EUnetHTA Joint Action SF e-meeting

June 8, 2011 13:00 – 15:00

Organised by: EUnetHTA Secretariat NBoH, Denmark

Agenda

1. Brief summary of discussions during EUnetHTA JA Plenary Assembly
2. Business Model, next steps
3. Update on pilots in WP activities
4. EUnetHTA JA 2 proposal - update
5. Communication/distribution of the WP deliverables with stakeholders
6. Other issues:
    1. WP3, 2011 Stakeholder Forum survey
    2. EUnetHTA Conference, December 8-9 2011, Gdansk, Poland
    3. Next e-meeting; September 20, 2011

Meeting Summary

The server link to the recorded playback of this meeting including the slides have been sent to all participants on June 8, after the meeting was ended

Finn Børlum Kristensen (FBK) opened the meeting and informed that the agenda of this meeting was suggested by the stakeholders, (by a representative from the payers group).
There will be a brief summary given on top of what has been informed by EUnetHTA in Brussels (May 3, 2011) and in the e-meeting held in March, 2011.
FBK informed that at the Plenary Assembly in London, EUnetHTA had 3 representatives from EUnetHTA Stakeholder Forum group.

FBK presented the agenda.

FBK informed that the next e-meeting will be held on September 20, 2011 at 13:00 pm. At the end of the meeting each participant will receive a link to the playback of the meeting.

1. **Brief summary of discussions during EUnetHTA JA Plenary Assembly**

- EUnetHTA Joint Action achievements 2010 and current activities
- General discussion of the current status of EUnetHTA and conclusions
- CAVOD initiative - orientation
- EUnetHTA future: Orientation on the JA2 proposal and Directive on patient rights in cross-border healthcare
- EUnetHTA Business Model
- Research in HTA (EUnetHTA and DG Research & Innovation Framework 7 Programme)

FBK informed that the highlight of the Plenary Assembly (PA) was the overview of achievements in 2010 and current activities including presentations of the 8 Work Packages. The current status of EUnetHTA was discussed as well.
On the second day a representative from Ernst & Young presented the CAVOD initiative.

EUnetHTA future was discussed under the 3 subheadings: the proposal for JA2 and the directive on patient's rights, art. 15., the EUnetHTA Business Model and the possibilities that are opened for research in HTA in the DG R&I programme, FP7.
As to the achievements, the WPs were more or less on schedule with few delays reported. All WPs have clear intentions to submit all the planned deliverables during the project, few of the deliverables are close to deadline according to the work plan. There was a question about how serious the delays are. There was a consensus that we should avoid delays, though the delays are not serious and have good explanations.
The general discussion on the current status of EUnetHTA was a brief half an hour discussion during day one. This is reflected in the notes that are currently being processed for distribution as draft notes for the PA participants. FBK underlined that we can conclude that the views of the partnership represented in the PA reflects more or less that members were satisfied with the current status of EUnetHTA, and the view of EUnetHTA is quite positive - also on the possibility of EUnetHTA to further develop, and move into sustainability and permanency.

On the CAVOD initiative FBK informed that an extensive orientation was given by Ernst & Young about what the project is about. Views were exchanged at the meeting about CAVOD in relation to EUnetHTA. These views were presented in a workshop in Barcelona during the same week by EUnetHTA representatives. We are still waiting to hear more about this exercise and about the Ernst & Young activities. From the CAVOD presentation it looks that there is a similarity in what they are planning to do and in what we are doing in EUnetHTA. There is a potential for overlapping.
FBK mentioned that EUnetHTA wanted to share the CAVOD slides from the PA in London with the PA, though until this day EUnetHTA hadn't received them.

As to EUnetHTA's future, the Commission informed about the current status of the directive which is now in a transposition phase. Member States (MS) until October 2013 should make the legal steps to implement the directive. MS should nominate bodies ("Competent Authorities") to participate in a voluntary permanent Network.
The Plenary Assembly also discussed research in HTA, including the importance of having strong research consortia to get funding for research on HTA.

