EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
e-Health and Health Technology Assessment

Brussels, 23 May 2014

Minutes of the 2nd HTA Network meeting

7 April 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.

All Member States (MS) and Norway, as well as EUnetHTA and EMA were present. In addition, the five stakeholder representatives attended as observers from the second part of point 2 of the Agenda. No interests were declared for the assessment of a potential conflict.

1. OPENING AND WELCOME

The Chair, Andrzej Rys, Director, ”Health systems and products”, DG Health and Consumers, welcomed participants and underlined the key role of the HTA Network to reach agreement on a common vision of HTA Cooperation at EU level, and to trigger reflections at national level on how EU cooperation can support national activities. He also stressed the importance of starting to reflect on the longer term scenario (post 2020) to find a sustainable way to secure scientific cooperation when funding from the Health Programme ends.

The draft agenda was approved.

2. EU COOPERATION ON HTA
DRAFT STRATEGY PAPER, CHAPTERS 1 AND 2
HTA NETWORK MEMBERS ONLY

Introduction

In November 2013, a working group (WG) had been set up by the Network to work on an HTA strategy. The Chair of the WG, Ms Marletta (IT), thanked the Rapporteur and the WG members and underlined the strategic importance of the draft paper. She stated the commitment of the Italian Ministry of Health to make progress in this area. The Rapporteurs of the WG, Mr Goettsch (NL), also thanked the WG members for their constructive comments and underlined the challenge of finding the right balance between progress on European cooperation and respect for national responsibilities and priorities.

The Secretariat summarised the comments received on the draft strategy paper circulated as Annex 1 to the Agenda. Written comments were received from: Germany, Spain, Norway and Sweden. Payers and Industry representatives had also sent written input. All

written comments were circulated to the HTA Network Members and observers before the meeting.

Discussion

The discussion on the strategy included the following points:

- all technologies not just pharmaceuticals should be covered,
- benefit to patients should be clearly reflected;
- the quality of the output of cooperation is crucial to ensure acceptance, as well as transparency, good governance and scrutiny;
- priority setting needs clarification;
- joint work is not synonymous with a Joint EU HTA report[1];
- the validity and feasibility of the strategy needs to be re-assessed in 3 -5 years.

On the issue of the relationship between EU cooperation and national HTA activities, Members commented that: EU cooperation and capacity building are important for small countries with limited resources for HTA; cooperation could be used to promote national HTA; early dialogues are valuable, as the exchange of good practices. MS should be clear about what they want to cooperate on but must also have the flexibility to determine the extent of their participation in various activities.

Conclusions

The Chair concluded that there is an overall agreement on Chapter 1 and 2 the draft Strategy paper, with some minor changes to enhance clarity.

2. EU COOPERATION ON HTA
DRAFT STRATEGY PAPER, CHAPTERS 1 AND 2
ALL PARTICIPANTS

European Commission strategic vision
Paola Testori Coggi, Director General DG SANCO

The Chair welcomed Ms Paola Testori-Coggi, and the stakeholders' representatives.

Ms Testori-Coggi congratulated the HTA Network on its strategy document and its ambition**.** She underlined the importance of placing the strategy in its broader political context, and referred to initiatives relevant to the HTA agenda, including i) the reflection of the Pharmaceutical Committee on how to combine the regulatory framework with timely access to medicines; ii) the Council reflection process under the Working Party at Senior level on Public Health, which has had a group led by the Netherlands on cost-effectiveness of medicines iii) recent legislative dossiers such as the Clinical Trials Directive and the implementing Decision on the Post Authorisation Efficacy Studies.

[1] See draft strategy paper Annex 5 – Definition "Joint Work"

She stressed the importance of turning the European cooperation between HTA Agencies from a project-based initiative (so far over 30 mill EU budget invested mainly via Joint Actions and research projects) into a permanent mechanism of cooperation. She underlined that such change would require commitments from all parties and well planned next steps.

She said that the Commission is exploring different possibilities for hosting and facilitating this cooperation. The European Medicine Agency is the option which appears, for the Commission, the most promising. The Agency has proven experience in providing an independent secretariat to networks of scientific agencies working together. It could provide the relevant infrastructure and devote some resources to the task. She underlined the importance of keeping a broad scope of cooperation in HTA at European level including all technologies, not only pharmaceuticals.

She welcomed the views of Member States on this and other possible ways forward to ensure permanent cooperation between HTA Agencies.

Discussion

During the discussion the following points were addressed:

- The task of a secretariat hosted by EMA would be to facilitate cooperation, not to do scientific work which would continue to be performed by national Agencies, as it is today under the EUnetHTA model.

- The need to keep well separated the regulatory phase and the HTA phase, but enabling synergies, when relevant.

- EU cooperation on HTA should maintain the broad scope defined in the draft Strategy paper and not focus only on pharmaceuticals.

- The Medical Device sector may have concerns about this approach.

- EMA has a good track record in involving and associating stakeholders in its activities using different secretariat models.

- A permanent secretariat, or another suitable structure, is needed to maintain the cooperation; the EU cannot continue to fund projects.

- Importance to clarify the activities which would benefit from a central coordinating function and then determine the best 'home'.

- It would be desirable to continue to explore other possible scenarios, for example the European Centre for Disease Prevention and Control (ECDC), the Joint Research Centre (JRC), a Member State Agency, and look at different models.

The Chair underlined that the European Commission is prepared to look at various scenarios, EMA is only one of them. But in order to maintain cooperation between HTA Agencies, a suitable structure would have to be identified which could host and facilitate such cooperation.

