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ADOPTED minutes 1st HTA Network meeting

16 October 2013

Introduction

These draft minutes were prepared by the Secretariat of the Health Technology Assessment Network (HTA "the Network") in accordance with the rules of procedure. The draft minutes, once adopted by written procedure, will be posted on the European Commission (EC) web site http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm.

Opening and welcome

The Chair, Mr Martin Seychell, Deputy Director General in DG SANCO, welcomed participants and underlined that we were at a key phase of EU cooperation on HTA. He stressed the following points:

- "The EC is highly committed to the success of HTA cooperation in Europe. Significant investments have been made since the 1990s. The EC intends to continue to provide a high level of financial support in the next programming period of the Health Programme 2014-2020.

- But, continuing to invest in this area makes sense only if such cooperation and such investments realise real benefits for Member States.

- Evidence shows (Ecorys study – http://ec.europa.eu/health/technology_assessment/publications/index_en.htm) that the more cooperation at EU level is geared toward joint production of transferable information, the higher will be the return on investment both in economic terms and in spreading expertise and know how.

- The role of the HTA Network is crucial. Up to now HTA cooperation has relied on capable scientists to do the work but now we also need committed leadership to provide the strategic direction and long-term vision, avoid duplication and facilitate national follow up and re-use of EU joint work.

- The objectives of the Network are well spelled out in the Art 15 of the Directive. Network's Members are the Institutions responsible for HTA in the Member States; the personal commitment of the people representing the Institutions is

needed if this project is to succeed. "We are at a turning point: either we accelerate and build on results achieved so far or we may need to reconsider the entire initiative".

After the introduction, the chair opened the floor for a tour de table and asked Members to introduce themselves and shortly outline their expectations.

The following Member States were represented: AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, GR, HU, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, ES, SE, UK Ireland was excused. Norway was an observer.

The setting up of the Network was warmly welcomed. Several members expect to "use" the Network and the existing scientific cooperation mechanisms to learn from the experiences of others especially in view of setting up dedicated national initiatives/departments on HTA. Others are keen to use cooperation at EU level to avoid double assessments, develop further national HTA capacity, improve current practices and achieve better use of HTA resources. The work of EUnetHTA is seen as valuable and important, and should be further developed and strengthened.

Other points made included:

- Disseminating better HTA information to stakeholders
- Achieving greater coordination with other relevant policy developments such as the EU semester agenda, and links to other initiatives such as the Open method of coordination
- Moving cooperation on HTA from piloting to real use
- Strengthening the sharing of methodologies
- Finding a balance between EU cooperation and preserving diversity of national practices

The chair welcomed the interest and commitment of Members and introduced the Commission staff present from DG SANCO and other DGs with an interest in the dossier (JRC, CONNECT, ENTR, other SANCO services, EAHC), as well as third parties, invited to the Network's meetings in line with the draft Rules of Procedures and the Implementing Act, namely Prof. Guido Rasi, Executive Director of EMA and Prof. Finn Børlum Kristensen, coordinator of the EUnetHTA Joint Action, which will provide scientific and technical cooperation to the HTAN until its contract ends.

The Chair also underlined the importance of associating stakeholders to the HTA Network. Involvement of stakeholders is foreseen under Article 15 of the Directive and the Implementing Act. Their input would be beneficial to the process and their involvement would facilitate its ownership.

Conclusions

This was also the rationale for having the vote on the multi annual work programme (MWP) in the afternoon after hearing the views of stakeholders. Following this clarification, the agenda was adopted unanimously. No addition was proposed.

No interests, which may result in potential conflicts, were declared by the participants.

HTAN Members agreed to circulate the list of participants including their names and affiliations in the meeting. In line with the Rules of Procedure and data protection legislation, the European Commission will publish on its website the list of Member States organisations nominated as members of the Network, without the names of individual representatives.