FBK asked for comments and mentioned that EUnetHTA Stakeholder Forum were represented at the PA by payers, providers and industry (patient representative couldn't participate due to other commitments).

There were no comments from SH.

2. **Business Model, next steps**

- This is a task of WP8 (one of EUnetHTA JA deliverables, due December 2011)
- Executive Committee supported by the Secretariat lead the development work (with the involvement of a professional consultant)
- Inputs that informed the current version:
  - EUnetHTA Collaboration proposal (2008)
  - Discussions in EUnetHTA JA Plenary Assembly (2008-2010)
  - Article 15 of the Directive on Cross-border Healthcare
  - Business Model discussions in the Executive Committee (latest on March 21-22, 2011)

FBK explained that a business model is an organisation's core logic for creating value and generating income/revenues.

FBK said that this topic was raised by Irina Odnoletkova, AIM who is substituted at this e-meeting by Rita Kessler, AIM. FBK asked Rita to elaborate.

Rita clarified that the idea of Irina Odnoletkova was when discussing the Business Model, we need to look at what EUnetHTA can bring as a deliverable and outcome for the SH organisations. The current SF should also be consulted.
FBK answered that this issue was reflected in the PA in London. It is made explicit that the primary customers of the output of EUnetHTA are the agencies and that there are a number of secondary customers, including stakeholders. FBK said that this aspect will be expanded in the next phase of the development of the Business Model. This is at the hand of the Executive Committee to decide on it and it will be further discussed in the EUnetHTA conference to be held in Gdansk. The notes taken at the PA will be shared with the Executive Committee at an e-meeting scheduled for June 15, 2011.

FBK asked for questions.
There were no comments.

The pilots and WP activities (as requested by Irina Odnoletkova, AIM - payers) were presented by the leads of WP 4, 5 and 7.

3. **Update on pilots in WP activities**

WP4, presented by Iris Pasternak, THL:

<u>WP4 Core HTA: Strand A (1)</u>

- **Core Model Online tool development**
  Advanced features: reporting results, storing, searching, adapting
  Stakeholder Advisory Group (SAG) and Public consultation for new features in 2012
  Coordination Working Group (CWG) starts in June 2011

- Topics: terminology, authorship, updating (generic versus specific), reference management, overall methodology issues
- **Policies for the use of the Core Model**
  WP4 survey on relevant policies in summer 2011
  SAG consultation for draft policies in early autumn 2011
  Public consultation in autumn 2011
- **Screening model**
  Public consultation in September 2011

WP4 Core HTA: Strand A (2)

- **Adaptation**
  From Core HTA information (result card) to national reports
  From national reports to result cards
- **Tools**
  for reporting in a way that enables adaptation (structure of the result cards, instructions for reporting)
  for adaptation (search function, instructions for estimating transferability and completing changes). Use of the Adaptation toolkit (from EUnetHTA Project)
- **SAG consultation for adaptation plan in July 2011**

In the past 2 months the core model online tool development moved from protocol function to advanced features.
New core model development will be through the establishment of a new group for internal WP4 coordination that will start next week with an e-meeting.
Work on policies for how and who is to use the core model is moving forward. WP4 agencies will answer a survey on the preferred policy of using the core model. The SAG's view on preferred policies will be sought and a public consultation will be made later in the autumn. Iris Pasternack, THL mentioned that WP4 have received many good comments from the SAG review, which took place two months ago. The small delay in the screening model are in order to gather more information before launching the screening model for public consultation in September and to avoid fundamental mistakes.
In strand A, which also covers the adaptation tasks, THL are now gathering an internal team to discuss and prepare features for the adaptation of the core HTA to national reports and vice versa. There will be a SAG consultation already next month.

In Strand B on core HTA piloting two core HTA pilot projects started in April, where the topic was established and scoped. The SAG will receive the protocols for the core HTA in July (not June). Two collaborative models have been defined and each of the domains of the models is managed by one agency. Information in each domain is built by several agencies, AGENAS is going to collect information from several agencies to produce cooperative reports.

