EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
e-Health and Health Technology Assessment

Brussels, 18 December 2014

Approved Minutes of the 3rd HTA Network meeting

29 October 2014

Introduction

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

Denmark was excused, Iceland, who was invited for the first time, was also excused. All other Member States (MS) and Norway, as well as EUnetHTA and EMA were present[1]. In addition, the five stakeholder representatives attended as observers. No interests were declared for the assessment of a potential conflict.

The meeting was chaired by Andrzej Rys, Director, "Health systems and products" DG Health and Consumers

1. OPENING AND WELCOME

The Chair, Andrzej Rys, welcomed participants, underlined that cooperation on HTA was a high priority for the European Commission and would continue to be so under the new Commission. He thanked the Italian Presidency and Ms Marcella Marletta for hosting the meeting.

Ms Marletta, welcomed participants and underlined the commitment of the Presidency to implement the Strategy. She underlined the importance for Member States to reflect on how the strategy can be applied in national realities and working procedures. She underlined that ensuring strategic political and technical continuity in the cooperation at EU level is very important to achieve the ambitious objectives set by the Strategy. She also reported about national developments which are in line with the need for enhanced cooperation called for by the HTA Network.

The draft agenda was approved without modifications.

2. APPLICATION FOR MEMBERSHIP – OBSERVER

The Chair explained that unfortunately Iceland could not be represented at the meeting and opened the vote. Portugal had given proxy to Cyprus (see footnote 1).

[1] Portugal was represented by the expert and not the Member. Therefore for voting Portugal gave proxy to another HTA Network Member (Rule of Procedures Art 6)

Conclusions and next steps:

Iceland was unanimously accepted as observer to the HTA Network. The Secretariat will inform Iceland accordingly.

3. EU COOPERATION ON HTA STRATEGY PAPER FINAL DRAFT

The Chair introduced the point by thanking the WG, the Chair Ms Marletta and the Rapporteur Mr. Goettsch, for their work and all members of the Network for their contribution. He welcomed the final draft and gave the floor to Flora Giorgio to report about the input received from observers during the drafting process.

Discussion:

Following the presentation, following points were raised by stakeholders:

- Welcomed the strategy and the summary of the comments. Asked for concrete involvement of stakeholders in potential JA 3, possibly by a dedicated WP and adapted working procedures to facilitate their input. Underlined the importance of including conclusions in "joint work" to indicate its result and facilitate its re-use, in full respect of national responsibilities and competences (Patients).

- Welcomed the strategy and called for the political leadership of the HTA Network to bring forward the cooperation on HTA; welcomed the topic "HTA for eHealth"; recognized the need to be pragmatic to advance to the next phase of cooperation, building on experiences and lessons learned to increase progress (Industry).

Conclusions and next steps

The Strategy was unanimously adopted.

The Chair then asked comments on the proposal to set up a WG to develop the next deliverable of the Network. The mandate of the WG would be:

"Based on the experience gathered so far, and in view of the directions set by the HTA Network strategy, to develop a draft reflection paper on the conditions to facilitate take-up and reuse at national level of HTA production, including information and joint assessments[2] (from now on "joint work")".

The reflection paper is planned for adoption by the HTA Network at the next meeting. Members agreed on the WG and its mandate. The following MS volunteered to be in the WG:

France, Bulgaria, the Netherlands, Slovakia, Croatia, Sweden, Norway, Germany, Spain, Austria, Belgium, Portugal, Hungary and Italy. EMA and EUnetHTA were also welcomed to join. Stakeholders will be invited ad hoc at WG meeting(s) to share their experiences.

[2] HTA Network Multiannual Work Programme, point 2.2

Following consultations between WG members, France volunteered and was then asked to Chair the WG.

4. NEXT STEPS FOR EU COOPERATION ON HTA – PART 1

The Chair explained that the objective of the session was to discuss possible priorities for proposed third Joint Action on HTA, based on lessons learned and on the key messages of the Strategy.

Prof. Finn Borlum Kristensen reported about the key messages from the EUnetHTA Recommendations on "the implementation of a sustainable European network for HTA". The Recommendations reflect the experience gained so far in the technical cooperation and provide suggestions on how to proceed in a possible third Joint Action. He highlighted the following recommendations: Ensure sufficient scientific and technical coordination capacity, consolidate collaborative production (more efficient, less duplication of effort among participating organisations), and capacity-building activities allowing for efficient uptake of the results of the joint work and effective participation in the activities. He also stressed the need to maintain a flexible mechanism to enable Member States to engage at different levels in different activities, at the same time, the importance of closely involving top decision makers at national level in order to facilitate take up and re-use of output of the cooperation (presentation available on the EC website).