1. STRATEGIC DISCUSSION ON EUROPEAN COOPERATION ON HTA

Introduction

The chair introduced the topic and asked Tapani Piha to present the document circulated in advance (Annex 6) to facilitate the discussion. Tapani Piha explained the rationale of placing this issue on the agenda before the discussion on the MWP: the Secretariat wanted to place emphasis on the strategic nature of the Network and focus the debate on what the Network should do.

The strategic discussion was aimed at preparing for the adoption of the MWP, outlining the broader issues the Network should consider for its activities and setting the scene for longer term cooperation.

Discussion

The discussion was based on members' responses to the questions set out in the various sections of the strategy document:

2.1.1 Technologies

- *Should EU action on HTA for the next 5 years or for the long term continue focusing on pharmaceutical products and medical devices or consider evaluating more complex interventions?*

- *Should EU action on HTA also address issues related to the performance of health systems, including tools for planning and prioritising investments, and whether interaction should be foreseen between the HTA Network and the initiatives mentioned above?*

On the first question, there was consensus that to respond to real life needs, EU cooperation should go beyond pharmaceuticals and medical devices to include complex interventions (for example surgical procedures, screening programs and other prevention activities). It was also suggested that HTA could be brought to bear on long-term care and other interventions that linked healthcare and social support. However, it was important not to try to take on too much and emphasis was placed therefore on the need to set priorities.

On the second question, there were diverging views: it was acknowledged that assessing the “performance of Healthcare Systems” is a very interesting domain in which Member States are already cooperating (EU Semester Agenda, reflection process under Working Party on Public Health at senior level); however concerns were expressed about whether HTA is the right tool for the objective. It was generally agreed that it would be more appropriate to promote consideration of HTA perspectives in the initiatives assessing performance of healthcare systems, rather than using HTA methodologies to perform such assessments.

2.1.2 HTA domains

- *Should the Network in its strategic recommendations focus on the clinical dimension of HTA only or consider other dimensions such as the organisational and economic ones?*

There was agreement that in HTAs at EU level all domains are important, but some are more "context specific" and directly linked to national and regional situations. However, even in "context" specific domains, such as "economic and/or organisational", issues common methodological approaches can be explored. In doing so it would be important to maintain a bottom up approach, based on what is currently done at national/regional level.

2.2 *"Benefits of the EU HTA cooperation for national decision making processes"*

- *Can a EU HTA business model be developed to enable broader joint production at EU level*

- *and can the Network facilitate the reuse of the tools and of the evidence generation produced at EU level into the national decision making processes?*

On the first point, it was recognised that the concept of "business model" needed to be clarified. The Secretariat explained that the intention was to reflect on a sustainable model for cooperation once EU funding ended. The results of current pilot projects will help to determine whether one or more business models should be developed.

On the second point, it was considered that the objective of the EU cooperation is not only to avoid duplication but also to increase the quality of assessments of evidence. To achieve this the focus should be on several types of activity i) more joint work, ii) reuse of joint work in national activities, and iii) filling in the gaps of activities not performed at national level.

It was also underlined that to facilitate re-use of joint work in national activities a clear and sound selection process to identify topics to work on jointly would be important.

2.3 HTA and the regulatory processes

- *How far should the upcoming HTA cooperation explore avenues for interaction and synergies of the successive phases of technology development, licensing and market access?*

the discussion showed overall agreement, for developing synergies and strengthening interaction, provided that the different remits and aims of the different processes are maintained. Several Members supported the importance of closer collaboration between Regulators and HTAs. Areas where synergies can be explored include:

- Timely exchange of information in the pre-marketing phase.

- Early dialogues

- Post marketing – pharmacovigilance

In this context, one Member called on everyone to follow the legislative process for the revision of the Clinical Trials Directive. This legislation may provide a useful

hook to enable the disclosure of clinical trials data which may not currently be possible under existing law.

Similarly, synergies should be explored in relation to Medical Devices legislation which was also being revised.

