

**EUnetHTA JA Stakeholder Forum and Executive Committee
e-meeting
March 2, 2011
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
Jean Mossman, EPF
Ilaria Passarani, BEUC
Irina Odnoletkova, AIM
Liuska Sanna, EPF
Nicole Denjoy, COCIR
Pascal Garel, HOPE
Pascale Brasseur, EUCOMED
Rita Kessler, AIM
Ursula Hofer, CPME
ESIP
EURORDIS

EUnetHTA Executive Committee representatives:

Alric Ruether, IQWIG, Germany
Finn Børlum Kristensen, NBoH, Denmark (Secretariat)
Inge Merete Skov, NBoH, Denmark (Secretariat)
Iris Pasternack, THL, Finland
Julia Chamova, NBoH, Denmark (Secretariat)
Sun Hae Lee Robin, HAS, France (*second half of the meeting*)
Urs Bruegger, SNHTA, Switzerland
Wim Goettsch, CVZ, Netherlands

Iga Lipska, AHTAPol, Poland (co-organiser of the Gdansk Conference)

European Commission

Anders Lamark Tysse, DG Sanco, EU

Apologies:

Andrew Cook, NETSCC, United Kingdom
Carole Longson, NICE, United Kingdom
Eleanor Woodford Guegan, NETSCC, United Kingdom
Eva Turk, NIPH, Slovenia
Gro Jamtved, NOKC, Norway
Marina Cerbo, AGENA's, Italy
Raf Mertens, KCE, Belgium
Sarah Kleijnen, CVZ, Netherlands

1. **Work in EUnetHTA JA SAGs**
 1. **Current and upcoming activities**
 2. **SAG members responsibilities and input – general principles and practice**
 3. **Public availability of the SAG member lists – proposal**
2. **Joint Action on HTA 2**
3. **EUnetHTA Conference, December 8-9, 2011, Gdansk, Poland**
4. **Other issues**
 1. **EUnetHTA Plenary Assembly, May 25-26, 2011 (London, UK)**
 2. **EPF survey on stakeholder involvement practices in HTA agencies**

Bert Boer (BB) welcomed participants to the 3rd EUnetHTA JA Stakeholder Forum e-meeting, thanked the Secretariat for a good preparation of the e-meeting and presented the agenda of today's e-meeting.

1. Work in EUnetHTA JA SAGs

Finn Børllum Kristensen (FBK) thanked the stakeholders for their collaboration in developing and establishing SAGs (Stakeholder Advisory Groups) as part of the structure for the EUnetHTA JA stakeholder involvement.

Julia Chamova (JUCH) presented the planned activities in the SAGs of WP4, 5 and 7. The Lead Partners of the presented work packages were available to answer questions and provide additional information if needed.

WP4

- Jan 31- Feb 25 – SAG comments on the HTA Core Model® for screening
- Jan/Feb 2011 – An HTA Core Model Handbook Feedback

will be used to improve the online tool for HTA Core Model, after which it can be used by Strand B for core HTA production, starting March 2011.

- Apr 2011 - 1st Draft of Policies on the Core HTA Structure (i.e. HTA Core Model and information produced through using it)

Review and public consultation takes place in May 2011 after which refinements are made and the first policy set is expected to be ready for approval by EUnetHTA in Sep 2012.

- April 2011 - Survey on adaptation processes

Advice is sought to survey design so that national and regional features can be captured as well as possible within the survey.

- June 2011- 1st draft of core HTA protocols

Review of protocols by SAG

QUESTIONS TO WP4 LP?

Andrea Rappagliosi, EFPIA, inquired if the SAG members could be involved at an earlier stage to provide answer in due time. Specifically, the time that is allowed to give comments is quite short. The feeling that the SAG members have is that what they receive for comments have “small margins for interactions” – request is for the SAGs to be involved even earlier in the stage of the production of the draft documents than it is the case currently.

