

EUnetHTA Meeting on Stakeholders' involvement in HTA

Brussels, Belgium, November 6, 2009

9:00 – 16:30

Co-organised by: EUnetHTA Collaboration and European Commission (DG SANCO)



Agenda

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| 1. Welcome from the European Commission and EUnetHTA Collaboration (aim, format, practicalities of the meeting) | 9:00 – 9:30 |
| 2. Presentation of the EUnetHTA Stakeholders' involvement Policy document | 9:30 – 9:50 |
| 3. Dividing plenary into discussion groups | 9:50 – 10:00 |
| <i>Coffee break</i> | 10:00 -10:15 |
| 4. Group work | 10:15 – 12:30 |
| <i>Lunch</i> | 12:30 – 13:30 |
| 5. Reports from the groups | 13:30 – 14:00 |
| 6. Discussion in plenary and conclusions | 14:00 – 14:45 |
| 7. Conclusions of the day and way forward | 14:45 – 15:00 |
| 8. Meeting of the EUnetHTA Executive Committee members | 15:00 – 16:30 |

1. Welcome from the European Commission and EUnetHTA Collaboration (aim, format, practicalities of the meeting)

Mr. Jerome Boehm (DG SANCO) stressed that HTA is an important element on the Commission's agenda, and that the stakeholders involvement is an important component in this respect. He underlined the focus on scientific cooperation in the Joint Action on HTA and emphasised the importance to build on the momentum created after the completion of the Pharmaceutical Forum. On procedure he informed that the feedback from the meeting will input into the development of the stakeholders policy. The policy will be finished at the start of the Joint Action in 2010 (cf. attached presentation)

Prof. Finn Børllum Kristensen confirmed the interest and dedication of the EUnetHTA Collaboration to create a transparent stakeholders involvement process, and highlighted a need to discuss in practical terms how this process can be efficiently and effectively organised. He further presented the EUnetHTA Collaboration (cf. attached presentation).

2. Presentation of the EUnetHTA Collaboration Stakeholder Policy document

Prof. Kristensen presented the draft EUnetHTA Collaboration Stakeholder Policy document (cf. attached presentation).

He stressed that this document should set the overarching values and principles for such involvement, and that the details on how this is done, eg, at the level of the work packages and the Stakeholder Forum will be set out in the standard operating procedures (SOP) manual.

It was made clear that the EUnetHTA Collaboration only develops stakeholders' involvement for its own activities and will not play a role in stakeholders' involvement at the national or regional level for context-specific HTAs. The draft policy document includes a stakeholders' definition, explains involvement through the Stakeholder Forum and public consultation processes and defines involvement of experts.

Prof. Kristensen also presented some initial thoughts on how to select organisations to be part of the Stakeholder Forum to be established by EUnetHTA Joint Action in order to get both a balanced representation and efficiently manageable size of the Forum.

3. First (short) discussion of the document in plenary

At the opening of the discussions it was clarified that the partner organisations in the Joint Action were nominated by the Ministries of Health of the EU Member States and EEA countries to be able to provide a scientific input and carry out the Joint Action on HTA. The discussions identified a need for further clarification of the role of the Stakeholders Forum, its membership criteria, and the difference between members of the Forum and "other" stakeholders. One suggestion was that different stakeholder organisations try in advance to "nominate" one representative for bringing their interests into the Forum.

The draft policy document also needs to be more explicit on the different ways a stakeholder/stakeholder-organisation could be engaged: 1) Through the Forum, 2) In the Work Packages (bringing data, offering knowledge on the intervention/disease etc) or 3) Through public consultations.

The plenary also discussed the role of experts, thus making it clear that these are persons invited on their individual merits to add their expertise to a process in the Joint Action. The declaration of interest will be of outmost importance in this respect.

EuropaBio, supported by EFPIA and EUCOMED added for the minutes that they would have liked to see more time being allocated to discuss the presentations, before dividing into discussion groups.

a. Dividing plenary into discussion groups

The participants were divided into 4 discussion groups, mixing the various interests at stake. Beforehand a number of questions had been posted for the participants, but it was made clear that the discussion groups could choose to focus on other topics as well.