The Chair (Tapani Piha) invited Stakeholders representatives to make any additional comments on the strategy. They stressed that stakeholders should be fully involved right from the start of the process; they wanted more clarity about the timelines; the

incoherence between different methodologies and different ways of implementing and take up of HTA results should be addressed; high quality was essential and priorities should be defined; the issue of obstacles to reuse of joint work at national level should be reviewed. From patients' perspective, flexibility should not be seen as a reason not to fulfil commitments in relation to do joint work.

In addition, the industry representative stressed that they would have preferred more discussion with Members on Chapters 1 and 2.

Conclusions

The Chair clarified that changes to current draft will aim only at enhancing clarity. They will not alter the basic policy messages agreed by the Network. The Secretariat summarised that the amendments will be limited to the following points:

- Clarify flexibility of commitments: balance engagement to re-use of joint work with national activities.

- Rephrase sentence on "additional evidence generation" page 8 (4th bullet point) to clarify that the aim is avoiding slightly different requests for additional evidence. Objective is avoid duplication and aim at convergence of requests.

- Possibly strengthen reference to quality and need to external validation process of joint work, as facilitating factor for re-use of joint work.

- Add in glossary definition of HTA Report.

- Clarify how to define priorities.

- Strengthen the reference to the "patients" as the ultimate beneficiaries of EU cooperation in HTA.

- Consider to include a clause for re-assessing and possibly revising the strategy in 3-5 years from its adoption.

The revised draft will be circulated to all HTA Members and Observers, for final quality and consistency checks in early May.

3. EU COOPERATION ON HTA DRAFT STRATEGY PAPER – CHAPTER 3

Introduction

The presentation from Ms *Wija Oortwijn*, from Ecorys summarised the main conclusions of the "Ecorys" study, which performed an Economic and Governance analysis of the establishment of a permanent secretariat for EU cooperation on HTA.

Following the presentation and questions for clarifications on the methodology and the assumptions made by the research team, the Chair introduced the discussion.

Annex 2 to the Agenda (circulated in advance of the meeting) provided background information on the type of activities which could be foreseen if EU cooperation on HTA

at scientific level continues on a permanent basis. The discussion focused on the following questions, included in Annex 2:

1) *How do the Members see different possible sources of funding for "joint work"?*

- *In kind contribution (for example staff from HTA Agencies or other relevant organisations)*
- *Cash contribution (for example an annual fee or fee for service)*
- *Other (for example fees for services to technology developers, royalties from "joint tools")*
- *A combination of the above*

2) *How do the Members see different possible sources of funding for "coordination activities", to enable HTA Agencies to work efficiently and effectively together and minimising the costs for EU and national budgets?*

- *EU support via existing structures, such as EU agencies and Commission services*
- *MS support via membership fees*
- *Others*

Discussion

The discussion underlined the need to further clarify the activities which shall be performed by the cooperation to identify the best business model, including funding opportunities for both "joint work" and "coordination work". It was noted that it is important to define priorities for EU cooperation so that the funding mechanism can be tailored to the priorities.

A mixed funding model may be the way forward. Several Members underlined that at national level HTA work is largely funded by public money, and only for small part by fees.

Conclusions:

The next meeting of the WG is planned for 12 June. The Meeting will be devoted to further develop Chapter 3. A new draft of Chapter 3 will be circulated before the summer break to all HTA Network Members and Observers for comments.

The Chair informed that Sweden had asked to be included in the Working Group. The Chair, noting no objections by the HTA Network, agreed to include Sweden in the WG.

The Chair reminded the HTA Network that the Strategy Paper is planned for adoption at the next HTA Network meeting in Rome on 29 October.

4. INFORMATION ITEMS

- Post-authorisation efficacy studies – update – *Florian SCHMIDT Unit D5 Medicinal products – authorisations, European Medicines Agency, DG SANCO*

The Group was provided with an update regarding the delegated act on post-authorisation efficacy studies. According to the medicinal product legislation those studies may be used to address a specific concern, which may have an impact on the maintenance of a marketing authorisation. The Commission delegated act is intended to supplement the legislation by specifying further the situations in which those studies may be required.

The delegated act was adopted in February 2014 by the Commission. Its drafting is based on a public consultation and the advice received during discussion with experts nominated by Member States and EMA. [Post-meeting note: the act has been published on 10 April as Delegated Regulation (EU) No 357/2014].

The discussion following the presentation showed the interest of some Member States and stakeholders to explore the synergies between the implementation of the PAES and HTA, in line with the life cycle approach described in the draft strategy paper. The EC acknowledged the interest but underlined that PAES are focused on regulatory requirements for licencing purposes.

- HTA DAYS, ROME

    - 29 October 2014 HTA Network Meeting

The Chair informed all participants that the Italian Member has kindly agreed to host the next meeting of the Network on 29 October 2014. The meeting will take place at the Ministry just the day before the start of the EUnetHTA Conference.

    - 30-31 OCTOBER 2014 EUnetHTA Conference Introduction and discussion

EUnetHTA Secretariat introduced the Conference Programme and called for HTA Network members to register and raise awareness on the Conference. The objective of the Conference is to disseminate the progress made by European cooperation in HTA and discuss the way forward by involving all relevant players.

The EC underlined its aim that the Programme reflects the main messages of the draft Strategy paper. EC welcomed the objective of enlarging the audience to HTA "providers" and "customers" of HTA, and encouraged Members of the HTA Network to get involved in the Conference and identify possible speakers at national level which could contribute to meet the objective of the Conference.

5. ANY OTHER BUSINESS

    - Next meetings 2015

The Secretariat will inform HTA Network members of meeting dates for 2015 possibly in advance of the next meeting.

Conclusions

The Chair welcomed the good common understanding within the Network on what can be done at European level on HTA; acknowledged the challenge of put the agreed principles in practice and thus defining a comprehensive work plan; he also appreciated the openness to discuss possible options for continuing the cooperation on permanent basis.

The Chair thanked all the participants and closed the meeting.

END