BB asked the rest of the audience if they share the same feeling or if it is the individual point of view of the representative of EFPIA. EUCOMED and EURORDIS indicated that they share this perception.

FBK responded that the SAGs established in the end of 2010 and the processes are starting just now. Time for evaluation has not been long, EUnetHTA JA has its 3-year work plan with the tight schedules for deliverables – EUnetHTA JA cannot go away from that as that will violate the contract with the Commission. Thus, the time for giving the feedback is indeed following a very tight schedule. So everyone needs to understand this prerequisites and what the opportunities are – which means that those stakeholder organisations that have SAG representatives have the system and structures in place as well as competent SAG members to provide feedback in the timeframe available.

Iris Pasternack, THL, supported the position and circumstances described by FBK. She also thanked the SAG members for the valuable contributions they provided during the 3 weeks review period. She also informed that the commenting period was extended by 1 week from previously indicated deadline – giving a total of 1 month for review and commenting. She further informed that the WP4 Lead Partner is now improving the process to allow for commenting in the earlier time of the documents development, eg, in the review of the protocols for the Core HTAs.

Irina Odnoletkova, AIM commented (via text-chat) that “AIM is a new stakeholder, we thus have no feedback on the previous experience but would like to understand how we optimally can contribute.”

Liuska Sanna, EPF, asked for clarification on any new stakeholder forum members.

BB concluded that the experience being gained at this early stage of the SAG’s involvement will inform further improvement of the process. He further emphasised that the SAGs involvement is planned in advance and everyone – including the SAG members – can plan in advance their input into the work process.

Andrea Rappagliosi, EFPIA, disagreed with the conclusion of the agenda point indicating that the issue at stake is the earlier involvement of SAGs in the document development process, and not the issue of the work plan deadlines.

JUCH thanked Iris Pasternack for indicating that specific steps have been already taken to improve the process to allow a quality input from the SAGs. She further reminded that the SAG involvement guidelines discussed and agreed previously indicate 2-weeks timeline for commenting of a draft document, ie, the document is not in its final form that is not to be changed – the input from SAGs is thought specifically for the purpose of the document improvement.

JUCH further commented that the SAG members were nominated to participate in the SAGs based on their competence in the subject matter that should be sufficient to provide a quality feedback within the timelines given.

BB asked if EUCOMED has any specific comments on the issue raised.

Pascale Brasseur, EUCOMED, commented that more proactive involvement would be ideal in their view. She further questioned the scientific rigour of the form that the SAG's comments are sought. No specifics were given to support the last statement.

FBK requested more details behind the EUCOMED's statement on the scientific issues. Regarding the involvement in the "earlier stages" – the opportunity that EUnetHTA JA provides to the stakeholders to be involved is extremely early in the development process and that can be realised by checking carefully the EUnetHTA JA WP work plans. Stakeholders have an early access to the process and drafts of what and how we work on.

He further requested that the stakeholders consider moving on from expressing the same needs over and over again with the EUnetHTA JA providing the justified answer repeatedly. The time should be spent more productively and not only on the procedural points.

BB concluded that the request of the stakeholders of being involved as early as possible in the development of the documents received a response from the EUnetHTA JA that the earliest possible involvement is already taking place with the process being under development and further improvement.

BB requested Pascale Brasseur to clarify her comment regarding the scientific quality.

Pascale Brasseur clarified that since she receives sometimes the responses of the SAGs to the requests to comment as being "no comment" she concludes that this contribution might be scientifically poor, ie, there is almost no "true" input.

Iris Pasternak had an adjustment to the timeline of the upcoming consultations in the WP4:

- the feedback on the HTA Core Model Handbook is delayed – till the end of March (instead of January/February)
- adaptation processes is a very preliminary planning and might be changed to May 2011

Andrea Rappagliosi commented (via text-chat): if we have to stick to the work plan why deadlines are postponed only in one way (when the WP is not ready), but cannot be worked out to facilitate stakeholder involvement?