FBK thanked Iris and called for questions.
There were no questions.

WP5 presented by Wim Goettsch, CVZ:
Wim informed that there is not much new information since the last SF meeting in Brussels, (May 3, 2011).
A meeting is scheduled for 9-10 June, 2011 (Oslo, Norway) and several smaller meetings are planned for the coming months.

WP5 SAG activities 2011

- **Subgroup (SG) 1:** Overview of the processes, the scope and the scientific methods used for REA of pharmaceuticals in European countries/US/Canada/Australia & New Zealand
- **SG2:** Rapid Model for REA of Pharmaceuticals
- **SG3:** Full Model for REA of Pharmaceuticals
- **SG4:** Methodological issues for REA

Update on activities WP5 SG1

- Review of:
  - Methods used for REA of pharmaceutical in 30 jurisdictions
  - Worldwide activities on REA or comparative effectiveness assessment

Start	*End*	*Activity*	
M13	M13	Consultation of draft background review by WP5 members	√
M13	M13	Consultation of draft background review by SAG	√
M14	M14	Process comments of WP5 members on draft background review	√
M15	M15	Consultation of draft background review	√
M16	M17	Finalisation of background review	June 2011
2011	2011	Writing and publishing of article on background review in peer-reviewed journal	

Update on activities WP5 SG2&3

- Based on the core HTA model (rapid=SG2 and full=SG3)
- There will be three phases during the construction of the Rapid and the Full REA model:
  - Phase 1: Develop 1st version of Rapid and Full model
  - Phase 2: Pilot test
  - Phase 3: Develop final version of Rapid and Full model

- **Update on activities WP5 SG4 – methodology guidelines**

1. Criteria for choice of most appropriate comparator(s)
2. Methods of comparison: direct and indirect comparisons
3. Clinical endpoints
4. Surrogate endpoints
5. Composite endpoints

Start	*End*	*Activity*	
M5	M14	1st version of rapid/full model	√
	M14	Select pharmaceutical for pilot experiment	√
	M15	Consultation on selection of pharmaceuticals by SAG and EMA	√
M16	M24	Pilot assessment (pazobanib)	
M26	M34	2nd version of rapid/full model	
	M35/36	Present the Rapid model at symposium in Budapest	

6. Endpoints relevant for patients
7. Health-related quality of life
8. Safety

9. Internal validity
10. External Validity
11. Grading experience in experts and experience

- **Update on activities WP5: SG4, Current situation and next steps**

- 2nd drafts (May 31 - June 6): all guidelines
- 2nd drafts to be sent to WP5 and pilot authors after Oslo workshop in June
  - workshop decisions will influence Internal validity and Surrogate endpoints guidelines
- 3rd drafts to prepare before WP5 consultation

- SAG consultation:
  - First batch: February 2012
  - Second batch: March 2012
- EMA and public consultation:
  - First batch: April – June 2012
  - Second batch: June – August 2012
- **Update on activities WP5, EMA**
- Two meetings in 2010 in London, one meeting in 2011 in Diemen
- Main topic in 2010 was adaptation of the EPAR template in line of comments from MEDEV/EUnetHTA
- Suggested changes by EMA were commented by MEDEV/EUnetHTA, final template was defined in July 2010
- Adapted EPAR template was implemented by end of 2010
- New EPARs in 2011 will be evaluated by EUnetHTA/MEDEV (to be discussed in Oslo next month)
- Planned fourth meeting by end of 2011 in Paris (HAS)
- Other issues will be guidelines and post-marketing data collection

Pascale Brasseur (EUCOMED); requested clarification concerning the pilots, she mentioned that Andrea Rappagliosi shared feedback from the PA in London and he was talking about two pilots of rapid and full model, maybe there was a wrong interpretation if it concerns the full HTA model.

Wim stressed that WP 5 discussed this and decided to do a pilot only on rapid assessment (one pilot).

