EUnetHTA Joint Action 2
Stakeholder Forum meeting
Brussels, Belgium
February 5, 2013, 10:00 – 17:00

Organised by: EUnetHTA Secretariat and KCE
Address of the meeting venue: Pacheco Centre, (entrance at the side of the Finance Tower)
Boulevard Pacheco 13, 1000 Brussels
Mobile: +45 7222 7975 – Anne Raahauge, EUnetHTA Project Manager

Summary report

Agenda

1. Opening, presentation of participants	10:00 – 10:15
2. Introduction to EUnetHTA	10:15 – 10:30
Presentation, Q&A	
3. EUnetHTA JA2 3-year Work Plan **a. Presentation of WP 1, 4, 5, 7, 8 work plans**	10:30 – 12:30
Lunch	*12:30 – 13:30*
5. EUnetHTA JA2 3-year work plan (continued)	13:30 – 15:00
a. Presentation of WP 2, 3, 6 work plans **b. Q&A**	
Coffee break	*15:00 – 15:15*
6. Orientation on the implementation of Article 15 (Directive 2011/24/EU) – permanent European network on HTA	15:15 – 16:00
7. Other issues and closing of the meeting **a. EUnetHTA JA2 Plenary Assembly meeting, March 21-22, 2013, Zagreb – 4 representatives of the SF as observers**	16:00 – 16:30

Opening remarks
Finn Børlum Kristensen (FBK), EUnetHTA Secretariat (DHMA), welcomed the participants to the first face-to-face meeting of the EUnetHTA JA2 Stakeholder Forum (SF). He presented the agenda and the purpose of the stakeholder forum functions in the EUnetHTA governance and organisational structure. (*Appendix 1, slides 1-5*). He informed that a member of the EUnetHTA Executive Committee (Exec Comm) is chairing SF meetings and that the Exec Comm has proposed to introduce co-charing with a representative from the SF itself.

Action point: The SF members are to decide if they act upon this proposal and inform the Secretariat on its position by March 15 (so that the next meeting (e-meeting on April 9) could be prepared accordingly)).

Each meeting participant introduced her/himself.

Introduction to EUnetHTA
FBK presented the phases in development and activities of EUnetHTA (*Appendix 1, slides 7-29*). He informed that all MS participate in the EUnetHTA JA2 through ministry-nominated

organisations to take part in the EUnetHTA JA2 activities. The approach to work with stakeholders in EUnetHTA JA 2 will be "more interactive" than stakeholder "consultation". Key discussion points can be summarized as follows:

- Via the SF mechanism and stakeholder advisory groups (SAGs) that will be formed to solicit stakeholders input in concrete work of the work packages, stakeholders can influence the development in EUnetHTA. Face-to-face meetings, e-meetings, written input on drafts of key EUnetHTA documents are concrete ways of interaction with stakeholders in EUnetHTA.
- Minutes of the SF meetings will be made public (via the EUnetHTA public website) once approved by the meeting participants. The slides used at the meeting can be shared with the meeting participants immediately after meetings.
- The tools developed in EUnetHTA are being tested now in JA2 via doing pilot projects of producing eg, full Core HTAs and rapid HTAs followed by national report production based on the commonly produced information.
- Some of the EUnetHTA tools are not open for public access (eg, POP database). Opening them for public access can be explored in JA2.
- Methodological work done in EUnetHTA JA1 (eg, WP5 methodological guidelines) included consultations with stakeholders on very specific methodological issues (eg, a workshop organised jointly with EFPIA with participation of representatives from the rest of the JA1 SF membership). There is a positive and useful development of building contacts with experts (eg in R&D) from the stakeholder organisations.
- A general presentation of EUnetHTA/EUnetHTA JA2 is being developed to be available on the EUnetHTA public website.
- The final technical report of JA1 will be submitted to the Commission in April 2013. It will be made public once the Commission's review is complete.

EUnetHTA JA2 3-year Work Plan

Anne Raahauge, DHMA (Denmark) presented the draft 3-year Work Pan for WP1. (*Appendix 1, slides 32-46*). The immediate comments/clarifications were:

- Open dialogue with EUnetHTA on how to address the issues of training, feasibility and capacity (also in the view of limited resources). WP2 will be addressing issues of training.
- EUnetHTA Conference is scheduled to take place in October 2014, in Rome.