FBK (via text-chat): Dear Andrea, I was expecting this question. It's a problem that there are delays. The work is demanding, the work put into establishing the SAG's by the WP leads did not help, and probably the call for Joint Action 2 will be yet another challenge. We'll monitor and discuss this with the EAHC and SANCO.

JUCH asked Iris Pasternak to share the updated schedule of the commenting in the WP4 SAG with the SAG members (and the Secretariat) as soon as possible. Iris confirmed.

BB asked JUCH to present the plans in WP5.

JUCH presented the WP5 SAG plan 2011 – she mentioned that any latest adjustment in the plans will be indicated by Wim Goettsch, CVZ participating in the e-meeting.

WP5:

- Jan 27- Feb 18 – SAG comments on the concept version of the background review for REA of Pharmaceuticals

public consultation is to start March 7

- March - selection of pharmaceuticals for the rapid and full REA model
- April - concept guidelines
- December - results of the pilot experiments

Specific product assessments (pilot experiments)

- WP5 will consult the manufacturers of the specific products that will be part of the pilot experiments for the rapid and full model. The timing of the consultation is simultaneously with the feedback of the SAG on the results of the pilot experiments (December 2011).

QUESTIONS TO WP5 LP?

Wim Goettsch, CVZ, thanked the SAG members for constructive and relevant comments on the concept paper. The public consultation might be postponed maximum 1 week due to the need to carefully incorporate the received comments into the draft paper that will go for the public consultation. Wim also confirmed that the delay in the start of the public consultation will not affect the overall duration of the public consultation – it will be the same time allowed for responses as it had been originally planned.

BB invited comments/questions to the WP5 LP on their plans.

Liuska Sanna, EPF, inquired how the public consultation will be conducted and suggested that the next consultation with the SAGs could be structured a little bit more, ie, the feedback sought could be in a list of specific questions as it was the case in WP4.

Wim responded that they will look into the improvement of the structure of the feedback sought though the original request for the feedback was structured and indicated specific areas of interest. He will contact WP4 to see what forms/structure they used.

Andrea Rappagliosi, EFPIA, asked if the list of the pharmaceuticals for the REA is already available.

Wim responded that there is no defined list yet, however, considerations for what pharmaceuticals should be on the list include that this list should reflect the reality as much as possible and include new pharmaceuticals with disease indication not being too small or too big. The list is to be put together by the WP5 members and the manufacturers of the pharmaceuticals. The SAG will be contacted to comment on the list as described in the WP5 work plan.

Andrea Rappagliosi expressed his fear that the list is not yet ready 3 weeks before the deadline and his interpretation that behind the polite answer might be the lack of willingness to share with the stakeholders the information on the considered pharmaceuticals on the list.

BB requested Andrea Rappagliosi to stick to facts and not bring up personal hypothesis or interpretations.

FBK commented that the pharmaceuticals list is the matter for the SAG and not for the Stakeholder Forum to go far into. He thanked Wim for providing the general information on the issue which is completely appropriate at this time and this audience. This should not lead to any insecurity on the part of the stakeholders regarding the seriousness with which the EUnetHTA JA does its work.

Wim Goettsch responded to Andrea's comment that the discussion of the pharmaceuticals for the list started some time ago and information will be provided to the relevant parties quite soon.

BB thanked the participants and asked JUCH to proceed to WP7 plans.

JUCH commented that the representative of WP7 LP is unfortunately not present in the e-meeting and all the clarifying questions will have to be collected and sent to the WP7 LP who will answer them directly to those who put the questions.

JUCH then presented the WP7 plans:

WP7

- March - the review of the first draft of criteria to select and prioritize new technologies for additional evidence generation
- March - review of the draft of the dataset, following completion of the Delphi activity, on prospective data collection in development
- September - the review of the first draft of relevant items that will define the content (the nature of information to be shared) of the database for additional evidence generation on new technologies

QUESTIONS TO WP7 LP?

Nicole Denjoy, COCIR, asked what is understood under the title “new technologies”.

