EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
**Health strategy and Health systems**

Brussels, 15 April 2009
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# AGENDA - 2ND MEETING OF THE NATIONAL HTA APPOINTED BODIES FOR THE SETTING UP OF A JOINT ACTION BETWEEN THE COMMISSION AND THE MEMBER STATES

## 1. 10:00-10:15 WELCOME BY THE COMMISSION AND MR KRISTENSEN

After welcoming the participants, Jerome Boehm (DG SANCO Unit C5) reminded that this meeting will be the last to be organised by the European Commission (EC) in this preparatory phase and that the work will now be coordinated by the Danish delegation. It was emphasised that the documents sent for the meeting were open for discussion. The Commission underlined that by the end of this project, there should be a clear view of what can be done at EU level on HTA. To review the application, the Executive Agency on Health and Consumers (EAHC) will focus on three areas: the added-value to the EUnetHTA; the specific and measurable objectives; and the possible future of the project.

## 2. 10:15-10:45 UPDATE FROM THE COORDINATOR

- Overview of nominated bodies from the received letters of intent

On the 14th April, 31 organisations from 23 MS and 2 EEA/EFTA were listed as partners. They will become Associated Partners (APs) in the Joint Action (JA). Some Countries were not represented CY, L, RO, SK (for the EU) and Iceland and Liechtenstein (for EFTA/EEA).

- Lessons learned from the previous EUnetHTA project, the EUnetHTA Collaboration 2009 and the way to continue in the Joint Action

EUnetHTA was a project of 64 partners. 34 Associated Partners and 30 Collaborating Partners and 25 MS were represented. It focused on making tangible results and on providing value, methodology and work processes. There was a strong emphasis on the dialogue and involvement of stakeholders as well as management and organisational support structures that ensured the project's success and the sustainability of its activities. It also demonstrated that it is crucial to pay attention to the policy processes on the EU and national levels. There is already a large production of HTA in many countries, but there still remains much to be done in bringing the work forward both at national and European level - the HTA Core model was an innovative way of addressing the issue of efficient and transparent production of HTA reports. The results of the internal evaluation were also presented. (cf. attached slide presentation).

As regards stakeholders' involvement, some lessons had been learned to better formalize it and make it more transparent.

- Timetable and presentation of the draft work-packages

April 16th (4 pm) is the deadline for sending the letter of intent. The APs must furthermore send an Associated Partner form and a letter of mandate (as requested by the EAHC) signed by a representative of their Ministry by 24 April. The Declarations of Honour are awaited for May, 5th. On April 29th, the Secretariat will submit a first draft of the Joint Action proposal to the APs and DG SANCO C5 for comments. The final application to the Executive Agency will be sent by the Coordinator of the JA on HTA on 20 May 2009.

- Presentation of the draft work-packages (WPs)

The EU health programme requires three horizontal Work Packages and maximum six Core WPs, with overall six objectives and of ten deliverables. Apart from the three horizontal WPs (Coordination/Dissemination/Evaluation), it was proposed to have WPs on Core HTA; on Relative Effectiveness of Pharmaceuticals; on new health technologies with two work streams (facilitating evidence generation and assessment of new non-pharmaceutical technologies); on HTA Information Management System. In addition, there would be cross-WPs Work Stream for the facilitation of the establishment and development of HTA institutions. Cross-WP attention to life cycle of technologies perspective including obsolescence should be ensured.

## 3. 10:45-13:00 DISCUSSION ON THE PROPOSED WORK PACKAGES – TOPIC RELATED ISSUES

The discussion focused on the content and deliverables of the topic-related work packages and on the identification of the interest of the nominated bodies to work specifically in these issues. From a Commission point of view, it was reminded that the involvement of New Member States as lead or co-lead partner of the WPs was crucial.

In response to a question on the Ministries of Health's role in the process, it was recalled that the Joint Action (JA) is a scientific initiative bringing together the Member States (MS) who had to appoint an institution or a department competent on HTA, and the European Commission (EC). Therefore, MS are not stakeholders, but there is of course room for them to be updated on the development on HTA by the scientific bodies at national level. The Joint Action on HTA can provide reports/updates on the progress of the JA on HTA work if requested to the Council (e.g the Council Working Party on Public Health at a senior level).

It was emphasised that this joint action is not aimed at providing policy solutions/recommendations, but information to policy-makers.

Many questions were raised on the capacity building issue and proposals were made to focus on this in a specific WP. In reply, the participation in the JA was presented as a process facilitating continuous development of HTA institutions and expertise in itself and some means of getting funds were highlighted: the structural funds and the financing through the Public health programme. The meeting decided in the end to establish a separate WP (WP8) for this issue and simultaneously explore other avenues of financing relevant activities that will not be covered by the Joint Action on HTA by this work package.

