EUnetHTA JA SF and Executive Committee/WP1
May 03, 2012, 1:00-3:00pm CET

E-meeting
Organised by EUnetHTA Secretariat
Danish Health and Medicines Authority, Denmark

EUnetHTA Participants:
Chair: Finn Børlum Kristensen (FBK), DHMA, Denmark, EUnetHTA Secretariat
Alric Rüther, IQWIG, Germany
Anders Lamark Tysse (ALT) DG Sanco
Francois Meyer (FM) HAS, France
Iris Pasternack (IP), THL, Finland
Inge M. Skov, EUnetHTA Secretariat
Julia Chamova (JUCH) EUnetHTA Secretariat
Naomi Dayan, EUnetHTA Secretariat
Nicola Vicari, Agenas, Italy
Sarah Kleijnen (SK), CVZ, Netherlands
Setefilla Luengo-Matos, ISC III, Spain
Sigurd Vitols, SBU, Sweden

EUnetHTA Stakeholder Forum Members:
Christine Dawson, ESIP
Rita Kessler, AIM
Pascale Brasseur, EUCOMED
Nicole Denjoy, COCIR
Yves Verboven, EUCOMED
Sarada Das, CPME

Meeting Agenda

A. Information about WP activities and SAG involvement:

1) Pilots in
- WP7 - HTA early scientific advice pilots coordinated by HAS
- WP 5 - Pilot, development of guidelines, model for rapid REA and collaboration with EMA
- WP 4 -Screening model 2nd public draft available,
  - Two Core HTAs coming to end,
  - Policies for the use of the Core Model soon ready for comments.

2) Selecting technologies and recruiting volunteer technology sponsors for pilots

B. General information and updates:

1) EU Directive 2011/24 Article 15 next steps
2) JA2 update – SF participation and involvement
   - A letter received from SF organisations on April 26, 2012 was attached
3) EUnetHTA Plenary Assembly Lisbon

- SF participation
- Agenda (for information)

4) Bilateral contacts with the SF members/participants
   - Meeting with EFPIA on March 29 2012
   - Meeting with EPF on June 14 2012

5) HTAi 2012 Annual Meeting- June 23-27, in Bilbao, Spain, EUnetHTA participation

C. Other issues:

1. Meetings
   - Planned SF face to face meeting in Venice, September 3, 2012
   - Next SF e-meeting, November 12, 2012 (All planned EUnetHTA meetings are available on the website: http://www.eunethta.eu/Public/Event-calendar/)
2. EUnetHTA Stakeholder Forum Update e-newsletter (two-way communication channel)

Finn Børlum Kristensen, (FBK) opened the meeting by presenting the agenda.

A. Information about WP activities and SAG involvement:

1. Pilots in WPs

WP7: HTA early scientific advice pilots coordinated by HAS. An update was presented by François Meyer (FM).
FM gave a short introduction of the two strands managed by WP7, (A+B):
Strand A, Facilitating evidence generation on new health technologies, and
Strand B, Facilitating exchange on current HTAs.
FM went through the three deliverables defined for Strand A:

1. proposal for criteria to select new technologies in need of further evidence
2. minimum dataset to share information on policy relevant clinical studies in development
3. database (EVIDENT) to share information & facilitate collaboration on additional evidence generation

In Strand B the focus is on facilitating exchange on current HT assessments with the emphasis on:

1. Information flow on HT assessments & alerts on parallel HTA projects
2. Collaboration on HTA projects
3. Database (POP) to provide updated information on planned and ongoing HTA projects

FM described WP7A Milestones that have been achieved from January till March 2012. He mentioned that regarding the selection criteria, the testing of criteria by WP 7 partners is to be closed. As to the EVIDENT database, in the Public Consultation 15 responses were received and the database's content was adjusted accordingly. The IT implementation began in March and it should be in place in September 2012. FM mentioned that the Next WP7 F-t-F meeting is scheduled for May 10th-11th in Vienna and it will be focused on validation of deliverables.
FM gave an update on early dialogue pilots. The aim is to discuss development plans in preparation for JA2. FM informed that two pilots will take place, in May and in June 2012. Several HTA bodies volunteered to participate in agreement of EUnetHTA WP1 / Executive Committee, and with a limited financial support of the EC DG SANCO (travel).
There will be one pilot on a drug, one on a medical device (including diagnostics) during the current JA, and early dialogues will continue in the next JA, (i.e. EUnetHTA JA2).
SF members were asked to disseminate this information among their members, to identify sponsors of a new (drug or non-drug) technologies that could benefit from multi-HTA scientific advice in 2012. Information has

