

**EUnetHTA JA Stakeholder Forum and Executive Committee
e-meeting
September 22, 2010
1:00-3:00pm CET**



E-meeting
Organised by EUnetHTA Secretariat
National Board of Health, Denmark

Participants:

Chair of the meeting: Bert Boer, CVZ, Netherlands

Stakeholder Forum representatives:

Andrea Rappagliosi, EFPIA
Christian Peters, ESIP
Fabrizia Bignami, EURORDIS
Ilaria Passarani, BEUC
John Wilkinson, EUCOMED
Liuska Sanna, EPF
Martin Visnansky, AIM
Nicole Denjoy, COCIR
Pascal Garell, HOPE
Sandar Ribon, CPME
Ursula Hofer, CPME

EUnetHTA Executive Committee representatives:

Finn Børllum Kristensen, NBoH, Denmark (Secretariat)
Alric Rüter, IQWIG, Germany
Carole Longson, NICE, United Kingdom
Eleanor Guegan, NETSCC, UK
Eva Turk, NIRP, Slovenia
Francois Meyer, HAS, France
Gro Jamtved, NOKC, Norway
Inge Merete Skov, NBoH, Denmark (Secretariat)
Iris Pasternack, THL Finland
Julia Chamova, NBoH, Denmark (Secretariat)
Kristian Lampe, THL Finland
Sun Hae Lee Robin, HAS, France
Christoph Künzli, SNHTA, Switzerland
Wim Goettsch, CVZ, Netherlands

European Commission

Anders Lamark-Tysse, DG Sanco

Apologies:

Andrew Cook, NETSCC, UK
Raf Mertens, KCE, Belgium
EGA
ECPC

AGENDA

1. **Stakeholder Involvement Policy document: public consultation review with further clarification**
2. **Clarification of the stakeholder involvement procedure (SOP)**
3. **Clarification of expert involvement procedure**
4. **Stakeholder Forum members' comments on the 3-year Work Plan, clarification**
5. **Other issues**
 - a. **Next steps**
 - b. **2010-2011 Timetable of Stakeholder Forum e-/meetings and JA WP1 / Executive Committee e-/meetings**

Bert Boer, chair of the meeting, welcomed those present to the first e-meeting of the EUnetHTA Joint Action Stakeholder Forum. He underlined the important role of the Stakeholder Forum in the function of the network and that is an essential part of the governance structure of the EUnetHTA Joint Action. He encouraged Stakeholder Forum members to provide maximum input in the direction of the EUnetHTA Executive Committee and invited them to make statements. He further clarified that the aim of the meeting is not in negotiating issues or in reaching final agreement (though it is a welcomed sign if there is an agreement), but in having a maximum input from all participants so the Executive Committee has sufficient feedback to proceed and is able to consider the SF recommendations explicitly. He explained the structure of the meeting emphasising that after the clarification from the Executive Committee there will be room for additional questions and concise statements during the meeting. Besides a broad summary will be given after all statements are made, but no repetition of each statement will be made (more in a way of process remarks than an attempt summarize all aspects of the discussion).

Julia Chamova (JUCH) briefly explained how the e-meeting interface could be navigated during the meeting. She informed that the recording of the meeting had started and the link to the recording of the meeting would be made available to all participants and those who were invited but could not attend the meeting. She further introduced the agenda for the meeting. No additional items were brought in by the participants.

1. Stakeholder Involvement Policy document: public consultation review with further clarification

JUCH informed about the process and outcome of the public consultation which was held between July 12 and August 23, five contributions were received and made available publicly on www.eunetha.eu

- **EFPIA**
- **HTAi Interest Group on Patient/Citizen Involvement**
- **Hungarian Hemochromatosis Patients' Association**
- **IPOPI (International Patient Org for Primary Immunodeficiencies)**
- **Novartis Pharma S.A.**

EUnetHTA Executive Committee reviewed the received comments and took them into account when preparing the current adjusted draft of the policy document. She further commented that the received responses indicated a need for clarification of several significant issues with regards to origins, organisation, governance, etc of the EUnetHTA Joint Action, eg,

