EC invited the stakeholders' representatives[2] to comment on whether the IIA was an accurate reflection of the current state of play in European HTA.

[2] It was decided that the stakeholders can join the meeting with two participants per category (patients/consumers; providers, payers and industry) plus the Chair of the EUnetHTA 2 Stakeholders' Forum. The following organisations represented the four categories: European Heamophilia Consortium and BEUC (patients and consumers), European Society for Medical Oncology - ESMO (health providers), AIM and

- The representative of MedTech industry (COCIR) stated that HTA was not used very frequently for medical devices (roughly 1% of the technologies). She also pointed to the specific access model, which is different from pharmaceuticals.

- The representative of pharmaceutical industry (EFPIA) underlined that the IIA came very timely. He pointed out that the goal should not be to introduce a new Joint Action but rather to establish a sustainable model for the future. He also suggested not to aim at creating a large number of joint reports but rather focus on the quality of a limited number and ensure their subsequent uptake.

- The representative of the payers (AIM) underlined that the internal discussions were still ongoing and comments will be sent to the EC in the coming weeks. He stressed that AIM had already been very open to cooperation in this field.

- The representative of EURORDIS (rare diseases patients) expressed the wish to have more clarification on the intended scope concerning the technologies to undergo HTA other than pharmaceuticals.

- The representative of the health care providers (ESMO) referred to the IIA as a fairly accurate summary of the state of play and uttered that the initiative was very welcome.

- The representative of patients (EHC) stated that the field of rare diseases treatment would be a perfect platform concerning the scope of technologies to undergo joint HTA.

During the discussion EC clarified that 1% of all medical devices to undergo HTA might seem a small number, but the number would depend of the overall number of technologies applying for market access. They also pointed to the increasing interest of HTA bodies to look at the added value of new medical devices.

***2nd part of the discussion:***

In the second part of the discussion the stakeholders' representatives were invited to give their opinion on the different policy options put forward in the IIA and to comment whether further possibilities had been left out in the mapping of the options.

- The representative of MedTech industry (COCIR) stated that there was not yet a clear opinion on the preferred policy option but that discussions were taking place and the comments would be send within the set deadline in January. It was stressed that IIA seemed more focused on pharmaceuticals. COCIR clarified that avoiding the duplication of efforts and a well-functioning access model were key elements and that a delay in market access caused by HTA would hamper possible benefits of patients. COCIR urged to bear in mind that the medical technology sector as such was much diversified and expressed the need of an adequate link to decision making.

- The representative of pharmaceutical industry (EFPIA) described the IIA as an excellent outline of the possible options but expressed that the actual selection was not possible yet. He stated that once a joint HTA was done, the exercise should not be redone at national level.

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ESIP (payers), EFPIA (pharma), COCIR (MedTech, EDMA) plus EURORDIS - rare diseases patients (as EUnetHTA JA2 Stakeholder Forum Chair).

The negotiations on pricing and reimbursement should remain the competence of Member States.

- The representative of the payers (ESIP) announced they would respond to the public consultation and that Option 1 should not be considered for the future. Furthermore an appropriate pathway for medical devices would be necessary if they were to be included in the scope.

- The representative of EURORDIS announced the organisation was currently working on an alternative option (option 6) but that details could not yet be shared at this point. He further expressed that horizon scanning should be a key element of the envisaged initiative.

- The representative of the health care providers (ESMO) stressed that providers will respond to the public consultation and agreed on the need of a more permanent mechanism. They stated that, even if challenging and ambitious, options 4 and 5 were most attractive.

- Representative of consumers (BEUC) welcomed the IIA and announced participation in the public consultation.

***3rd part of the discussion:***

In the third part of discussion the participants were invited to give their opinion on the implementation mechanisms (financing and organisation).

In general, the stakeholders' representatives considered that that the evaluation of a suitable financing model was the responsibility of the EC and the MSs, however a centralised system would be cost saving for Member States and industry. Depending on the amount of added value, pharmaceutical industry might be willing to contribute financially to the future structure. ESIP commented that the establishment of a system with mixed financing might bear the danger of creating a conflict of interest as well as an inequality between large enterprises and SMEs. The representative of EURORDIS argued in favour of a long-term EU budget for cooperation on HTA and stressed the need of a permanent secretariat to organise the system and to support national HTA bodies. Furthermore the national agencies would also have to be well funded.