been sent to relevant stakeholders and many showed an interest to participate. Companies that would like to participate should send a letter of intent four months before the pilot early dialogue meeting.
This activity will be coordinated by HAS and Interested companies should contact Mira Pavlovic and/or François Meyer, as soon as possible. FM encouraged technology sponsors to contact the WP7 LP if more information is needed. He has mentioned that there are a few candidates for participating in the drug pilot, while there are less confirmed candidates for testing medical devices.
Iris Pasternack (IP) asked about the aim of this early dialogue piloting. FM explained that information can be found in the description of the planned work for WP7 during JA2. It has been decided to start it before JA2 due to a request from sponsors to test multi-HTA early advice on non-drug technologies and due to a need to pilot multi HTA early advice on drugs to compliment the extensive experience in the field of drugs gained by EMA - sometimes with the involvement of HTA bodies. Other EUnetHTA partners can join the process if they wish.

WP5: information about WP5 activities was provided by Sarah Kleijnen (SK). SK reminded about the objective for WP5 (REA of Pharmaceuticals) which is a development of HTA tools and methods for REA of Pharmaceuticals especially the development of a model for Rapid REA.
SK gave an update on WP5 activities:
An ongoing pilot on rapid assessment of pazopanib
A consultation phase included WP5 members and Marketing authorization holder and lasted from November 2011 to January 2012. The SAG consultation took place from March 20, 2012 to April 20, 2012. Comments were received from 4 SAG members. The Public Consultation is planned from June 6, 2012 to July 6 2012.
The experience shows that working with 29 organisations requires intense coordination on several levels.
The timeline of three and a half months for the scoping and assessment phase is possible but very intense.
Relevance of all research questions (assessment elements) for a rapid assessment is not fully clear and the harm/ benefit analysis is still in a development (synthesis).
SK mentioned that based on the experience gained in the first pilot, WP5 would like to have a 2nd pilot of a rapid assessment before the start of JA2. SK explained the reasons for the second pilot:

1. First pilot was a bridge between the HTA core model and relative effectiveness assessment.
2. It is too time consuming for a rapid assessment in a daily practice to apply the full HTA Core Model (except the economic domain).
3. An adaptations in model and process will take place and should be tested (More focus on first four domains).
4. The second pilot must be a bridge between the current draft model and the approach in JA2.

SK informed that the setup for the 2nd pilot on REA in JA1 will include a lead and co-lead that will author and co-author the report and a number of WP5 partners will be acting as reviewers
As to the topic selection procedure, all four marketing authorization holders decided not to be involved in a pilot, therefore, currently no topic was selected.
SK informed about the guidelines on methodological issues and SAG consultation.
The first batch was shared for consultation from March 7 to April 13, 2012, a huge number of comments was received and is being analyzed by authors. SAG comments will probably be dealt with at the same time as EMA and public consultation comments. The 2nd batch consultation is ongoing, it has started on April 18 and it will end on May 21, 2012.
The Public Consultation will be held from May to September 2012, (in 2 batches).
A possible meeting on endpoints might be organised with EFPIA and other stakeholders, though the date is not set yet. SK presented the Core HTA model and the scope for assessment and mentioned that the SAG consultation will be from June 18 to July 31, 2012. The Public Consultation is planned from October 1st to November 14th, 2012.
SK informed about the ongoing collaboration with EMA on improving EPARs. The amended EPAR template has been reviewed by EMA and EUnetHTA partners based on a set of EPARs using the new template. The results were discussed in an f-t-f meeting held in February 2012 and the planned future actions are:

1. Consolidated proposal for further improvements of the EPARs, highlighting HTA expectations, to be coordinated by HAS
2. Review to be presented to the CHMP and published in "Value in Health"