- **High Level Pharmaceutical Forum and EUnetHTA Joint Action**
- **Differentiation between stakeholder and expert involvement**
 - Role of the EUnetHTA Joint Action Stakeholder Forum
- **Consultative role of stakeholders with involvement defined by the Work Package Lead Partners (through the mechanism of EUnetHTA JA Executive Committee)**
- **Stakeholder groups involved in the Stakeholder Forum (4)**
- **Role of the European Commission**
- **Public consultation contributions and minutes of the EUnetHTA Joint Action Stakeholder Forum meetings will be made publicly available**

Finn Børllum Kristensen (FBK) explained that the list above is not exhaustive of all the comments provided by the Executive Committee to the Stakeholder Forum on each of the received contributions (comments were put as inserted “commentaries” inside the response documents received from stakeholders) and welcomed additional requests (if any) for clarifications. He further provided an explanation on the relationship between the High Level Pharmaceutical Forum (HLPF) and the EUnetHTA Joint Action: EUnetHTA Joint Action is a response to the Call for proposals 2009 for joint actions as a part of the annual Health Programme of DG SANCO. With regards to the HLPF and according to the call for proposals, the EUnetHTA Joint Action takes forward the specific recommendations of the HLPF working group on relative effectiveness of pharmaceuticals, ie, EUnetHTA JA is taking forward a specific task that was recommended to be taken forward after the finalisation of the HLPF in 2008.

On the issue of the stakeholder and expert involvement: EUnetHTA Joint Action separates stakeholder involvement from the involvement of experts and vice versa. Stakeholders have a lot of expertise and knowledge in the conditions, views, positions, interests, etc of stakeholders. It is for the Stakeholder Involvement Policy to ensure that EUnetHTA Joint Action has and can receive information from stakeholders, while expert involvement is focused on methodological and scientific matters where EUnetHTA Joint Action might need external (to EUnetHTA JA members) expertise. There is an additional issue of subject-matter specific expertise associated with a certain technology (ie, pharmaceutical, device, etc), eg, when WP4 Strand B selects a specific technology for their Core HTAs, and there is a need to have expertise in this specific technology.

FBK further explained that the consultative role of stakeholders and their involvement is defined by the Work Package Lead Partners through the mechanism of the Executive Committee. This will allow a direct input into the work of the work packages as they move along their work plan.

JUCH informed that based on the suggestions received from the Stakeholder Forum participants and discussions held in the Executive Committee it was decided that Stakeholder Forum will include 4 stakeholder groups, ie patients/consumers, industry, payers and providers, health media was removed. WP2 Dissemination will facilitate engagement with the media.

JUCH clarified the role of the European Commission as being a counterpart of the EU Member States through the EUnetHTA Joint Action Grant Agreement regulating the collaboration between the counterparts. A delegate of the European Commission can participate in the meetings of the EUnetHTA Joint Action.

The minutes of the Stakeholder Forum meetings as well as the contributions to the public consultations will be made publically available (through the EUnetHTA website).

Bert Boer invited the participants to first ask clarifying questions, and then bring in additional comments/views.

Andrea Rappagliosi (EFPIA) asked about the relationship of the EUnetHTA JA to the Recommendation 6.5 of the HLFP with regards to involving the stakeholders “while observing the above agreed principles”, ie, the reference to the principles agreed in the HLFP is missing in the documents. Why was this recommendation dismissed? The second question is when concretely the stakeholder involvement in the work packages will take place as we are now already at the end of the 1st year of the EUnetHTA Joint Action.

FBK responded that the practical organisation of the involvement of stakeholders in the work of the EUnetHTA Joint Action and structuring of it through the Stakeholder Forum is developed by EUnetHTA Joint Action, ie the Member States and the Commission. EUnetHTA Executive Committee checks with the Commission if the practice of the development is in line with their understanding. EUnetHTA JA did not ignore the principles of the stakeholder involvement expressed by the HLFP, they were considered and the result is the currently developed policy and concrete practical implementation descriptions in SOPs.