WP 7 as presented by Mira Pavlovic, HAS:

WP7 SAG activities 2011
Strand A: there were three important issues regarding the facilitating evidence generation on new terminologies:

- Criteria to select new technologies in need of further evidence
- Minimum dataset to share information on policy relevant clinical studies in development, and

- Database (Evidence Database on New Technologies) to share information & facilitate collaboration on additional evidence generation

Strand B: Facilitating exchange of information on current HT assessments, which includes:

- Information flow on assessments & alerts on parallel HTA projects
- Collaboration on HTA projects
- Database (POP) to provide updated information on planned and ongoing HTA projects done by HTA agencies

Stakeholder involvement is planned only for strand A activities. The SAG includes
15 representatives from 12 organisations: CPME, HOPE, AIM, ESIP, AESGP, COCIR, EDMA (2), EFPIA (2), EUCOMED, EuropaBio (2), EPF, EURORDIS.
Stakeholders are involved in two different ways:

- SAG: solicited participation to review first drafts
- Public consultation on deliverables (final versions)

The plan for SAG involvement is that:
Tasks and deadlines will be specified in advance.
Standard period for response: **two weeks** (**beginning on the date of receipt of the document**)
For organisations that have **more than one** representative in SAG→ feedback should be compiled into **one response form.**
A defined period for analysis and synthesis of relevant comments, **possible clarifications and further questions to SAG.**
Selection: The WP7 team is responsible for deciding on the way to take comments into account.
Transparency: All received comments will be answered systematically listed in a document, sent out to all SAG members.
Stakeholder involvement in WP7 according to the work plan and timeline:
SAG consultation: reviews of the first drafts of:
The **criteria** to select new technologies for additional evidence generation, **April - June 2011:** *ongoing*
Review of the document by SAG was performed (67% response rate); heterogeneous responses: from very short to much elaborated ones.
Current step; analysis of the responses, further exchanges will take place to clarify the comments received.
The dataset on policy relevant clinical studies in development (performed by NETSCC)
Stakeholder involvement in WP7 according to the Work Plan:
Public consultation – comments on the final version of the dataset on policy relevant clinical studies in development from October to December 2011
The relevant items of the EVIDENT database from November to December 2011.
The criteria to select and prioritise new technologies: from December 2011 to February 2012.

FBK called for questions.
there were no questions.

FBK thanked the 3 WP representatives.

FBK concluded that things had indeed moved forward in terms of concrete stakeholder involvement this spring.

4. EUnetHTA JA 2 proposal - update

The JA2 Application was submitted and received before deadline in The EAHC,. The official title is: **EUnetHTA JA2.**

FBK informed that a copy was shared with APs and CPs - it is a confidential document that can be shared with the respective ministries. It includes APs from all member states apart from one, 37 APs from 26 member states with (currently) 15 CPs (not budgeted partners who contribute in kind). For now Luxembourg will join as a CP, since this country is establishing an organisation linked up to its ministry, with the intention to become an AP.
The proposal will go through steps of evaluations and the Secretariat expects a formal answer to the 120 pages proposal during the autumn. After that the negotiation stage will start with the EAHC in Luxembourg and the SF will be updated.

The list of WPs is as follows:
WP1 Coordination (and sustainable network implementation) (LP – NBoH, DK)
WP2 Dissemination (and capacity building) (LP – NOKC, NO, Co-LP – KCE, BE)
WP3 Evaluation (and data collection on costs and efficiency) (LP – HVB, AT)
WP4 Testing collaborative production of HTA information for national adaptation and reporting (LP – Age.Na.S, IT), (WP4 develops systematic networking to jointly produce HTA information (e.g. full core HTA) for national reporting while piloting the application of EUnetHTA tools)
WP5 (Testing partners' capacity to) apply(ing) the HTA Core Model for Rapid Assessment in collaborative production of HTA information (for national adaptation and reporting)
(LP – CVZ, NL, Co-LP – LBI, AT), Strand A*: pharmaceuticals* and Strand B: *other health technologies*
WP6 Information Management Infrastructure and Services (IMIS) (LP – KCE, BE; Co-LP – DIMDI, DE)
WP7 Methodology development and evidence generation: Guidelines and pilots production
(LP – HAS, FR; Co-LP – IQWiG, DE)
WP8 Maintenance of HTA Core Model infrastructure to support shared production and sharing of HTA information (LP – THL, FI), implementing things into practice.

