EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Health strategy and Health systems

Brussels, 20 February 2009
SANCO.C5/jboe D(2009)

MEETING OF THE NATIONAL HTA APPOINTED BODIES FOR THE SETTING UP OF A JOINT ACTION BETWEEN THE COMMISSION AND THE MEMBER STATES

Subject: Final minutes 20 February 2009

1. 10:00-10:15 WELCOME BY BERNARD MERKEL, HEAD OF UNIT C5 SANCO/ HEALTH

In his presentation, Bernard Merkel reminded the participants that the Pharmaceutical Forum ended last October, with the agreement that the recommendations on Relative Effectiveness Assessment should be taken forward. He also recalled the success of the EUnetHTA project, where there are some tangible outcomes that should be further built upon. In a wider context the focus on HTA is also appropriate given the current economic down-turn and discussions on sustainable healthcare systems. Mr Merkel emphasised the importance of ensuring that all Member States can benefit from the information HTA can provide.

The importance of Health Technology Assessment (HTA), which seeks appropriate spending and use of health technologies has been a constant theme over the last 20 years, this has resulted in different structures and mechanisms in the various EU countries. Consequently, the directive on patients' rights, which is being discussed by the Council and the European Parliament, foresees concrete cooperation between Member States, through a permanent structure.

2. 10:15-10:45 THE JOINT ACTION MECHANISM

Following the presentation of the joint action mechanism by Guy Dargent, from the Executive Agency for Health and Consumers (cf. attached), several questions were raised on the administrative and financial arrangements. Mr Dargent insisted on the need for each partner to take responsibility for performing and completing the work agreed in the joint action. If a partner does not fulfil his work the Commission will not pay for that work, but this does not mean that other partners can not agree to take over the responsibility, moreover the contract with the Commission can be changed to reflect the new situation. He explained that the budget and objectives should generally correspond and that the agency and the partners will do the negotiation on the details in the final stages. He also indicated that the EU coverage of the joint action budget beyond 50% will depend on the results of evaluation and application of criteria to judge the Joint Action proposal's exceptional utility.

He lastly explained that national officials (salaries) have to be considered as expense but also income with the consequence that they are not covered by EC funds. It has to be noted that Governmental bodies can hire non national officials staff (a national official is an official of a public body who is directly remunerated by the budget of the State or a local authority; his/her work concerns the implementation of tasks typically devolved to public institutions). Other additional costs e.g. travel, equipment incurred by governmental bodies are eligible costs.[1]

3. 10:45-11:15 BACKGROUND INFORMATION

Jérôme Boehm recalled the conclusions of the Pharmaceutical Forum (cf. attached), and gave some ideas on the setting up of the joint action

Following Mr Boehm's presentation, Finn Børlum Kristensen presented the conclusions of the EUnetHTA project (cf. attached), by emphasising the need to develop a structure promoting the partners' involvement through concrete piloted implementation (HPV, age-related macular degeneration, information sharing through the network).

4. 11:15-13:00 DISCUSSION ON THE SCOPE OF THE WORK

The draft guidance note, distributed before the meeting served as a basis for the discussion. During the discussion, there was general support for the necessity to have cooperation at EU level on HTA and on the need to ensure transparency and definition of basic principles in the dialogue with stakeholders. Denmark received support from all participants to act as the Joint Action coordinator and accepted to take on this responsibility.

Moreover, strong demand was expressed by many participants on capacity-building, non-pharmaceutical HTA (ensuring balance between all types of technologies), core HTA models and their practical application (piloting, including models to cover the full life-cycle of technologies from emerging to potentially obsolete), development of tools for exchange and dissemination of information on HTA (clearing house function), implementing HTA, working with EMEA/national regulatory authorities to assess how available information at different bodies can be mutually used and stakeholder involvement. Some Member States expressed their concerns regarding their capacity to finance participation in Joint Action on HTA. Overall, the discussion showed a strong commitment and an extensive list of ideas for what the Joint Action could tackle in its three years running period.

[1] Additional comment from Mr Dargent following the preparation of the minutes: The decision to qualify a staff member as public official or not is not in the hands of Member States/the participants. If someone is directly paid by the State (or local authority budget) and his/her work concerns tasks typically devolved to public institutions, then he/she will be automatically considered as public official. For instance a HTA specialist could not be considered as implementing tasks usually devolved to public institutions and therefore will not be considered as public official. The distinction is not always easy. For the application the agency will review all the situations put in the budget, and if necessary ask for adaptation.

5. 13:00-14:00 LUNCH BREAK

6. 14:00-15:30 DISCUSSION ON THE SCOPE OF THE WORK

Mr Boehm highlighted the need to formalise the work packages through possible areas of work and deliverable indicators. On the financial aspect, the Danish delegation explained its experience with the EUnetHTA project where several partners had put more resources into leading and doing work than originally budgeted after the negotiations with the Commission. Denmark stressed the need for active involvement from the participants. In addition, it was recalled that the fixed budget for the joint actions amounts to 7.5 million Euros, which has to be shared between four important actions.

Regarding ensuring/monitoring the implementation of HTA, which consists of capturing its effectiveness and whether the needs of decision-makers are met, the delegates debated whether this Joint Action was the right platform to do such work. Concomitant research funded by FP7 was mentioned as a possibility. No conclusion was reached in this regard. It was suggested to have a structured information exchange mechanism to capture information on the policy decisions made after or on the basis of performed HTAs

There was a general discussion on the emphasis to be put on pharmaceuticals, this has already been part of the scope of the EUnetHTA, and it was agreed that the Joint Action should find the right balance between all technologies. Participants were reminded that the action should answer the mandate from the Pharmaceutical Forum. As a conclusion, it was proposed to integrate Relative Effectiveness of drugs in the scope of the work. Several Member States emphasised that the work should be integrated with the HTA Core Model, and it was also acknowledged that the HTA core models might not always be completely appropriate for the evaluation of pharmaceuticals in the context of reimbursement decisions. The Netherlands in particular volunteered to take an active part in this part of the work.

As to the discussion on the case studies, various proposals were made (organisation of care for certain diseases, scanning/screening programmes, mental health, diabetes, etc). It was also agreed that there is a need to leave room to be flexible as new technologies might appear in the course of the Joint Action that deserve the attention of the group.

Another subject for discussion was the possible access to information for the public with the aim to be consistent with the transparency requirements (both the Pharmaceutical Forum and EUnetHTA webpage could be used for this). It was decided that agreed minutes and possibly also a shorter summary of discussion should be made public.

Lastly, the question of national representation was raised. The involvement in the JA of the regional HTA agencies is recognised as an important issue to solve. There is also a clear need to balance the efficiency and effective management of the Joint Action and at the same time ensure that Member States with several responsible HTA-bodies can contribute. Some participants mentioned their need to keep at least two national bodies as representatives of their country.

Next steps

The Commission secretariat will draft minutes and send them for approval by the participants in the meeting.

A draft proposal of the letter of intent should be presented by the Coordinator by 8th March. The letter is to be sent by the interested nominated organisations by March 20, and the formal submission of a full application to Joint Action on HTA should be done by Member States and eligible EEA/EFTA states before 20th May. By 31st March, depending on availability of meeting rooms[2], a meeting will be organised to further develop the application for the Joint Action. On 3 March 2009 in an e-meeting, the current EUnetHTA Collaboration partners from 13 Member States, Norway and Switzerland will discuss ways of working together with the remaining Members States in preparing the Joint Action on HTA.

[2] The meeting is now foreseen for 15 April 2009