Conclusion:

It was agreed that the proposal to set up a working group to bring forward the discussion and develop the first deliverable of the draft MWP (first bullet task 2.2.) would be considered after the adoption of the MWP. It was also agreed that stakeholders would be consulted by the Working Group before the document is finalised.

2. DRAFT WORK PROGRAMME – PART I

Introduction

The chair introduced the topic and asked Jerome Boehm from the Secretariat to present the Draft MWP.

Jérôme Boehm, reported about the consultation process which had lead to the current draft He underlined that the document should be seen as an evolving document which may be amended as necessary to respond to relevant policy developments. Comments received from HTAN members, EUnetHTA and stakeholders were positive and constructive.

The Chair then introduced Prof. Finn Børlum Kristensen to address *"Synergies and complementarity between DRAFT strategy work plan and EUnetHTA work plan"*. Prof. Kristensen outlined the process leading to the setting up of EUnetHTA and its synergies with the HTAN. He also set out the key priorities of the current EUnetHTA work and its links with the draft MWP.

Discussion

The following points were raised:

- A clarification on *2.3 "Possible other tasks"*: how can such tasks be addressed/developed?

The Secretariat listed some possible activities which may be considered under this heading, namely:

- Involvement of stakeholders in HTA process

- Research on HTA, including areas to be further developed within the Research and Innovation H2020 programme and dissemination of results of existing R&I initiatives

- Facilitate links with EU policy developments, including the EU Semester agenda, the Network of competent authorities for pricing and reimbursement and the reflection Process on sustainable health systems.

Such activities may be addressed in Network meetings or working groups, following proposals from Members or observers.

It was agreed that network "position papers" may reflect the positions of different members, if no consensus is reached.

It was agreed that under Task 2.2 item *"Adoption of a reflection paper on the interaction between regulatory and HTA issues"* there will be reference to existing activities in this area, such as the existing EMA-EUnetHTA cooperation and early dialogues within EUnetHTA and EMA. The Secretariat would propose amending the text along these lines before its adoption.

Conclusions

The MWP would be amended in line with the agreed proposal and voted on in the afternoon after the input from observers, as planned.

3. DRAFT RULES OF PROCEDURE

Introduction

The chair introduced the topic and clarified that after the discussion the Network should agree on two items: the text of the RoP and the proposed list of observers circulated as Annex 7.

The chair then asked Flora Giorgio from the Secretariat to present the REVISED Draft Rules of Procedure (RoP).

Flora Giorgio outlined the extensive consultation process which started at the beginning of 2013.A preliminary draft was circulated in early July to Member States national experts, EUnetHTA and stakeholders. Over the summer the Secretariat revised the draft in light of comments received and circulated a new draft to the appointed members of the HTA Network in early September. The draft was open for comments for two and half weeks and a revised text had been circulated for adoption today. The RoP set out the general principles governing the work of the HTA Network and its main principles for interaction with the scientific and technical cooperation mechanism (EUnetHTA up to 2015). It also foresees some flexibility to enable network members to decide about specific issues on an ad hoc basis (for example involvement of experts and observers in working groups,)

Discussion

Several issues were raised:

- Involvement of stakeholders and third parties in network meetings

  To meet the provisions of article 15 of Directive 20011/24 (15.1 and 15.3) calling for appropriate stakeholders consultation, it is proposed to rely on the EUnetHTA Stakeholders Forum comprising over 20 organisations divided in 4 categories namely: patients, health professionals, payers and industry. The Secretariat clarified that using this Forum to facilitate stakeholders' consultation for the Network would avoid duplication of efforts and resources. The HTA Network Secretariat had asked the Forum to appoint their representatives to the Network (one per category + the co-

Chair of the Forum). Following an election process the Forum had selected the 5 representatives proposed in Annex 7 (List 2).

It was also clarified that part of future network meetings may be limited to Network Members only.