FBK responded that there are no limitations on the type of technologies that can be placed under this title. It is not focused only eg, devices or drugs, it could be new diagnostic procedures or interventions.

Pascale Brasseur, EUCOMED, remarked that EUCOMED did not receive any communication that there are delays in WP7. Further she inquired if the requests for comments on the two items scheduled for March will come together at the same time.

FBK commented that any information on the delays should be communicated to the whole of the SAG membership. He further informed that WP7 LP (HAS) had some personnel changes at the project manager level which might have caused some glitches in communication.

Nicole Denjoy asked for more specificity on the definition of the “new technologies”.

Bert Boer responded that in a view of the WP7 LP absence the questions specifically targeting the subject matter of the WPs' work should be directed to the WPs, and the current forum should not go deep into the details of the WP work specifics. Otherwise we will go into duplication of discussions that take place at the SAG level and in the Stakeholder Forum.

JUCH commented that delays in starting the consultations should not affect the duration of the consultation itself, ie, the time for response will stay the same as if it would have been if no delays had happened.

Andrea Rappagliosi requested clarification of the comments indicating that certain issues are "to be discussed at the level of SAG" – the process as he understands is that the SAG members are asked to comment on certain issues relevant to specific documents and there is no discussion as such with the SAG members.

FBK responded that the matter of semantics should be dealt with carefully – a better word – other than "to discuss" - would be "to bring up in" the SAGs.

Bert Boer reiterated his request not to start the discussion about procedures again –after they have been agreed.

1.2 SAG members responsibilities and input – general principles and practice

JUCH presented the agreed and known principles and procedures for SAG member involvement since the practice of SAG work showed the necessity to present it once again.

Procedures

- Both members and participants of the Stakeholder Forum may appoint (up to 3) individuals for representation in each of the WP SAGs and have to inform the EUnetHTA Secretariat of their names
- WP LPs manage SAGs
- Composition of SAGs can change over time due to the change of the topic
- Each member of the SAG signs a confidentiality undertaking document prior to commencing the work.
- The SAG Counsels sign the confidentiality undertaking as well
- If more than one individual is appointed to represent the Forum participating organisation, a collated singular response on major documents is requested per each Forum organisation represented in the advisory group.
- The individuals – members of the specific WP SAGs are appointed and participate in the WP SAG process on the grounds of sufficient individual competence to provide feedback during the SAG review processes.
 - They may turn for advice to the SAG Counsels who were identified by the SAG's members in advance to their commencement of the work on the SAG.
 - However, the process of the SAG review is not equal to the process of consultation with the whole of the umbrella stakeholder organisation.
 - The views of the stakeholder umbrella organisations may be provided during the public consultation process.

The above means that the EUnetHTA JA does not accept nomination of many SAG counsels to be consulted by the SAG members on each occasion of the SAG consultation.

Nicole Denjoy (via text-chat) inquired who the SAG Counsels are.

JUCH clarified that the “SAG Counsels” are the individuals indicated by the SAG members who they SAG members might need to consult in order to provide their input to the SAG activities. These people are either representatives of the Stakeholder Forum organisation’s headquarters office or the superiors at the place of employment of the SAG member who they need to consult.

Pascale Brasseur inquired if the SAG member needs to get advice on a specific question – without disclosing the confidential documents – with the individuals outside of the counsel group - is it allowed? JUCH confirmed that this allowed as long as the confidential documents are not shared.

Nicole Denjoy asked if it is possible to nominate additional individuals to the SAGs (still within allowed number of people per SAG per SF member) who do not possess any competence to provide input but to “monitor” what is going on.

JUCH responded that this nomination of additional individuals without any competence to SAGs is not allowed. There are plenty of means already provided by the EUnetHTA JA stakeholder involvement practice (eg, Stakeholder Forum, SAG Counsels, SAG members) that gives ample opportunity for “monitoring”.