FBK responded to the second question that currently the Work Package Lead Partners are finalising the concrete plans of the involvement and we can share the plans after the face-to-face meeting of WP1/Executive Committee on October 14-15. EUnetHTA Joint Action acknowledges that it is the second half of the first year of the 3-year Joint Action, we are moving as fast as we can in clarifying many details of the working process and of the stakeholder involvement so we can reach best possible solution and can implement the involvement practically before the end of the year 2010.

Ljuska Sanna (EPF) stressed the relevance of the comments sent by the HTAi Special Interest Group on Patient/Citizens involvement in HTA regarding the expert involvement. The current policy seems to exclude the individual expertise of the patients. There was a positive comment from the Secretariat that this point should be further explored, however, the current version of the policy document does not reflect any changes – does this mean that the Executive Committee still deliberates over the point?

FBK clarified that expertise in patient views and patient aspects is of value and it is of equal value with eg, expertise in organisational aspects or effectiveness of interventions. That is reflected and can be seen from how EUnetHTA developed eg, the HTA Core Model® where patient aspects are addressed in the “social” domain. EUnetHTA JA will continue pursuing this approach based on research and expertise knowledge in patient aspects in order to have a corresponding/equal level with the expertise coming out of clinical research. In parallel, patient involvement as stakeholders (i.e. involvement of patient advocates) is seen as more in the sphere of the EUnetHTA JA Stakeholder Forum and not in the domain of the scientific work where we would go for the expertise of the scientists who have done research into patient/citizens views and experiences with the disease.

Ljuska Sanna advocated for better assessments if individual patients can participate as individual experts. Of course it should be done with regards to the work to be done in the individual Work Packages, however, individual patient expertise should not be excluded a priori.

Andrea Rappagliosi again asked the question about the concrete timing of the stakeholder involvement and clarification on the process, making reference to the specific wording in the SOP on Stakeholder Involvement (Modes of participation). FBK reiterated EUnetHTA’s recognition of the high importance of the question which he suggested to be taken in the order of the agenda for the meeting, ie, as the next point on the agenda. Bert Boer supported this approach.

John Wilkinson (EUCOMED) expressed disappointment with the role of stakeholders described as “consultative” in the policy document as the expectation was a more participative, inclusive role of the stakeholders. However, EUCOMED looks forward to the clarification of the procedures and processes of stakeholder involvement to see how this is going to be practiced.

2. Clarification of the stakeholder involvement procedure (SOP)

JUCH clarified that the SOP of Stakeholder Involvement has the EUnetHTA JA Grant Agreement and the Stakeholder Policy as the basis for development of specific procedures. Based on the suggestions received from the Stakeholder Forum participants, the following procedures were proposed for identification and participation of the Stakeholder Forum representatives in the Plenary Assembly meetings: each stakeholder group in the Stakeholder Forum identify their own representative to participate in the Plenary Assembly meetings; there will be time specifically dedicated during the meetings for the stakeholder representatives input.

FBK clarified the process of participation in the EUnetHTA JA Stakeholder Forum: due to the limited number of seats in the Stakeholder Forum those organisations that expressed their interest to participate in the Stakeholder Forum and found eligible for participation by the EUnetHTA Executive Committee, but were not selected to be member of the Stakeholder Forum, will have a possibility to receive information and provide input either through the representatives of their respective stakeholder group or if this mechanism is not working for some reason – they can do it through the EUnetHTA Secretariat.

JUCH informed that the provision of the feedback on the contributions received from stakeholders will include placing all contributions on a specific webpage and including them as annex to the final document. The reporting shall include a description of how the contributions were used. The Executive Committee is still discussing various implementation options that will need to be both feasible and practical.

FBK informed about the modes of participation of stakeholders in the Work Packages as described in the SOP: 3 modes of participation, ie 1) through advisory groups connected to WP4, 5 and 7; 2) through providing specific subject-matter knowledge on specific technologies (eg, assessment of specific medicine or device or surgical procedure, etc) – this can be an opportunity for stakeholders to point out the source of specific subject matter knowledge; and 3) through participation in the general public consultation on outputs from the work packages.