Marina Cerbo, AGENAS (Italy) presented the draft 3-year Work Pan for WP4. (*Appendix 2*).The immediate comments/clarifications were:

- Methodological standards for collaboration on a topic between the organisations working in different contexts will be developed
    - Choice of the collaborative model depends on the topic itself and competences available in the participating organisations. Collaborative models used in e.g., REA assessments might be considered for application in WP4, no decision yet.
- At least 20 national reports are planned to be produced on the basis of the Core HTAs coming out of JA2 WP4.
    - The national reports produced on the basis of the EUnetHTA JA2 Core HTAs can in principle be used for reimbursement decisions - it is a decision to be made at the national level.
- Topics for Core HTAs can be proposed by the Stakeholders as well as the DG SANCO (in addition to the EUnetHTA Partners and Associates). A procedure for topic selection is being developed
    - There is no "list of specific topics" from DG SANCO that supersedes the application of a transparent topic selection procedure.

Sarah Kleijnen, CVZ (Netherlands) and Claudia Wild, LBI (Austria) presented the draft 3-year Work Pan for WP5. (*Appendix 3*).The immediate comments/clarifications were:

- For Strand B pilots manufacturers of a technology will be approached for commenting
- Keeping focus on the first 4 domains of the Core Model (e.g., rapid REAs) should not exclude consideration (at an appropriate time and manner) of e.g. aspects that are more important for patients or organisational aspects (these aspects are not covered in the 4 domains of rapid REAs). Checklists have been developed to identify important aspects in the remaining domains. Stakeholder groups other than industry

should be involved in the processes in WP5 (e.g., SAG should include representatives from all stakeholder groups).

- It is important to inform the manufacturers as early as possible on what is expected from them in the "submission file" for rapid assessments
    - SubGroup 4 in WP7 has a task of developing a structure of a submission template that will detail scientific information requirements with a view to the HTA Core Model.WP5 and WP7 will be closely collaborating on this (and when a template is developed WP5 will pilot its usage in WP5 pilots processes)
- 10 pilots for rapid assessments of pharmaceuticals and at least 4 pilots for rapid assessment of other technologies are planned in JA2 WP5. Thirty national reports are planned to be produced on the basis of the WP5 pilots.
    - Topic selection and identification of main author and co-author for a pilot would take into account EUnetHTA Partner/Associateorganisations' interest in "translating" the pilot results into a national report. Specific strategies and approaches to ensuring translation of the commonly produced information into national settings will be explored and introduced.
    - The author and co-author will propose a scoping strategy. The specific technology sponsor is planned to be involved in scoping as well as other stakeholders.
    - For pharmaceutical pilots various types of drugs are planned to be subject to pilot assessments – probably "less complicated" cases will be taken first. Orphan drugs will be on the topic list. The interest to volunteer a drug, device or procedure of the technology sponsor plays a very important role in defining which technology will be finally chosen for a pilot as the assessors need to have data from the technology sponsor and not only published evidence.
    - The first pilot in WP5 Strand B has already commenced (duodeno-jejunal bypass liner for patients with obesity (timeline – January-April 2013). 1st author – LBI, 2nd author – AAZ, manufacturer – GI Dynamics.

Anne Gourvil, HAS (France) presented the draft 3-year Work Pan for WP7. (*Appendix 4*).The immediate comments/clarifications were:

- The scope of the methodological guidelines will be discussed in the first meetings of WP7. A concept paper will be developed that will then be offered for comments by the WP7 SAG.
- There is a potential for a valuable input from WP7 for the primary research agenda (e.g., clinical studies design, choice of comparator) and for forward-looking coordination of projects supported by the FP7 (DG RTD).
- The experience coming out of JA1 methodological guidelines development highlighted the value of early stakeholder involvement – JA2 efforts should learn from this experience.

Ulla Salaasti-Koskinen, THL (Finland) presented the draft 3-year Work Pan for WP8. (*Appendix 5*).The immediate comments/clarifications were:

- Clarity and consistent use of terminology associated with the HTA Core Model® is extremely important, e.g., currently the HTA Core Model® applications mean various "sub-models" developed on the basis of a generic Core HTA Model (a generic one is to be revised in JA2 in the light of e.g. the intervention and the screening "sub-model" to ensure consistency).
- WP8 will develop a policy for commercial use of the HTA Core Model® (currently Terms of use do not allow commercial use of the HTA Core Model®) to be ready in May 2013.
- The HTA Core Model® Guide is a short easy to use document – that covers all the domains (length of the document does not signify that some parts of the Model are omitted).
- Trainings will be offered by WP8 targeting EUnetHTA partners and will provide a hands-on training in use and application of the HTA Core Model. A general introduction to the concept of the Core HTA Mode®l and its application are thought to be included in the training that will be offered by WP2 (details are still to be clarified).