1.3 Public availability of the SAG member lists – proposal

JUCH presented a proposal from the WP4,5 and 7 LPs on how to handle the availability of the SAG member lists:

- The names of the EUnetHTA Stakeholder Forum organisations participating in the EUnetHTA WP SAGs will be made publicly available on the EUnetHTA website with the description of mandate and input sought from the SAG members
- The names of the individuals – members of the WP SAGs will be available for the EUnetHTA JA members and Stakeholder Forum organisations
- The names of those SAG member organisations who have actually contributed to the contents of the EUnetHTA deliverables are published within acknowledgements of relevant documents. Additionally, when the contribution has been substantial, name(s) of the individuals – members of the WP SAG can be included within the acknowledgements, provided that the respective person(s) agree to this.

The proposal was accepted.

Maria Mavris, EURORDIS (via text-chat) - I would have liked to know more about the kind of individual competences required to be accepted as SAG member in any of the WP.

JUCH clarified that the competence is connected to the subject matter of the specific WP where the SAG member is assigned to – the competence is based either on the academic background or experience in the subject matter that would allow the individual to provide sufficient and quality input into the SAG work.

2. Joint Action on HTA 2

FBK informed about the call for the complementary Joint Action on HTA (Joint Action 2) will be issued as a part of the Health Programme Annual Work Plan 2011.

- The conditions defined for Joint Actions by Executive Agency for Health and Consumers
- The current EUnetHTA Joint Action
- The Cross Border health Care Directive
- **The process ahead**
 - **proposal (March – May)**
 - **assessment of the proposal (June -)**
 - **Negotiations with the executive agency (autumn)**
 - **JA 2 contract signed (before end of 2011)**

FBK commented that it is favourable there is this call, however, it is a challenge that it comes so early – there will be an overlap with the current JA, and it also happens during the ongoing JA1 where a bigger number of assumptions needs to be built into the JA2 proposal since the results are yet to come in JA2 at this point of time.

The text of the call:

- complement the joint action on health technology assessment (HTA) 2010-2012
- carry out a significant number of pilot HTAs
- piloting and implementing the developed models and tools to support collaborative production of core HTA information
- further development of production-related ICT infrastructure
- increase of HTA capacities
- production of transferable core HTA information
- simultaneous collaborative production of structured core HTA information
- specific collaborations between joint action partners on shared topics for HTA
- testing capacity of national HTA bodies to conduct single rapid HTA's together
- collection of data on the costs and efficiency gains
- testing of the capacities to produce structured core HTA information across technologies (pharmaceuticals, medical devices, interventions)
- analysing various coordination capacities for the permanent secretariat function
- testing involvement of stakeholders in network activities
- increase the number of HTA's produced at the national level with the facilitation by the European coordinating mechanism
- produce recommendations on the design and running of the EU HTA cooperation process
- facilitate an increase in the stakeholders' capacities in HTA enabling their appropriate contribution to the HTA process
- results should be published as scientific, openly accessible literature

FBK further informed that the Member States were formally requested to nominate institutions for participation in JA2, and there will be JA proposal preparatory meetings held in Brussels with participation of this nominated institutions and the European Commission.

Bert Boer commented that JA2 is not an official task of EUnetHTA Joint Action and therefore the purpose of this item on the agenda is to inform the Stakeholder Forum without any request for further discussion of commenting on the point.

Andrea Rappagliosi expressed a recommendation that the task of EUnetHTA Joint Action is to produce results and deliver on time, to demonstrate the acceptable level of stakeholder involvement to be a candidate for the Joint Action 2, otherwise he suggest to the Commission to rethink the timing of the Joint Action2.

3. EUnetHTA Conference, December 8-9, 2011, Gdansk, Poland

JUCH made a brief introduction of the EUnetHTA Conference in Gdansk Poland. CVZ, NL is responsible for the programme of the conference and AHTAPol, Poland is responsible for the logistics and organisational details. EUnetHTA Secretariat is supporting both organisations in their tasks, and the Executive Committee is overseeing the whole preparation process.