FBK provided further details on the WP4, 5 and 7 advisory groups mode of working: these advisory groups will be given an opportunity to comment along the work of the work packages – subject to clarification of timing and specifically at which points in the process this will take place in each of the work packages (based on needs of the work packages and the stakeholders’ interest to participate); no conflict of interest declaration will be required of the stakeholder representatives in these advisory groups. Regarding the timing and activities in each work package the Lead Partners in cooperation with the partners in each work package are currently finalising the plans (the final planning will be reflected in the 3-year work plan). FBK stressed the necessity to have a broad stakeholder groups representation in the advisory groups and encouraged the stakeholder organisations that have not yet indicated their participation to do so. Hopefully, all 4 stakeholder groups will be represented.

Bert Boer suggested that more details should be provided on the timing of stakeholder involvement activities so that the Stakeholder Forum members have a clearer picture of when they are given an opportunity to influence and provide input. FBK confirmed that the timing and details on each work package stakeholder involvement plans are being developed “as we speak” and stakeholders will

have concrete opportunities to influence. FBK further invited the WP Lead Partners present in the e-meeting to give some details.

Wim Goettsch (CVZ, WP5 Lead Partner) confirmed that WP5 partners are now clarifying how the advisory group will be working and when. The WP1 and Executive Committee will have a face-to-face meeting on October 14-15 to decide on consistent planning across work packages after which final plans will be available. Specifically WP5 will provide sufficient opportunities for commenting on products in WP5, there will be no final product without an opportunity provided to the stakeholders to give their input and play their important role. Thus, in the end of October – beginning of November the actual stakeholder involvement activities will start.

JUCH informed that the WP Lead Partners will develop their concrete timing and planning of stakeholder activities until October 4 – when they send their plans to the Secretariat for circulation across work packages for further fine-tuning for consistency and cooperation efforts across work packages. Final clarification and decision-making on the plans will take place on October 14-15 during the WP1 / Executive Committee meeting.

Andrea Rappagliosi asked why advisory groups are limited to WP 4, 5 and 7 whereas the discussion previously was around stakeholder involvement in the whole of the EUnetHTA Joint Action. FBK clarified that WP1/ WP8 and Executive Committee covers the issue of coordination and business model development– the EUnetHTA Stakeholder Forum is linked to the Executive Committee and therefore there is stakeholder involvement there. WP2 is dissemination and WP3 is evaluation. WP6 is information handling/sharing in the network which is very technical work package. It might be so that there is an interest in stakeholder involvement in this work package. That is why WP4,5 and 7 were mentioned as work packages with advisory groups – since these 3 work packages focus specifically on the HTA issues per se (ie, WP4 - HTA Coe Model®, WP5 - relative effectiveness assessment of pharmaceuticals; WP7 – new technologies).

Bert Boer suggested that the Executive Committee is requested by the Stakeholder Forum to consider possibilities of stakeholder involvement in eg, WP6. It was agreed.

Nicole Denjoy (COCIR) inquired if her understanding is correct with regards to a direct contact to the WP Lead Partners on the issues of stakeholder involvement, without going through an advisory group or Executive Committee. She found a procedure of going through the Executive Committee as very heavy. FBK clarified that there is a need to coordinate the work in the Joint Action, there is a need for policies and procedures that are common and coordinated across work packages with specific implementation modes in each work package as per their specific work plan. Thus , transparency and clear policy across Joint Action is ensured.

Andrea Rappagliosi commented (via text chat): “I keep hearing that stakeholders want to have an opportunity to "influence". I think (and for sure it is the opinion and the spirit of the constituency that I represent) that as a stakeholder we can provide the information and the expertise on HTA that you would not find elsewhere. What I define as filling the EUnetHTA knowledge gap”.

FBK responded to the text chat that EUnetHTA JA is keen on receiving the specific knowledge on subject-matter associated with specific technologies – the 2nd mode of stakeholder participation as described in the stakeholder involvement SOP. This is exactly what Andrea is offering and pointing to – ie, as soon as we are moving into the specific technologies (or groups of technologies) we will be happy to receive the advice, suggestions from the Stakeholder Forum where to go to get this specific knowledge. It could be, eg, specific knowledge on the research done in the development of a technology or it could be other kinds of information, which is very valuable since very often it is not published in the journals or not available in the grey literature. Kristian Lampe and Iris

Pasternak of THL (WP4 LP), Wim Goettsch of CVZ (WP5 LP) and Francois Meyer of HAS (WP7 LP) concurred with FBK's view.