As to the **WP4 on Core HTA**, Finland will be leading the work in the work package (THL). The work package will include 2 streams – stream A on the HTA Core Model further development, maintenance and utilisation and Stream B on the Core HTA production (Italy (AGENAS) agreed to co-lead the work focusing on Stream B). The Commission emphasised the necessity to consider sustainability of the solutions and processes to be developed. The following approach was suggested and supported for organising the work on the Stream B: The topics (i.e. technologies and scoping) of the Core HTAs will be selected and work divided in such a way that national/regional interests of partner organisations are taken into account as much as possible. Core HTAs are produced primarily by clusters of participating agencies (there is possibility to consider production by single agencies too). This is a practical approach and the intention is to contribute information that has clear relevance for all parties involved. The Commission suggested to build on the work done by Austria on Relative Effectiveness (RE) within the Pharmaceutical Forum either under WP4 or 5.

**WP5 on RE:** Netherlands (CVZ) will be leading the work in this WP (with France (HAS) as a co-lead). It was made clear that the first focus will be on clinical effectiveness, in line with the conclusions of the Pharmaceutical forum, rather than cost/ effectiveness. Some participants indicated that this was a difficult area because of the different definitions of values in Europe.

**WP6 on New technologies:** France (HAS) will be leading the work in the WP (with Austria (LBI-HTA) co-leading). All participants agreed that there is a need for further data collection for new innovative technologies. The NHS has already invested a lot in pragmatic trials and the participants agreed to consider how to include this perspective. The WP will also include a work stream on practical solutions of how to bring people/bodies together who are working on the same topics. The data reporting issue was highlighted as many agencies did not seem to introduce data in existing databases. The language issue was also mentioned. However, it was also clearly pointed out that this Joint Action is going to be demanding and that it requires efforts from all participants for its success. It will be important to ensure that there is no overlap with WP 7 through a coordinated participation of the relevant WP leads in the Work Package 7 work.

**WP7 On Information Management System:** Belgium (KCE) will be leading the work in the Work Package with Germany (DIMDI) as a co-lead. The main idea of this WP is to provide a single point of access to information resources for "HTA doers", to reduce the duplication of efforts, to exchange information and to address language and legal issues associated with data sharing. A possible overlap with the coordination WP and the dissemination one was discussed. There was a consensus on the need to think about the sustainability of the system being developed.

## 4. 13:00-14:00 LUNCH BREAK

## 5. 14:30-15:15 DISCUSSION ON THE STAKEHOLDER POLICY

The aim was to agree on a stakeholder policy, learning from amongst others the experience of EUnetHTA. The Commission reminded the participants that principles of good governance must apply in this JA. It could notably include the possibility for stakeholders to comment on the frame and terms of reference, as well as on assessments and models. HTA bodies would of course make the final decisions.

Also, ideas and comments from EUCOMED were mentioned (general support on values and missions and demand for a transparent process).

The participants received positively the following messages:

- EUnetHTA Joint Action's remit will involve European umbrella associations;
- There should be an opportunity to comment on the EUnetHTA Joint Action documents;
- It will be possible to involve individual experts from outside the group of Joint Action Partners in topic specific ad hoc working groups (if needed, and based on specific individual scientific merits in relation to the topic);
- The partners of the JA on HTA hold the rights to the final results and decide when and if intermediate results are accessible outside of the partnership;
- There should be a balanced broad engagement with all stakeholder groups;
- Lastly, the participants agreed to use the EUnetHTA Collaboration draft policy as a start for their work (i.e. setting up a stakeholder forum), but made it clear that it needs to be redrafted and streamlined.

It was agreed that the membership of the stakeholder forum should be broadly defined and be decided by the Plenary Assembly of all APs. For the various pilots involving specific technologies that will be done by the participants, the stakeholder policy of that agency/body will apply.

The participants also stressed the importance of closely exchanging information with the EMEA and it was suggested to inform the DG Enterprise Working Group on Clinical Investigation and Evaluation that works in relation to the European Medical Device Directives.

## 6. 15:15-15:45 DISCUSSION ON WORK PACKAGES – ADMINISTRATIVE ASPECTS (COORDINATION, DISSEMINATION AND EVALUATION)

The following Work Packages were then briefly discussed:

**Work Package 1: Coordination Work Package**
**Work Package 2: Dissemination Work Package**
**Work Package 3: Evaluation Work Package**

Under WP 1, it was agreed that the coordinator will also ensure the implementation of the stakeholder policy, the exchanges of information with the EMEA, for instance, and the Commission Working Group on Clinical Investigation and Evaluation.

## 7. 15:45-16:00 SUMMARY OF DISCUSSION AND NEXT STEPS

A new WP on capacity-building - co-lead by Poland and Spain - will be added. Slovenia accepted to lead the Dissemination WP (with Sweden (SBU) co-leading) and the UK to lead WP3 on evaluation.

The deadline for submission of the Joint Action is May 20th. Final decisions on the Work Packages and the leads/co-leads will be made in the week of April 15-24. Budgetary needs will also be discussed. The preliminary document should be ready by 29th April.