WP8

Appendix 2:

SF-Executive Committee ftf meeting summary, May 2011, Brussels, Belgium

EUnetHTA Stakeholder Forum Meeting
Brussels, Belgium
May 3, 2011, 10:00 -16:00

Address of the meeting venue: Belgian Health Care Knowledge Centre (KCE), Centre Administratif du Botanique, Door Building (9th floor), Boulevard du Jardin Botanique, 55, Brussels

Summary Report

Agenda

1. Opening, presentation of participants	10:00 – 10:15
2. Update on the developments in the EUnetHTA Joint Action	10:15 – 10:30
Presentation, Q&A	
3. Current experience with stakeholder involvement in EUnetHTA Joint Action	10:30 – 11:30
a. WP SAGs activities	
Presentation and discussion	
4. Orientation on the stakeholder involvement in the view of the Directive on cross-border health care	11:30 – 12:00
Presentation, Q&A	
Lunch	*12:00 – 13:30*
5. EUnetHTA Business Model	13:30 – 14:30
Presentation, Q&A	
Coffee break	*14:30 – 14:45*
6. Joint Action 2 on HTA	14:45 – 15:30
a. Capacity building/training of stakeholders in the context of Joint Action 2 on HTA	
7. Other issues and closing of the meeting	15:30 – 16:00
a. EUnetHTA Conference	

1-2. Opening, presentation of participants and Update on the developments in the EUnetHTA Joint Action

Finn Børlum Kristensen, EUnetHTA Executive Committee Chair, welcomed the participants to the EUnetHTA Joint Action Stakeholder Forum (SF) meeting.
He presented the agenda for approval. Bert Boer from CVZ was unable to participate in the meeting, and thus Finn would chair the meeting.
Participants introduced themselves (see List of Participants).

2. The Chair outlined the status of work of the EUnetHTA in particular the draft documents not previously shared outside the Executive Committee, (such as the Business Model). He opened the floor to the audience to provide any feedback on their experienced interaction with EUnetHTA JA.

During the ensuing discussion the following comments and clarifications were made:

Most of the Stakeholders (S.H.) are expressing the advantage of the work that has been done but share the feeling of the time pressure in the deadlines for commenting. The involvement with the work packages (WPs) is very important BUT people are busy with other tasks and are short in human resources. For certain stakeholders the Commission should consider providing resources for more staff, as the documents are complicated and in order to fill them more human resource is needed.

A need for clarification of confidentiality rules was raised, and it was asked whether it is appropriate that SAG members cannot share the information received with their umbrella organizations.

The Chair responded that information that was marked confidential should only be circulated to those individuals who signed confidentiality agreements. Information that was not indicated to be confidential could be circulated at the discretion of the SAG members.

EFPIA informed the Forum of an industry meeting that took place on 12 April. The value that industry brings to the HTA process and how it could provide input to the EUnetHTA JA was discussed. The Industry representatives would be happy to share the results of this reflection with the SF, and offered to let it be part of industry's input to the EUnetHTA Conference in Gdansk in December.

A request has been made to receive the agenda of the Plenary Assembly meeting in order to organize the representation of patients/consumers. Since the Plenary Assembly was conflicting with several other commitments an umbrella organisations would like to contribute in writing.

EUCOMED invited EUnetHTA JA to provide earlier information on SF meetings, also in view of giving sufficient time for follow-up to eligible but non-member organizations to provide input in the process.

A question was made by EGA regarding the preferred form of input from umbrella organisations, should it be one common response or many detailed ones from members. The Chair specified that a common summary response is preferred, as the qualitative aspect is what matters most, not numbers.

The need of a stronger "Marketing" process in general for EUnetHTA was emphasised. Knowledge on EUnetHTA is rather low, and the Home page is not sufficient dynamic.

3. Current experience with stakeholder involvement in EUnetHTA Joint Action (WP SAGs activities)

Iris Pasternack (WP4) reported on the status of work in WP4. She indicated that the core model for screening had been sent out for comments to SAG, and that 11 out of 12 members provided comments. The comments were of quality, combining both scientific comments and editing/English comments. She noted that, whilst some comments could not be taken on board at this stage, they were kept as pending

issues for the next round of documents. She also indicated that SAG would receive feedback on their comments in the course of next week. A core model will go out to public consultation and a draft pilot will take place on screening for abdominal aortic aneurism. She also indicated that the deadline for comments of three weeks that had been used for the online tool and handbook was too short, and that only 4 SAG members tested the tool whilst only 1 response was received. She indicated that WP4 strand B had started its pilot on a diagnostic core model for gene expression test for breast cancer.