WP4: Information on WP4 Core HTA model for population screening was provided by Iris Pasternack IP.
A SAG consultation was held in February 2011. Eleven out of 12 SAG members responded and 17 general comments were received, as well as175 domain specific comments. The draft model was delivered on March 2011 for the pilot doers. An updated on the first public draft was submitted for public consultation in October and November 2011. Eight individuals (from seven organisations) responded, three from HTA agencies and four from industry, in total 96 comments were received. The second public draft was published in March 2012. IP informed that further changes are currently made, based on the work of REA model developers (WP5) and the Core HTA pilots (WP4 (and WP5)). The validation of the final version will be done between August and October 2012, date is not set yet for a consultation of pilot doers, iWP4, SAG and public. The last and final deliverable will be submitted by Dec 2012.
IP informed about the HTA Core Model Online Tool & Service developments. The policies for using the Core Model were drafted recently, WP4 SAG members will receive the documents soon. The Public Consultation is planned to be held in June 2012.
For validating the Core Model and Online Tool, WP4 SAG's consultation is planned for autumn 2012.
Part of the validation will be probably added as a separate SAG consultation on the adaptation features, planned for Oct-Nov 2012.
IP informed about two pilot projects on the topic of 3 gene tests for breast cancer (Mammaprint, Oncotype, uPA/ PA-1) and population screening for AAA. The work will be completed in June 2012. The WP4 SAG consultation of the draft products is planned for July-August, (date is not set yet).
IP added that there are further plans to validate the utility of the (almost) final products with the help of WP4 SAG consultation in autumn 2012. IP summed WP4 planned SAG consultations:
- June 2012, commenting HTA Core Model policies
- July-August 2012, Commenting draft Core HTAs
- September-November: The Validation of screening model, the validation of 2 Core HTAs, the Validation of Core Model and Online Tool and commenting adaptation features of the Core Model.

2) Selecting technologies and recruiting volunteer technology sponsors for pilots.
FBK raised the issue of selecting technologies and recruiting volunteer technology sponsors for pilots, and mentioned that this topic is brought up after the observation of a lack of interest to participate in pilots.
FBK proposed the option of WP Lead Partners (LPs) to seek assistance with recruitment via the relevant SF member/ participant and ask for views and proposals. FBK mentioned that this issue is relevant mainly for representatives from the SF industry group, (pharmaceuticals and devices).
Sarada Das (CPME) asked if this assistance can be explained in more details and what is the process suggested. FBK answered that EUnetHTA expect that SF will acknowledge the problem and will give a "green light" for organisations from EUnetHTA to ask SF industry representatives to assist in finding sponsors that are willing to participate in pilots. FBK asked other SF group members to discuss this issue with the SF industry members and said that this is a call to all EUnetHTA SF to discuss the issue of direct LP SF contact. FBK said that he doesn't suggest a specific mechanism for that contact.
SK (CVZ) said that she supports this initiative, as it is very important and relevant also for JA2.
Nicole Denjoy asked if agencies have already a list of selected technologies. FM (HAS) answered that for the early dialogue they don't have a list of selected technologies and explained that the first move should come from the sponsors of technologies, mostly industry companies, but also academic teams. SK (CVZ) said that for their first WP5 pilot, the topic selection procedure was based on all pharmaceuticals that had been approved for marketing during the previous one and a half years. After that WP5 listed the preferable topics and approached the relevant companies. SK mentioned GSK as the company that had agreed to collaborate and added that it was a very fruitful collaboration. For the 2nd pilot, the topic which was on the list

of drugs to be assessed by CVZ was the one to be selected. WP5 members voted and manufacturers of the leading four topics were approached. Unfortunately, none of the manufacturers was willing to be involved in a pilot. SK informed that for JA2 WP5 will do 10 pilots on 10 topics. Therefore, any idea for relevant topics will be very welcomed by WP5. SK asked SF to contact WP5 (CVZ) with suggestions, (before or after marketing authorization).
Christine Dawson from ESIP commented that her question had been answered by the last speakers, hence the question is: if the selection of technologies is relevant only to SF from the industry group or to other SF group members as well. FBK answered that this is relevant to other SF groups, as they might see the necessity of conducting specific pilots as well.
FM added that for early dialogue, sponsor companies are requesting confidentiality. Therefore, the information cannot be disseminated.
It was agreed that the Executive Committee and Stakeholder Forum share a common understanding that it is appropriate to seek assistance through the SF and it should not be limited to only one SF group. However, for finding technology producers it will be mainly the industry group in the SF that will be contacted.
Pascale Brasseur (EUCOMED) commented (via text chat) that they are already in contact with FM, they will be happy to assist and will contact him directly with proposals.
She further commented that concerning the pilots already done, it could be useful to maybe have a summary of the lessons learnt from a process point of view, to learn about the experience of both sides, stakeholders and HTA agencies.
IP informed that from her experience working in WP5, there are plans to report the experiences from pilots in a journal manuscript. Nicola Vicari responded via the text chat stating that “for WP4 strand B we involved SAG in the Core HTA protocols (1st draft); their feedback was shared and included in the core HTAs (nearly all comments where positive ones); during the production of Core HTA 1 (Genetic Tests for breast cancer) we also contacted manufacturers with a survey with specific questions on their technologies; their answers at first were quite disappointing (most of them was "commercials") but anyhow the information was shared in the domain team”.