Jerome Boehm (EC) presented the result of a survey carried out within the Working Group drafting the strategy. With the limits inherent to the limited scope of this survey (14 Member States involved), the questionnaire aimed at gathering more knowledge on some of the output of the EUnetHTA activities, more specifically, it was asked to assess the potential for European cooperation and for national reuse of some of the EUnetHTA activities (early dialogues, rapid evaluation assessments, Full HTAs, and guidelines/methodologies). The results showed that all activities were valued with some preference for "Early Dialogues (ED)" in relation to "potential of European cooperation", and "Rapid Evaluation Assessments (REA)" in relation to "the potential for national reuse" (presentation available on the EC website). Jerome Boehm raised the issue of the opportunity of conducting full HTA's, notably on medical devices, given the difficulties for reusing at national and regional level, as outlined by EUnetHTA itself.

Flora Giorgio (EC) outlined the indicative timelines for the adoption of the 2015 Work Programme (WP) and the next steps leading to a possible submission for a third Joint Action. The process should start the first quarter of 2015 for the adoption of the WP and possibly end with a submission by Member States of a proposal for a third Joint Action on HTA before the summer break. Timelines are subject to changes.

Following the presentations, two questions were discussed:

- **How can a possible third Joint Action serve your needs as national authority responsible for HTA (e.g. indicate specific areas of interest, concrete output products etc. ?**
- **What are the facilitating factors to be put in place, to enable greater involvement of people doing statutory HTA reports at national level in European cooperation activities (e.g. funding; translation facilities; "adapt" output; selection of topics for "joint work" etc.) ?**

Discussion:

During the discussion the following points were made:

- To serve national needs it is important that pilots are timely, of high quality and delivered quickly. To better share the information on national priorities/work plans to enable joint work to respond to national needs.

- To improve cooperation both on pre-marketing phase but also on post marketing phase to fully implement life cycle for both medicines and medical devices.

- Any possible future Joint Action should still enable Member States to engage in different activities at different level of commitment. Focus should be on improved joint work and facilitating reuse of joint work.

- EDs have high potential for European cooperation and are a good way to promote synergies with Regulators of Medicines. For Medical Devices implement synergies with notifying Bodies is more challenging, nevertheless necessary.

- The importance of involving payers in the cooperation, the Network of Competent Authorities responsible for Pricing and Reimbursement (CAPR), could be a good instrument, and a back to back meeting between HTA Network and CAPR was mentioned as possible option to be explored.

- Stakeholders' representing payers (AIM and ESIP) have different remits and this makes it difficult to provide consolidated input. For medical devices, the decision makers are often hospital managers.

- European portal to facilitate access to HTA reports and outputs of Joint work would be a very useful tool for cooperation.

- International dimension of HTA was noted as important, however focus of any future Joint Action should be on strengthening European activities.

Following the discussion the Chair asked Members of the Network to report any national developments on HTA which may be of interest to the whole Network. He proposed that such a point could be covered regularly on the Agenda of the Network, to facilitate the exchange of information.

Greece announced that it is in the process to set up HTA capacity and would seek advice and guidance from other MS with established capacities; Cyprus was in a similar situation, and asked for support specifically from MS in which HTA capacity is carried out by the Regulatory agency, as it will be in the case of Cyprus. Hungary reported that they have a small HTA Agency, which is a part of a larger structure, resulting from the merger of several agencies.

Several members underlined the importance of having more clarity on HTA scenario at European level. EUnetHTA is a great resource for this, but an update on the situation on who is doing HTA and for which type of technologies in Europe would be extremely useful.

Conclusions and next steps:

The points made during the discussion were well noted and will feed into the debate for preparation of a possible third Joint Action on HTA

It was noted that a mapping of bodies/authorities doing HTA for medicines, medical devices etc. would be helpful; the Secretariat is working on such activity and it may request HTA Network support for completing such exercise.

"National developments on HTA" would be included as regular point on the agenda.

5. HTA AND EMERGING CHALLENGES

At the opening of the afternoon session, a video on the HTA Network was showed. The video may be shortened for further dissemination.

When introducing the point, the Chair explained that the objective of the session was to stimulate discussion and share experiences on topics which have been identified as emerging challenges and for which the HTA Network can provide important contribution:

"Sharing experiences of EMA on cooperation between regulatory and HTA issues".

Prof. Rasi (EMA) underlined the importance of life cycle approach for technologies and the efforts EMA is making to create synergies with information needs of HTA bodies, to facilitate and streamline *regulatory and HTA* interaction within the different phases the life cycle of medicines.

He referred to several initiatives involving EMA, showing the commitment of the Agency to the objective of strengthening synergies. The following initiatives were mentioned: the Scientific Advices (SA) carried out within EMA involving HTA bodies (referred to as "Parallel Scientific Advice"); the involvement of EMA in SEED pilots, also doing parallel Early Dialogue (the Equivalent to the EMA/ HTA parallel SA); the long standing and successful cooperation with EUnetHTA; the emerging concept of adaptive pathways for medicines, in which HTA bodies should play a key role; the involvement of EMA and several HTA bodies in IMI project "Get Real", the ENcePP initiative, the opportunity for further cooperation in the implementation of post authorisation efficacy studies and of registries as tools of great relevance both for regulators and for HTA bodies .