Francois Meyer (HAS) commented that the three appropriate levels of stakeholder involvement in the EUnetHTA JA are defined. We have Stakeholder Forum as a mechanism of involvement for the general topics, coordination and strategy (through WP1 /Executive Committee). The more specific level of involvement in the work packages are being developed so there will be a common process of stakeholder involvement specifically with WP4, 5 and 7.

3. Clarification of expert involvement procedure

FBK clarified that expert involvement in EUnetHTA JA is focused on scientific and methodological work. This is a specific expertise – mainly academic, research and science expertise. We acknowledge that there are many other types of expertise, but we focus on this type of expertise that is explained by the scientific/methodological nature of the work done. We want to ensure the Stakeholder Forum's understanding of the EUnetHTA JA focus on expertise required. Individuals that are invited or volunteered to provide such type of expertise are required to declare their potential conflict of interest through filling in the conflict of interest form. Both external and internal (to EUnetHTA JA) are required to make the same kind of declaration.

Andrea Rappagliosi informed that EFPIA sent to the EUnetHTA JA a list of individuals that they consider to be experts for involvement in concrete Work Packages. He would like to confirm that the response on the concrete procedure of involvement will be available after October 14-15, meeting in WP1 / Executive Committee. He further wanted to clarify point g. in the Expert Involvement SOP, ie if the suggested procedure will be done on a case by case basis and when, how, etc this procedure will take place.

JUCH responded that the concrete plans (ie, what, when, how) of stakeholder and expert involvement procedures are being clarified by the WP Lead Partners now until October 4, when their plans will be shared within the Joint Action for consistency and coordination. On October 14-15 there will be finalisation of the plans.

FBK commented that much of the work that requires expert involvement has not been started yet, this is 3-year project. Expert involvement on specific issues is an ongoing activity, this process should be manageable so that the Stakeholder Forum is given an opportunity to point out experts for involvement yet again with the shared understanding of what kind of expertise is looked for. We received in June suggestions of 5 or 6 individuals from EFPIA as experts. Later in the month the Secretariat was copied into a mail from EuropaBio that was addressed to the Director of DG SANCO, Dr Rys, with a list of individuals suggested as experts. We acknowledge that we received these mails, and currently we are considering how to reply after making sure that Work Packages have a shared understanding about what kind of expertise is required for scientific and methodological work in EUnetHTA JA. The Lead Partners present agreed with FBK's comments.

Bert Boer summarised that there is no debate about intentions to involve the right expertise, but we have to develop the most manageable and transparent process for that.

Andrea Rappagliosi commented (via text-chat) : “Reading the EUnetHTA work plan in some work packages there are already activities that would benefit the contribution of experts. Unfortunately time is fleeting...”

Iris Pasternack (THL, WP LP 4) commented that WP4 is working towards Oct 4 deadline to identify timing and specific points in the WP4 activities for expert and stakeholder involvement.

The Core HTA production as such is planned to start in 2011. The development of the screening application of the HTA Core Model® has started, and in the issues of scoping they plan to involve Stakeholder Forum or the new WP4 advisory group this autumn (2010) before the public consultations. Andrea Rappagliosi thanked Iris for this clarification.

4. Stakeholder Forum members' comments on the 3-year Work Plan, clarification

JUCH informed that the Secretariat had received one contribution (EFPIA) with the comments on the 3-year work plan. The original response from EFPIA with comments from the Executive Committee (there were put as "commentaries" inside the original document from EFPIA) was shared with the Stakeholder Forum. JUCH went through the general comments on the work plan regarding the role of the Commission (this is defined by the Grant Agreement), the work commenced in January 2010 and EUnetHTA JA is developing concrete ways of providing opportunities to the stakeholders to provide input and influence the work, streamlining of activities eg, coordination of surveys, is a point of attention to be improved. The basis for the 3-year work Plan is the Grant Agreement with its Technical Annex – the work plan provides planning details on the implementation of the objectives and tasks described in the Annex; WP1 Coordination ensures coordination across work packages and the Executive Committee provides governance and management support. The rest of the detailed response from the EUnetHTA Executive Committee can be found in the written document sent to the Stakeholder Forum.