EMA is also associated to the activities of the Network; this had been agreed when adopting the Implementing Act setting up the HTA Network.

The Secretariat will also invite EC services whose activities are relevant to the Network.

- The scientific and technical cooperation mechanism

The point was raised on how to involve regional HTAs agencies and/or academic institutions which are not members of EUnetHTA nor of the EUnetHTA Stakeholders' Forum. The most practical approach was to rely on the current constituency of EUnetHTA for as long as it was in being. After 2015, if a new Joint Action is set up, this point would need to be re-considered, keeping in mind the importance of having a Consortium of a manageable size.

The Secretariat clarified that the specific reference to EUnetHTA as the scientific and technical cooperation mechanism associated to the HTA Network had been requested by the vast majority of Members. It was also recognised that the RoP may need to be revised after 2015 to amend this reference and because of the point about the Stakeholders' Forum, above.

- Provisions on confidentiality

The draft RoP foresees the possibility for the Network to decide that some of its deliberations (including position papers and/or reports) should remain confidential or be subject to specific public consultation (Art 6.3). The Secretariat does not expect such provision to be used extensively. The governing principle of the Network is to ensure transparency and good governance therefore appropriateness of applying this clause will be properly guarded. However, it was considered appropriate to foresee this possibility in the RoP. It was also clarified that this provision is without prejudice to the EC rules on access to documents (ie any citizen can ask to receive a document and the EC has to comply appropriately within given deadlines).

The same approach is adopted in relation to publication of Minutes. Minutes will be made public once agreed in written procedure; however the Network may decide to keep some parts of the minutes confidential (Art 10.3). It was also clarified that despite Art 10.3 stating that *"The minutes shall not mention the individual position of the Members and Observers"* Members (or observers) can ask that their individual position is recorded in the minutes.

- Other issues

In response to a question on voting procedures, it was clarified that the necessary majority is two thirds of the members present at the vote. However, a member who cannot be present may give a written mandate to another member to vote on his behalf (Art 6.2). Such mandates shall be notified to the Secretariat.

On Annex 7 list 2, it was clarified that Ms Irina Odnoletkova, represents "payers" rather than "providers" as mentioned in the current list.

Conclusions:

With these clarifications the RoP and the list 2 (Annex 7) of proposed observers invited to the Network were adopted unanimously.

The Chair closed the session and thanked participants for the productive morning.

4. WELCOME TO OBSERVERS

Introduction and discussion

The Chair opened the session, welcomed representatives of stakeholders and informed them that they have been unanimously approved as Observers to the Network.

He thanked them for the written contributions to the discussions which had been circulated to HTAN Members and asked the Secretariat to report on the outcome of the morning session.

The Chair invited the observers to introduce themselves, explain the constituencies they represented, and state their expectations.

François HOUYEZ, co-chair of the EUnetHTA Stakeholders Forum, EURORDIS (Rare diseases) welcomed the involvement of stakeholders in the HTA Network. He saw this as a way to improve dialogue leading to better quality of the decisions. He asked for more transparency in the way decisions are taken and called for better communication to stakeholders on the results of HTA process.

Liuska SANNA, European Patient Forum (EPF), had been appointed as the representative of patients' and consumers' organisations of the Stakeholders Forum (BEUC - consumers, EURORDIS, European Multiple Sclerosis Platform and EPF). She shared the comments of the co-chair and she also hoped the Network would facilitate quicker access to innovative technologies for patients.

Irina ODNOLETKOVA from AIM (the International Organisation of mutual and health funds) represented payers' organisations of the Stakeholders Forum namely AIM, ESIP (social insurance) and the national Payers organisation of Cyprus. She expected the Network to contribute to increase the efficiency and transparency in HTA and to have more methodological work done at European level. She also hoped that the Network could lead to increase compliance by national/regional initiatives with common European framework. She called for more research on the needs of decision makers in HTA, and said that her organisations would welcome a common methodological framework for non clinical evidence.