Discussion:

After the presentation the following points were raised:

- The reference to life cycle approach; the efforts of EMA in engaging with HTA bodies are welcome.

- Early dialogues are seen as a key tool to facilitate interaction and to optimise the process to enable faster decisions on access to technologies, ED are considered important both for facilitating more convergence between HTA bodies and to enable synergies with regulators. The issue of sustainability of ED once EC funding ends has to be addressed to continue the activity. Involvement of patients in ED/SA is also considered important.

- EMA and EUnetHTA work can be instrumental to strengthen trust between the two areas and strengthen the much needed synergies.

- The regulatory Pharmaceutical committee has started a reflection process on safe and timely access to medicinal products (STAMP) to examine the "adaptive pathways approach" with Member States' experts. EMA will be associated and the HTA Network will be kept informed.

- EMA encouraged any HTA bodies willing to get engaged in EMA/ HTA parallel Scientific Advice (SA), to contact them to explore feasibilities of including them.

- A call for action was made so that the principles outlined in the HTA Strategy, including the synergies with regulators are implemented

New therapies for Hepatitis C

Wim Goettsch, ZIN (NL) presented the work carried out by EUnetHTA and MEDEV to collect information on the assessments done for Hepatitis C in different MS and comparing the results. From the analysis of the results it appeared clear that the main issue in the assessment was the budget impact due to the high price of sofosbuvir and the substantial eligible population for the treatment. Presentation available on the HTA Network website.

Discussion:

When opening the discussion the Chair thanked ZIN and EUnetHTA/MEDEV for the excellent work, done in very short time. After the presentation and few technical clarifications the following more general points were made:

- The exercise showed that there is scope for greater cooperation between HTA bodies to avoid duplication, and earlier exchange of information may help. However, it was also noted that significant part of the work will still need to be done at national level, fully in line with the spirit of the HTA Network Strategy. Member States can share and jointly do parts of the assessments but appraisals will remain different.

- "Early warning system" for HTA bodies should be considered as way to facilitate interaction between HTA bodies and thus avoid duplication in this type of situations. Marketing authorisation for sobosfuvir was granted in January 2014 so earlier interaction with EMA and between HTA Bodies could have helped.

- More breakthrough products, with expected similar challenges, are in the pipelines of the industry, therefore this example may help to optimise the cooperation and prepare for the future.

- Reliable and updated data of prevalence would be extremely important for this type of exercise

- The need to do comparative HTAs for treatment options may be of interest for European cooperation.

HTA for eHealth – is it possible?

Mr D'Angelantonio (HIM) and Mr Kidholm (Odense University Hospital, DK) made the case for the need for an adequate evaluation framework for telemedicine and eHealth solutions more in general. They presented MAST assessment model and its genesis, the role of MAST to date in EU-funded projects, planned activities, and examples of use and the current situation in terms of adoption (Presentation available on the HTA Network website).

In conclusion, the experience acquired so far by the core group of partners and the rapid spread of MAST confirmed that it had achieved its primary objective, which was adequately evaluating telemonitoring interventions. The scope of MAST was broadening to meet the demand to encompass new and increasingly complex interventions based on the use of technology and aimed at improving care processes and care delivery networks. He encouraged national HTA agencies to adopt MAST when evaluating telemedicine interventions.

Discussions:

After few clarifications questions, the following points were made:

- Several members welcomed the systematic assessment approach proposed, building on HTA Core model, and noted that it is needed in eHealth applications.

- MAST is not addressing technical issues like interoperability or availability of broadband etc. These are pre-requisites which are been dealt with by the eHealth Network (set up under art 14 of Cross border care Directive)

- The impact on costs of eHealth applications is often high, this is also due to low number of users in early phases of development and implementation.

- Impact of clinical outcomes may vary according to the organisation and availability of healthcare systems (high populated areas vs low density populated area with limited access to face-to-face healthcare).

- The work started from EUnetHTA (HTA Core model) now should be taken up by HTA bodies to increase the testing and adapt it further as needed. Scope for cooperation between MAST team and EUnetHTA should be further explored.

Decisions and next steps

The Chair thanked all presenters and members for the very constructive, rich and fruitful discussions. The discussion was very much focused on medicines, and at the next meeting medical devices will be addressed more specifically.

6. INFORMATION ITEMS

- New Commission, update - European Commission

The Chair informed that DG SANCO will retain responsibilities or pharmaceutical products, while medical devices will be allocated to a new DG "Internal market, Industry Entrepreneurship and SMEs". The good cooperation within the EC, demonstrated by the presence of DG ENTR and DG CONECT at the meeting today, will also continue under new arrangements.

- Health Ministers Informal Council September 2014– outcome of the discussion on HTA – European Commission

Ms Marletta informed that following the meeting, the Italian Presidency may propose Council Conclusion to follow up on the rich and useful discussion covered in the introduction.

7. ANY OTHER BUSINESS

- Dates next meetings 2015

Spring meeting 23 March 2015 in Brussels

Autumn meeting – to be announced, pending discussions between Luxemburg and French Members, as possible hosts.

END