Eleanor Guegan (NETSCC, WP 3 LP) commented that there is an agreement with the suggestion of coordinating activities of WP3 with the WP1 whenever possible.

It should be noted, however, that since this is an evaluation of the Joint Action activities on behalf of EUnetHTA JA and European Commission, on occasion there is a need of having separate activities.

6. Other issues

a. Next steps

b. 2010-2011 Timetable of Stakeholder Forum e-/meetings and JA WP1 / Executive Committee e-/meetings

JUCH informed about the next steps in the process of finalising the documents.

- *by Oct 4 - WP LPs make final versions of their respective WP stakeholder involvement and expert involvement planning, send to the secretariat (for inclusion into the 3-year Work Plan)*
 - *By Sept 29 – SF members inform the EUnetHTA JA Secretariat on their intent to be represented in the WP 4,5 and 7 advisory groups*
- *by Oct 31 - policy document as Deliverable; stakeholder SOP and expert SOP final documents*
- *November 24, 2010 – next e-meeting of the Stakeholder Forum*
 - *review of initial implementation steps on stakeholder and expert involvement processes*
 - *other agenda items? (SF input by Oct 20)*

JUCH informed that by Sept 29 all organisations participating in the Stakeholder Forum should inform the EUnetHTA Secretariat if they intend to be represented in the advisory groups. If these organisations already have the names of their representatives, they are also welcome to share the names.

All Stakeholder Forum participants are welcome to suggest agenda items for the next Stakeholder Forum e-meeting on November 24. The suggestions should be sent to the Secretariat by October 20.

Nicole Denjoy asked about the timing of the availability of the final versions of the documents. JUCH responded that the policy document as well as the stakeholder involvement SOP and expert involvement SOP will be available in final form by October 31. The Plenary Assembly has to endorse the final versions after the work of the Executive Committee is finalised.

Bert Boer asked about the process of the Executive Committee's handling of the Stakeholder Forum's recommendations raised during the e-meeting. JUCH indicated that after the WP1 /Executive Committee face-to-face meeting on Oct 14-15 and endorsement process by the Plenary Assembly the next versions will be ready by the end of October.

Nicole Denjoy asked for clarification of the process of involving the Plenary Assembly in the endorsement process of the documents and how it relates to the meeting of the Plenary Assembly scheduled for May 2011 in London. JUCH clarified that the endorsement process is supported by the electronic means of communication and it will take place in October 2010. The face-to-face meeting will take place in London in May 2011.

b) 2011 Timetable of WP1 / Executive Committee and Stakeholder Forum e-meetings
 Timetable of the Stakeholder Forum and JA WP1 / Executive Committee e-/meetings

E-meetings are always scheduled 13:00-15:00 CET

Year	WP1 / Exec Comm	Stakeholder Forum	Notes
2010	Sept 8, e-meeting	Sept 22, e-meeting	
	Oct 14-15, Brussels meeting	Nov 24, e-meeting	
	Dec 9, e-meeting		
2011	Jan 26, e-meeting	March 2, e-meeting	
	March 21-22, Paris meeting		
	April 13, e-meeting	May 3, Brussels meeting	
	May 25-26, EUnetHTA JA Plenary Assembly meeting in London	May 25-26, EUnetHTA JA Plenary Assembly meeting in London	4 EUnetHTA JA Stakeholder Forum observers each representing a specific stakeholder group in the EUnetHTA JA Stakeholder Forum can participate in the Plenary Assembly meeting
	June 15, e-meeting	June 8, e-meeting	
	Sept 7, e-meeting	Sept 20, e-meeting	
	Oct 5, Warsaw meeting		
	Nov 16, e-meeting	Nov 22, e-meeting	

No further remarks or questions were raised. Session closed, with thanks to the secretariat.

Next Stakeholder Forum e-meeting: November 24, 2010, 13-1500 CET