Iga Lipska, AHTAPol, presented the organisational details and Wim Goettsch, CVZ, presented the themes for the programme.

Date and venue:

- ❖ 8 -9 December 2011
- ❖ Poland, Gdańsk

2. Participants:

- ❖ EUnetHTA partners
- ❖ Decision makers, reimburses, MoH representatives
- ❖ DG Sanco
- ❖ Stakeholders (industry, payers, patients, providers)
- ❖ Research Institutions, HTA assessors
- ❖ International networks (HTAi, INAHTA, ISPOR,)

4. Calendar

- ❖ Registration open - May (tbc)
- ❖ Early registration deadline – 15 September
- ❖ Registration closed – 14 October

5. Fees

EUnetHTA Members - 800PLN early registr. /1000PLN (200€/250€)

Others - 1500PLN early registr./2000PLN (375€/500€)

The programme will start in the early afternoon of December 8 and will go on to the early afternoon of December 9, 2011. The programme is thought to be of 2 parts: Dec 8 will be dedicated to the general issues in EUnetHTA JA, Dec 9 will focus on the pharmaceuticals. Representatives from the Polish Ministry of Health and the Commission are thought to provide input in the first day followed by the presentations from the EUnetHTA Secretariat. We are also planning and counting on having an input from the stakeholders in this part as well. The representatives from the 4 stakeholder groups are thought to present their views on the current developments in HTA and in EUnetHTA JA in particular, and a round table discussion with EUnetHTA representatives is also thought to be employed for general discussion. The second day will focus on the developments in the pharmaceutical area – with presentation from the development of the pilots on REA of pharmaceuticals in EUnetHTA and guidelines. The second day will also focus on discussions how the information from the European level of collaboration is translated into the developments on the national level. Representatives from the 4-5 MoHs are thought to be invited.

Andrea Rappagliosi asked if there is possibility to collaborate on the agenda for the conference.

Bert Boer commented that the modes of stakeholder participation were already mentioned during the presentation of Wim.

Wim confirmed that the considerations are given to offering an opportunity to the stakeholders to present and then participate in the round table discussion. We are open to discuss this with the stakeholders on how this can be organised.

FBK informed that Francois Meyer had joined the e-meeting and would be able to take up the questions regarding the WP7 SAG work.

Bert Boer welcomed the questions to Francois Meyer.

Pascale Brasseur, EUCOMED, asked about the timeline of the WP7 SAG work and any delays as well as the timing of the 2 consultation that are both scheduled for March 2011.

Francois Meyer informed that the documents for consultation on the dataset is to be sent out in the end of March (the process is managed in collaboration with NETCSS, UK), the other document for consultation is for the criteria for selection of the new technologies for additional evidence generation – to be sent out by HAS at the end of March as well. This info will be disseminated by email. Period of response – 2 weeks.

JUCH brought up the request expressed by COCIR (Nicole Denjoy left the e-meeting by now) to clarify/give more detail behind the title “new technologies”.

Francois Meyer clarified that the title should be read in a context of the WP7 work – “the new technologies for which additional evidence generation is required”. The new technologies are the ones that are innovative, they are ready to enter the market and be reimbursed since they are bringing additional value to what already is available on the market, however, there are still some uncertainties and questions that need to be answered through additional evidence generation.

Irina Odnoletkova, AIM, (via text chat): “Back to the individual competence contribution issue: will it be correct to see one-expert contribution as reflection of the stakeholder group”

FBK responded that the SAG contribution is not seen as reaching or aiming at the representativeness of the view/positions of the whole of the stakeholder group. It is to ensure that there is an opportunity given to the stakeholders to share their expertise at an early stage.