The Chair indicated that the core model was conceived as a generic and non-specific model. He referred to the skewed perception that all HTA is done by HTA agencies when in most cases they are actually based on submissions. He considered that guidelines for submitters would bring real added-value, and that this was one of the proposed tasks of the next JA.

WP5 Wim Goettsch (WP5) reported that Large consultation was made in Europe and outside of it. The time was limited. However, there were many good comments. It was found to be a good model. a small consultation on potential topic molecules with the pilot had been made and there is a need of a decision in terms of which kind of pharmaceuticals should be chosen. There were 4 positive responses with willingness to contribute.
Two consultations had been held and there was one more to come. At the beginning of 2012 a consultation will be made, pending on the work that going on.

From the industry point of view it was put as a question what the role of the S.H. will be while the pilot is running - will it make any difference in the way the HTA is done.

WP7 Francois Meyer presented the status of development in WP7 (see slides)

The Chair concluded that experience with the SAGs was now growing and that the SF would be invited to discuss the SAGs again in the autumn.

4. Orientation on the stakeholder involvement in the view of the Directive on cross-border healthcare

The Chair introduced the discussion by highlighting the existence of article 15, which would enable Community support in the future and mentioned that good governance and appropriate stakeholder consultation was in the text. He asked the Commission to provide more insights into the implementation processes

The Commission informed that by 25 October 2013 the Directive should be transposed into national legislation. The Directive text is the result of clarifications between the European Parliament, The Council, and the Commission. In order to implement article 15 (and others), a Committee composed of Member States representatives will be set up already this year (article 16). The lessons learned from JA1 and JA2 will be used as a basis for the permanent network to be set up. Upon request of **EGA**, he confirmed that generalists would sit in this Committee, probably from ministries. Experts might be invited one or several expert groups.

5. EUnetHTA JA Business Model
FBK introduced the discussion (see slides).

A number of comments were given to the Business Model (BM)

1. How the B.M. can be operational?
2. What are the purposes of a BM for EUnetHTA?
3. Where is the “market” represented in the model?
4. Considerations on status as legal entity is missing.
5. What is the meaning of “fee” in the model?
6. There are points on the model that need further development

7. A corporate BM should reflect how profit can be generated. This aspect is not reflected in the B.M.
8. Customers should be taken into account

The BM should be considered a "living" document to encapture the political, policy, HTA and scientific developments in Europe towards a permanent network (Article 15). Upon request of **EUCOMED** and **COCIR**, **The Chair** confirmed that a document would be filed to the Executive Agency according to the work plan by December 2011 but that further reflection would take place.
An update on the development of the BM could be provided for discussion at the next Forum e-meetings in June or autumn.

EFPIA found that the SF as outlined in the business model was weak, and that to EFPIA's understanding, the discussions that took place in the context of the European Parliament on the Directive requested a stronger stakeholder involvement. The Chair emphasized that the BM was closely reflecting the stakeholder involvement in the JA and the Article 15 text.

The Commission agreed in a suggestion that there was no urgency to put this document to public consultation.

The Chair thanked the Forum for their valuable input and it was agreed that the Executive Committee would come back to the Forum for their further input.

6. Joint Action 2 on HTA
The Chair introduced the discussion by outlining that this was a call for a complementary JA and referred to the text in the Health work programme 2011.
In relation to the mentioning of stakeholders in the call it had been clarified that the main purposes was to contribute to building stakeholder capacity (patients and healthcare professionals) and that health professionals are not only doctors or pharmacists but also other professions in healhcare.

The Chair noted that pilots were about conducting assessments, not appraisals and that it would be useful to involve stakeholders in scoping and to pilot the WP SAG approach further.

EUCOMED underlined the importance of involving other stakeholders than represented in the Forum, such as physicians snd clinical researchers, especially where they might not have connections with provider umbrella organizations – e.g. Scientific Societies might be the relevant organisations to involve in when adressing certain technologies.