WP3 SF survey JUCH informed about, which will be sent to SF members and participants on May 29, 2012 to be completed by June 19, 2012. Pre-notification email will be sent on May 21, 2012.
SF members/participants that are expected to be out of office and will not be able to answer this survey are asked to nominate a colleague to complete the survey on their behalf and inform the WP3 LP about it. The response should be an organisation response (not for individuals).
Rita Kessler (AIM) referred to the EU commission consultation on article 15, patient’s rights directive, for stakeholder involvement, and asked about the connection to the WP3 SF survey mentioned before (i.e. JUCH informing about WP3 SF survey).
JUCH explained that the WP3 SF survey is an annual survey done to review the experience of EUnetHTA JA SF. The EU Commission public consultation is with regard to the future permanent network and the implementation of article 15

B. General information and updates:

1) EU Directive 2011/24 Article 15 next steps

Extracts from Directive 2011/24 Article 15 on x stakeholder consultation was presented on a slide:
“That network shall be based on the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations” and “facilitate the consultation of stakeholders on the work of the network.”
The European Commission’s public consultation on "modalities of stakeholder involvement in the HTA network” (until August 1, 2012) was presented.

Anders Lamark-Tysse (ALT) explained that the directive is calling for the establishment of a voluntary permanent network on HTA. The transposition of the directive has a deadline on October 25, 2013. In order to plan for this action, the EU Commission did two things, the first one is a study conducted by ECORYS for different scenarios of hosting a secretariat including costs, synergies, and governance issues, and the second is a consultation launched on May 2, 2012, that addresses models of stakeholder's involvement in such a network. The purpose is to receive feedback from stakeholders about their own capacity to interact on HTA and their experience in doing consultations and on how the commission could facilitate stakeholder consultations within the future network.
ALT said that both the outcome of the public consultation study and of the ECORYS study will be brought to the committee to assist the Commission in the implementation of the directive, when establishing the formal basis of the future network. ALT referred to the four sections on the questionnaire, three sections for stakeholders and a fourth section for public authorities, HTA commissioning bodies. Hence EUnetHTA members should fill in section number four.
FBK informed that the Secretariat published this public consultation (linked to the consultation website), both on the public website and on the Members Only website.
ALT added that the reason for this public consultation is to have a wider stakeholder input (beyond the SF)
Nicole Denjoy mentioned the EU network on e-health, and said that in the e-health network instead of public consultation, there was a call for stakeholder interest. Nicole Denjoy asked what was the reason for these different procedures.
ALT answered that in the case of the e-health network, the commission had nothing to build upon. This is different from the HTA network as the commission financed EUnetHTA already. Therefore the commission's needs are not the same. The similarity is in the structure of the two networks, however the nature of the networks will be different. Regarding the HTA network, it is clear to member states how the work should be done. HTA bodies are to be involved in the HTA network, while this is not the case with the e-health network. ALT said that this explains the different actions taken.
Nicole Denjoy added that even though the needs for the two networks are different, (for HTA there are already agencies), the process should be similar. The query was regarding the logic behind the two different approaches. FBK said he tended to agree in the point of similarity, though due to the different purposes the implementation of stakeholder's involvement will be different. ALT added that it is not clear yet how SF will be structured for the HTA network. The commission has establishes an e-health network already, this is not the case yet for the HTA network. For the HTA network, how to coordinate the involvement of stakeholders it will be decided at a later stage. ALT concluded that there are not necessarily different approaches but different stages in processes.
FBK added that for HTA, there is a mechanism for stakeholder involvement through the current JA that will continue to the next JA2, though it is not clear how in the permanent network stakeholder's involvement should be practiced.
Nicole Denjoy asked for clarifications regarding the mechanisms for public consultations in the future network. FBK answered that more information on this would be provided after the public consultation on stakeholder involvement that had been launched. Hence it is not a given fact that the future stakeholder involvement will be the same as it is now.
ALT gave an overview on the steps for setting up the HTA Network:

1. Creation of The Committee on cross-border healthcare ("implementing committee") - examination procedure Launch meeting: 21 June 2011 - the committee was established by the EU Commission.
2. Draft Implementing act, (under the form of a COM Decision) on: Measures for the establishment, the management and the transparent functioning of the HTA network arrangements for granting the aid, the conditions to which it may be subject and the amount of the aid
3. Discussion in the Committee of the draft Implementing act
4. Vote in the Committee (qualified majority vote in favor), after Commission inter-services consultation
5. Adoption by the European Commissioni.e. the HTA Network will be established (before end of Oct. 2013)

6. Adoption of the rules of procedures by the Network

ALT added that EUnetHTA JA2 will require the resources in HTA organisations. Therefore, it will be EUnetHTA JA2 that will carry out the work after October 2013, although the HTA network will be in place. JA2 will give better clarity on how the permanent HTA network will be functioned in the future.
Rita Kessler (AIM) asked if the current stakeholders will be included in the coming network.
ALT answered that the directive is very clear in calling for an appropriate stakeholder's involvement and in that respect the experience gained in EUnetHTA JA and JA2 will be crucial.