5. Other issues

- 1. EUnetHTA Plenary Assembly, May 25-26, 2011 (London, UK)**
- 2. EPF survey on patients involvement practices in HTA agencies**
- 3. Next meeting – May 3, Brussels**

EUnetHTA Plenary Assembly

Time:

- May 25-26, 2010,
- 13:00 - 18:00 (May 25),
- 09:00 - 16:00 (May 26)

Venue:

- Mint Hotel, 30 John Islip Street
London SW1P 4DD
Tel.: 020 7630 1000

Organiser:

EUnetHTA Secretariat (with assistance from NICE, UK)

4 Stakeholder Forum representatives (4 people) to attend (each representing a specific stakeholder group: patients, providers, payers and industry)

- **it is up to the stakeholder group to organise a process of identifying who will represent it at the Plenary Assembly meeting**
 - **by April 15 – inform the Secretariat on the name of the stakeholder group representative to be registered for the Plenary Assembly attendance**

At the meeting:

- **stakeholder representatives will be given specified time to bring in stakeholder group input**
- **certain items on the agenda may be discussed without presence of the stakeholder representatives**

Andrea Rappagliosi, EFPIA, commented that it was never agreed that the stakeholders cannot be present for the certain items on the agenda and finds it interesting to see this in the view of the transparency and striving for openness.

FBK responded that the procedures and documents clarifying the role of the stakeholders at the Plenary Assembly meetings need to be checked. If there are certain issues of the internal character that need to be discussed only by the Plenary Assembly members, the Plenary Assembly needs to retain the right to do it internally without the stakeholder presence. Stakeholder cannot be involved in all processes.

Andrea Rappagliosi, EFPIA, further insisted that EUnetHTA JA is a public exercise supported by the public money and should be open. He further commented that the European Commission should express their views on the point.

Alric Ruether, (Chair of the Plenary Assembly), IQWIG, commented on EFPIA's repeated requests for "more transparency" without recognition of the already high level of transparency and stakeholder involvement provided by EUnetHTA JA. He further supported the view that there might be points that are inherently internal to the Plenary Assembly competency and have all the legitimacy to be discussed only by the Plenary Assembly members. It does not mean that there is no transparency, eg, about the results of such discussion.

Bert Boer invited to proceed to the next point on the agenda and welcomed Liuska Sanna, EPF, to present it.

Liuska Sanna, EPF, informed that EPF held a seminar on patient involvement with a main outcome of "a call for a stronger patient involvement in HTA". Based on that EPF developed a survey of HTA agencies, patient organisations, and appraisal committees and decision makers. It was started last year. The survey of the HTA agencies has been completed and a report is being prepared (release – March 2011). EPF would like to thank all the agencies contributed. The draft report will

be shared with the agencies for comments before its release. The final report will be published on the EPF website.

5.3 Next meeting – May 3, Brussels

JUCH informed that the next SF meeting is a face-to-face meeting on May 3, 2011 in Brussels

- 1 representative per Stakeholder Forum member organisation
- Logistics information and agenda will be provided in due time for preparation of the meeting

JUCH brought in the request from Andrea Rappagliosi (via text.chat) on the position of the Commission with regards the transparency of the processes in EUnetHTA JA and participation of the stakeholder representatives in the Plenary Assembly.

Anders Tysse, DG SANCO, responded that a year was spent to set up a structure and processes for stakeholder involvement in the EUnetHTA Joint Action. Stakeholders are not partners in the Joint Action as clearly stated in the contract which is signed between the Commission and the Member States. The Commission's position is such as a platform was created to allow for an interaction with the stakeholders in the EUnetHTA Joint Action and the Commission clearly sees a coherent effort from the EUnetHTA JA to provide fair opportunities for the stakeholders input. Specifically for the Plenary Assembly – the meeting of the Plenary Assembly is a decision-making event for the partners of the EUnetHTA Joint Action, and therefore, participation of the stakeholders in the Plenary Assembly as described by Andrea cannot be agreed with – the stakeholders have place in the PA meeting as described by the Secretariat (observer status) and in accordance with all the documents that have been decided as the basis for the stakeholder involvement in the EUnetHTA Joint Action

Bert Boer thanked all the participants and closed the meeting.