## 7. "SYNERGIES BETWEEN REGULATORY AND HTA ISSUES ON PHARMACEUTICALS" (Topic 5)

The Chair thanked the Rapporteur (IT), and the Co-Rapporteurs (UK and NO) for coordinating the work on the Reflection Paper. He informed about the additional comments made by France with which the participants agreed. He informed that the Reflection Paper, as agreed in the last meeting, was shared with Heads of Medicine Agencies and the Commission Expert Group on Safe and Timely Access for Medicines to Patients (STAMP) who contributed to the Paper.

***Simona Montilla*** (AIFA, IT) presented the Reflection Paper and stressed that the document has been drafted to address the needs to identify activities throughout the entire life cycle of HTA's and to identify activities of cooperation between the Regulatory and HTAs bodies that are of added value. The cooperation between the two sectors shall facilitate the access to

efficient, effective, innovative and safe health technologies and to guarantee the sustainability of an EU healthcare system.

The Reflection Paper identifies specific areas that can be addressed in the medium-long term in which the cooperation can bring benefits. Three different phases: pre-marketing, market entry, post-marketing are part of the approach and each of them identifies possible areas of collaboration. The areas that have been identified include early dialogues/scientific advice, horizon scanning programmes, disease-specific guidelines (pre-market phase), sharing information between regulators and HTAs (market entry phase) and collaboration around real world data (RWD) generation (post-marketing phase). The process from February 2016 to October 2016 that has led to the final version of the Paper was described and the main comments from STAMP and HMA were presented.

***Conclusion:***

The Reflection Paper was adopted unanimously.

***Reflection Paper – follow up:***

The Chair introduced Flora Giorgio (DG SANTE) who completed the discussion point with the additional information on the follow up of the Reflection Paper.

***Flora Giorgio*** underlined the importance of the adoption of the Reflection Paper and explained the next steps, taking into account the comments received in the development of the Paper.
Having discussed with the Rapporteur and to respond to several comments received within the drafting phase, noting that the document was not specific on how the identified actions will be brought forward, the Secretariat proposed to set up an "ad hoc" coordination mechanism called "Synergy Group" to avoid that topics are developed independently within different fora. The Group could identify which group /fora is already working on some of the identified topics and who is planning to do so, to avoid duplication and to create synergies.
The idea was generally supported, but a Member State expressed concerns on creating additional structure which could add complexity rather than simplification. The comment was well noted and to avoid this risk, some guiding principles were proposed. The principles include: keeping the Synergy Group small, having equal representation of HTAs and Regulators, focus its activities on identifying who is addressing the action, and involving key players (STAMP, EMA, HMA and EUnetHTA JA3).

***Conclusion:***

The HTA Network agreed with the approach to set up the Synergy Group and identified the volunteers (DE, FR, IT, PT, UK) to support the Secretariat in bringing forward the proposal. The other key players will be approached to check/verify their interest. The HTA Network will be informed accordingly.

## 8. AOB

### EU updates relevant to HTA

***1) Helen Lee*** (DG SANTE) gave a presentation summing up the content concerning the "Update on the European Commission Expert Group on Safe and Timely Access to Medicines for patient (STAMP)".

Representative of consumers (BEUC) thanked the Commission for having organized the event on "Adaptive Pathways" scheduled on the 8th of December and stressed the importance to have in that occasion many of HTAs bodies because it will be the first public debate about this concept. Moreover, it was proposed to organize an event about the difference between PRIME and Adaptive Pathways in order to clarify these concepts. It was clarified that the workshop on adaptive pathways would give the possibility to clarify both concepts.

***2) Flora Giorgio*** (DG SANTE) presented shortly the discussions and conclusions of the EC-EUnetHTA Forum of 21 October. The discussions were organised with the framework of three sessions on: the past achievements and shortcomings of the EU HTA cooperation, synergies with HTA bodies and regional collaboration on HTA, and on the future of HTA in Europe and HTA and EU cooperation on access to medicines. A report of the Forum will be soon available.

## 9. CONCLUSIONS AND CLOSURE OF THE MEETING

The Chair thanked for the participation to the 7th HTA Network meeting and invited the HTA Network to the next meetings on **29 March** and **23 November 2017** in **Brussels**.