JA2 will have an overlap of 3 months with the current JA and it will end in September 2015.
The emphasis of JA2 is implementing things into practice based on what has been developed up till now.
It is important to emphasise that EUnetHTA will continue to have a focus on SH involvement. The SF is a forum with the privilege of being informed at an early stage and with an option to influence EUnetHTA's work.

The feedback EUnetHTA received until now on WP 4 and 5 is promising for the future. In the stakeholder involvement process we have moved beyond the "political level" to the content level and the methodological level which is the focus of EUnetHTA.

Andrea Rappagliosi commented that as to SH involvement in JA2, to the extent that EUnetHTA shares the early information, he appreciates the current EUnetHTA, though it would be much more interesting to take the SH involvement to the next stage, to see the opportunities in more SH-involvement in this work (not just information exchange).

FBK answered that this is in good line with what EUnetHTA is planning and that we expect that SH-involvement will be further developed. We will explore the involvement of stakeholders who are working in R&D in trials and design. This will mainly be seen as a welcomed development by partners and stakeholders.
FBK said that, in order to have continuity, EUnetHTA will expand on the basis of the current structure. There is a constant need to have a clear view that the job is done independently.
In article 15 of the CBKC directive we find that this text on SH involvement is in good accordance with the practice we are developing in concrete terms in EUnetHTA.

Pascale Brasseur from EUCOMED had a comment: On JA2, for the joint assessment you have mentioned 2 strands, rapid and full. Andrea Rappagliossi mentioned 50-70 assessments over the JA2, do you currently have any idea how the selection of topics will be handled?

FBK answered that the counting of number of reports is at the national level. We will count the HTA reports produced by partners that are including core info from the network activities into the information base of the report. We cannot make 50-70 Core HTAs, this is impossible. Balancing medicines, devices, and interventions will be influenced by the needs of the partners. We would expect that increasingly e.g. a shared systematic review of clinical evidence will be done for reports in several countries.
FBK asked if this clarified the issue of the numbers.

Pascale Brasseur responded positively to this.

Andrea Rappagliosi said that during the PA-meeting he understood that in JA2 the focus will be on pilots. He said that he remembers the Commission, during the PA in London, stressed the role of pilots in the qualification of the JA2.As JA2 will be focused on pilots, it is important to have a good understanding at an early stage about this.
FBK stressed that in JA2 there will be a focus on pharmaceuticals, but not only pharmaceuticals. The percentage of distribution of work is yet unknown.

5. Communication/distribution of the WP deliverables with stakeholders

FBK explained that in the process of its work there is an opportunity for SF to participate and EUnetHTA will continue with providing this.
FBK added that the SF has the possibility to see and comment on work in progress. The participation of experts (with declaration of conflict of interest) was clarified previously. As to SF representatives participating in concrete work, this needs to be discussed within the EC.

6. Other issues

1. WP3 2011 Stakeholder Forum survey – a reminder, FBK asked the participants to look at the e-mail received from Eleanor Guegan, NETSCC for WP3 and to complete it before the deadline.
2. EUnetHTA Conference, December 8-9 2011, Gdansk, Poland. In general the programme is almost completed. The registration site will start working in June, 2011. An email was sent to SF asking who would participate in the relevant sessions. Wim Goettsch, CVZ asked for a response to that. Rita Kessler, AIM asked if one name is per group or per affiliation. Wim

Goettsch clarified that it is one person per Stakeholder group. FBK stressed that the groups should clarify who will participate and asked the SF-participants to promote the meeting.

3. **The next e-meeting is scheduled for September 20, 2011 at 13.00, if your organisation cannot participate, please notify the Secretariat in due time.**

FBK wishes a good summer to all and thanked the participants for their presence.

Participants list

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