2) EUnetHTA JA2 status update,

JUCH informed about the final version of the grant agreement received for signature at the Secretariat by end of April 2012. The contract was signed by the coordinator. The signed grant agreement was expected within days. The technical contents will be shared with partners and afterward with members and participants of the SF. EUnetHTA JA2 will consist of 38 Associated Partners from 26 MS and currently15 collaborating partners. JA2 will start in October 2012 and will last for 36 months. The governance and management principles in JA2 will be the same as in JA. The SOP and stakeholder involvement principles will stay the same. There is an overlap of three months in JA and JA2 (i.e. October-December 2012). During this period EUnetHTA JA will finalise the reports to be submitted to the EU Commission in before end of March 2013. During this time EUnetHTA will focus also on the planning for JA2. The draft of the three year work plan should be in place on January 2013. EUnetHTA PA will endorse it in March 2013. JUCH informed that from January 1, 2013 new online information platforms will be in place including a platform for communicating with SF.
JUCH described the composition of EUnetHTA SF and said that the current SF composition will be continued until the end of 2012. SF will be informed and consulted on the developments in JA1 and JA2. In October 2012, there is a plan for an open call for declaration of interest to participate in EUnetHTA JA2 SF. EUnetHTA JA2 SF will start its activities in January 2013. The described procedure and the plans to increase the number of seats in each SF category from 4 to 6 will be brought up for the approval of the PA in Lisbon, May 2012. The plan is to not have any gaps between the two Joint Actions with regard to SF involvement.
FBK referred to a letter received from SF organisations on April 26, 2012, regarding SF Participation and involvement in JA2. FBK presented the SF requests that were mentioned in the letter. FBK said he did not expect a deep discussion at this point; however the letter would be brought up for discussion in the Plenary Assembly in Lisbon. FBK expressed the view that substantial progress had been made in stakeholder involvement in cross border collaboration in HTA. Nevertheless, the points raised in the letter will be taken into account in the considerations on the permanent network.

3) EUnetHTA Plenary Assembly Lisbon

Agenda (for information): JUCH presented the agenda items planned for the meeting. JUCH informed that one of the items is the strategy document and business model that will be presented for endorsement. JUCH added that the Strategy document will be shared with the Stakeholder Forum by May 7, 2012; Comments can be sent to the Secretariat until May 20, 2012. FBK added that the Strategy was presented in EUnetHTA conference in Gdansk 2011. A few amendments were made since then. FBK invited the stakeholder forum to provide comments on strategic, higher level aspects of the strategy.

SF participation: FBK mentioned that unfortunately no participants at this point had registered from the patients and providers groups. However, the meeting notes will be shared with all SF members and participants.
Rita Kessler (AIM) commented on the name of participant, Christian Peters is from ESIP and not from AIM (as appeared on the slide).

4) Bilateral contacts with the SF members/ participants: FBK informed about a meeting with EFPIA held in March 29, 2012, where experiences from EUnetHTA had been discussed. The meeting was very useful. A follow up meeting will be considered. FBK informed about a planned meeting with EPF, scheduled on June 14, 2012.

5) HTAi 2012 Annual Meeting – June 23-27, 2012 – in Bilbao, Spain, EUnetHTA participation: FBK informed about a full-day EUnetHTA Workshop, June 24th, 2012, 09:00 – 17:00.

C. Other issues:

1) Meetings: FBK informed about the next planned SF meetings.
A SF face to face meeting will take place in Venice on September 3, 2012
The next SF e-meeting is scheduled for November 12, 2012 which is at the end of EUnetHTA JA. (All planned EUnetHTA meetings are available on the website: http://www.eunethta.eu/Public/Event-calendar/)

2) EUnetHTA Stakeholder Forum Update e-newsletter (two-way communication channel): EUnetHTA Members Update: a quarterly newsletter contains news and WP updates
The Secretariat suggested including a section with information on SF organisations' activities in the HTA areas in the EUnetHTA e-newsletter. The Next issue will be sent to partners on June 30, 2012 and few days later it will be shared with SF. SF input is kindly asked to be provided 1 week in advance.