The questions raised beforehand were:

- a) *Lessons learnt from the past: the EUnetHTA project 2006/2008*
- b) *Comment on the Policy Document and notably:*
 - *Stakeholders definition for the EUnetHTA Stakeholders Policy*
 - *Involvement of experts – shall be a part of the Stakeholders policy?*
 - *Realistic measurements of success of the EUnetHTA stakeholders' involvement process?*
- c) *Standing Operating Procedures for being involved*
- d) *Working methods in stakeholders' involvement:*
 - *Comment on the deliverables of the Collaboration*
 - *Make proposals for the core HTAs. Manageability of input. Provide input in the core HTAs developed*
 - *Incorporate stakeholders' input in the reports of the deliverables.*
 - *Provide feedback on the way this input has been taken into account in the final conclusions made by the EUnetHTA Collaboration.*
- e) *Specific suggestions for the procedures of stakeholders' involvement in the public consultation process.*
- f) *Role of the Stakeholders Forum*
- g) *Case studies proposals of interest for stakeholders*

4.

5. Reports from the groups and discussion

A rapporteur from each group presented the results of the discussion (cf. attached presentations)

There were several points in common:

- a) The willingness to listen and include stakeholders in the HTA-process was highlighted. In this respect, the former EUnetHTA project was not optimal, however, it provided a valuable experience for further improvement of the process.
- b) The Pharmaceutical Forum was mentioned as having provided an opportunity for advancing a culture of cooperation with everybody round the table, however, with limited opportunity for scientific advancements and challenges to keep a differentiation between European and national level of discussions. Politically-driven orientation of the process was also recognised.
- c) There is a need to be clearer on the different levels of involvement of stakeholders at the level of the Work Packages, eg, involvement in the Core HTA development work
- d) For the Stakeholder Forum, there was a clear expectation that tools need to be developed to exchange views also between the yearly face-to-face meetings of the Forum. Mr Kristensen added that the resources available under the joint action are to be taken into account.
- e) Clear criteria for the selection of the members of the Stakeholders Forum need to be formalized, and the process also needs some thought in order to make the selection process manageable.
- f) Working methods or standing operating procedures need to be created at the level of each Work Package and for the Stakeholder Forum
- g) There were no clear message as to the role of experts, and inclusion of experts in the policy document
- h) Procedures to handle a potential large number of stakeholder/stakeholder interest both in joining the Stakeholder Forum and for the public consultations needs to be addressed
- i) cooperation between regulators and the EUnetHTA Joint Action should be better defined

EMA referred in the discussion to having a clear mandate from the Pharmaceutical Forum to work on the EPARs. This would mean cooperation with the work done in the Joint Action Work Package looking specifically at the follow-up of the Pharma Forum process on relative effectiveness of pharmaceuticals. Any work beyond the EPARs would need a mandate from the Commission.

EuropaBio on behalf of the industry organisations present at the meeting (EUCOMED, EFPIA, COCIR) used the opportunity to say that it is time to overcome the ideological barrier against industry that they perceive still exists. They further stated that industry is one of the largest HTA producers, and the Joint Action should not miss the opportunity to have this know-how from the industry. All industry organisations have for a long time already developed HTA principles..

6. Conclusions

Prof. Kristensen added for the conclusions that the Joint Action itself does not have a Work Package for stakeholders, so each Work Package should therefore find the appropriate way of involving stakeholders in their work. He thanked all participants for their ideas and for adding to the constructive discussion.

The next steps are the following:

The input from the meeting will feed into the further development of the draft policy document and in developing the Standard Operating Procedures. The Executive Committee aims to propose a revised policy document and SOPs for approval at the EUnetHTA Plenary Assembly meeting in May 2010.

A public consultation on the revised policy document is foreseen for March 2010.

With regard to selecting the members of the stakeholder Forum an application process will be developed in first two months of 2010, but organisations could already now express their interest of becoming a member.

7. Meeting of the EUnetHTA Executive Committee members

The meeting took place after the closing of the stakeholders meeting.

8. Enclosures: Attendance list, presentations made by Jérôme Boehm and Finn Borlum Kristensen, reports from the 4 working groups