Jacques de HALLER, Standing Committee of European Doctors (CPME), represented health professionals and providers organisations in the Stakeholders Forum, namely HOPE (European Hospitals organisation), CPME (European doctors) and Weight Watchers Europe. Dr de Haller underlined that HTA must be patient-centred and should help providers to have access to innovative products. However HTA should respect the autonomy of providers to decide on what to use in the care

process. Stakeholders should be involved in proposing priority areas to be addressed by the scientific and technical cooperation mechanism.

Andrea RAPPAGLIOSI, (Sanofi, Pasteur MSD) , represented EFPIA and the industry organisations of the Stakeholders Forum, namely, AESGP (pharmaceutical-self medication), COCIR (radiological, electromedical and healthcare companies), EDMA (Diagnostics), EFPIA (research-based pharmaceuticals), EGA (Generic and biosimilar pharmaceuticals), EUCOMED (medical technology). He underlined the importance of having innovative products on the European market. Industry is committed to demonstrate the value of the products, but he stressed that it is also important to look at how the products are used in practice. Industry is keen on more joint work at European level, which is expected to lead to higher up take of joint work in national and regional assessments and possibly reduce diverging approaches. Mr Rappagliosi also acknowledged and supported the importance of more synergies between regulatory and HTA requirements, however he underlined that for medical devices the issue would be particularly challenging.

5. DRAFT WORK PROGRAMME–PART II

Introduction and discussion:

The chair informed the observers that the MWP had been discussed in the morning session

Members had requested the inclusion of a reference to existing activities in the third item of task 2.2. *"Reflection paper on the interaction between regulatory and HTA issues"* The Secretariat proposed to add at the end of the paragraph "Rationale" the following:*"Activities in this direction are on-going; the reflection paper will take these into account".*

The Chair also said that the HTA Network had agreed to set up a working group to deliver the first item of the MWP Task 2.2. *"Position paper on long term provisions of EU cooperation on HTA, including recommendations for priority areas to be addressed by the scientific and technical cooperation mechanism"*. Observers will be consulted by the working group in the drafting phase.

During the short discussion observers raised the following points:

- To look at areas in which there is need of assessments but maybe less evidence, for example advanced therapies.
- The importance of health literacy on HTA. This meant the dissemination of material in non-technical language so that it could be more widely understood.
- The need to increase stakeholders input into HTA and also the consistency in how they are involved in HTA processes.

Conclusions:

With the proposed amendment, the MWP was unanimously adopted.

The following Members of the HTA Network volunteered to be in the working group:

- Belgium, Croatia, Finland, France, Germany, Italy, Netherlands, Lithuania, Luxemburg, Portugal, Spain, United Kingdom. (P*ost meeting note- following the meeting Austrian representative who had to leave the meeting shortly before the end also expressed its interest to take part to the WG).*

- The first meeting of the working group should take place before the end of the year in early December, the Secretariat will propose dates shortly. A first draft of the position paper is planned for the second meeting of the Network in April 2014.

The Secretariat underlined the importance of the direct involvement of Members of the Network to ensure ownership and avoid situations in which experts may not be in a position to commit the national representatives, which could create delays and uncertainty in the drafting process.

6. ANY OTHER BUSINESS AND CLOSING

The provisional date of the next meeting, 7 April 2014, will be confirmed eight weeks before the meeting.

It is proposed to have the following meeting in October in Rome alongside the EUnetHTA conference. This would provide a good opportunity for the Network members to be informed on progress of the work within EUnetHTA, as well as other EU initiatives on specific methodological challenges in HTA.(funded under the 7th research Framework Programme)

Conclusions:

These proposals were accepted. The Secretariat will follow up on the Rome meeting with the Italian Network member and the EUnetHTA Secretariat.

The Chair thanked all the participants and closed the meeting.