7. Additional issues and closing of the meeting (EUnetHTA JA Conference)
Wim Goettsch informed the Forum about the agenda of the December Conference in Gdansk. The afternoon of December 8 would be dedicated to the JA1 and the business model / strategy for the future with an introduction by Commissioner Dalli (invited). Capacity building would also be addressed, and a session would be left free for stakeholders (speakers from the 4 stakeholder groups) to discuss their views on the evolutions in Europe and the impact on the national level. On December 9 the results of the pilot relative effectiveness assessment of a pharmaceutical would be presented, and if the results were not yet available methodologies and guidelines would be presented by HAS. The Commission would also present its plans for JA2 and representatives from national ministries (4-5) would be invited to explain how they see the HTA developments for their own national HTA and reimbursement assessments. A panel discussion involving Member States, EUnetHTA and EC would close the day
EPF noted that the timing would make it a bit late to discuss JA2, since it would already have been approved by the EC
Wim confirmed that there were still some opportunities to develop the agenda
Upon request of **COCIR**, **Wim** confirmed that the conference would be open to all interested stakeholders, but that a limited number of seats would be reserved for EUnetHTA JA members and special invitees and that a balanced representation of stakeholders would be sought

The meeting was adjourned at 15.45, and participants agreed that it had been really useful to meet face-to-face.

Participants List

As of May 3, 2011

EUnetHTA Stakeholder Forum

Attendee	E-mail	Organisation
Irina Odnoletkova	irina.odnoletkova@mloz.be	**AIM (Association Internationale de la Mutualité)**
Ilaria Passarani	ipa@beuc.eu	**BEUC (The European Consumers Organisation)**
Nicole Denjoy	denjoy@cocir.org	**COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry)**
Annabel Seebohm	annabel.seebohm@cpme.eu	**CPME, Standing Committee of European Doctors**
Andrea Rappagliosi	andrea.g.rappagliosi@gsk.com	**EFPIA (European Federation of Pharmaceutical Industries and Associations)**
Edith Frenoy	edithfrenoy@efpia.org	**EFPIA (European Federation of Pharmaceutical Industries and Associations)**
Elke Grooten	elke.grooten@sandoz.com	**EGA (European Generic Medicines Association)**
Pascale Brasseur	pascale.brasseur@medtronic.com	**EUCOMED – Medical Technology**
Liuska Sanna	liuska.sanna@eu-patient.eu	**EPF, European Patients' Forum**
Christine Dawson	christine.dawson@esip.org	**ESIP (European Social Insurance Platform)**
Fabrizia Bignami	fabrizia.bignami@eurordis.org	**EURORDIS (European Rare Diseases Organisation)**
Maria Mavris	maria.mavris@eurordis.org	**EURORDIS (European Rare Diseases Organisation)**
Pascal Garel	**sg@hope.be**	**HOPE (European Hospital and Healthcare Federation)**

EUnetHTA Executive Committee

Attendee	E-mail	Organisation	Country
Wim Goettsch	WGoettsch@cvz.nl	**CVZ (College voor zorgverzekeringen)**	The Netherlands
François Meyer	f.meyer@has-sante.fr	**HAS, Haute Autorité de Santé**	France
Alric Ruether	alric.ruether@iqwig.de	**IQWIG (IQWIG, Institute for Quality and Efficiency in Health Care)**	Germany
Finn Børlum Kristensen	**fbk@sst.dk**	**EUnetHTA Secretariat, National Board of Health**	Denmark
Naomi Dayan	**eunethta@sst.dk**	**EUnetHTA Secretariat, National Board of Health**	Denmark
Raf Mertens	Raf.Mertens@kce.fgov.be	**KCE (Belgian Health Care Knowledge Centre)**	Belgium
Marianne Klemp	Marianne.Klemp@kunnskapssenteret.no	**NOKC (Norwegian Knowledge Centre for the Health Services)**	Norway
Iris Pasternak	iris.pasternack@thl.fi	**THL, National Institute for Health and Welfare**	Finland

European Commission – DG SANCO

Attendee	Organisation
Anders Lamark-Tysse	**DG SANCO, European Commission**
Jerome Boehm	**DG SANCO, European Commission**

Apologies:

NETSCC, UK; NICE, UK; SNHTA, Switzerland; NIPH, Slovenia