Ingvil Sæterdal, NOKC (Norway) presented the draft 3-year Work Plan for WP2. (*Appendix 6*). The immediate comments/clarifications were:

- Training (subject and practicalities) is to be put as an agenda point on the next SF meeting (ie, e-meeting on April 9, 2013)
- Stakeholders' input both in terms of evaluation of the learning material and the courses themselves (i.e., after they have been delivered) will be planned.
- Target audiences for the courses will be identified in Spring 2013. The subject matter of the courses will be EUnetHTA tools and processes including methodological guidelines.
- Involvement of stakeholders is intended to be through the SF; establishment of a specific SAG for WP2 might be considered if deemed necessary

Ingrid Wilbacher presented the draft 3-year Work Pan for WP3. (*Appendix 7*).The immediate comments/clarifications were:

- The scope and perspective of evaluation in WP3 is targeting EUnetHTA and evaluating benefits that are brought about to the members of the network and HTA process in Europe through the activities in EUnetHTA

Patrice Chalon presented the draft 3-year Work Pan for WP6. (*Appendix6*).
No immediate questions were raised.

Julia Chamova, DHMA (Denmark) presented the timeline for the stakeholder input to the work plans. There is now a strong focus on and support for a strong project management in and across work packages and in EUnetHTA in general.

Key points from the discussion that followed the work plan presentations:

- Earlier stakeholder involvement in processes (e.g., in the planning and scoping EUnetHTA JA2 WPs activities including pilots) might be beneficial for delivering better outputs
- Concrete ways of stakeholder involvement in EUnetHTA are manifested through Stakeholder Forum activities, stakeholder advisory groups (SAGs) adjacent to specific work packages, expert meetings, stakeholder surveys – active participation and input provision through these channels are expected from the stakeholders that expressed willingness and interest to get involved in EUnetHTA. Appropriate timeframes to respond should take into account the stakeholder representatives also have their immediate job duties and need in some non-confidential cases input from others.
- The tasks, working processes and scope of involvement of a SAG depends on the subject matter of the work package and is defined by the WP Lead Partner and Co-Lead Partner (if applicable). For example, the WP5 SAG will be involved in the development of a template and procedure manual, in the scoping phase – but not the assessment process of a specific technology in a pilot.
- The timing of forming SAGs and their composition should fit the purpose of the SAG input, i.e., sufficient time should be given in order to form them and bring in a relevant competence and expertise into them. Stakeholder Forum members will be facilitating and responsible for identification of right individuals to be involved in the SAGs for a respective WP.
- A choice of the collaborative model for pilots in WP4 and WP5 will be made with considerations given to the experiences in both work packages (learning from each other), availability of competence and manpower in agencies involved, subject matter, etc. Potential differences could be justified by the different type of content (full vs rapid assessment) Potentially specialisation of HTA agencies/organisations in certain e.g., HTA Core Model domains, might be result of this process
- Rapid assessments with a focus only on a limited number of domains might compromise quality of an assessment and ultimately result in products of inferior quality being reimbursed and included in healthcare practice or of superior quality being excluded.. All identified stakeholder groups should be involved in the assessment process as defined and provide input on all the domains (eg, patient and providers should be consulted in rapid HTA pilots).
- Discussion on innovative methodology for clinical trials and related HTA approaches should be considered when taking up the task of development of methodological guidelines (as part of WP7 activities). Disease-specific scientific communities can be an asset in this process and could be involved. There is a potential for making a difference to future research. Early advice activities of WP7 can also provide input

into this process. EUnetHTA has also established links to DG Research and Innovation (DG R&I) and specific projects that received grants from DG R&I.
- Small and medium enterprises (SME) are currently facing substantial challenges in dealing with the hurdles related to a fragmented European HTA environment. SMEs would largely benefit from coordinated activities like joint European HTA early advice, European HTA training and support activities.
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Orientation on the implementation of Article 15 (Directive 2011/24/EU) – permanent European network on HTA

Jerome Boehm, DG SANCO briefly informed on the process of Article 15 implementation:

- 2 expert meetings are held to assist the Commission in the comitology process and drafting of an implementing act. The Implementing Act draft is to be presented to the CBHC Committee on March 11. The final Implementing Act is to be endorsed by the CBHC Committee in early June.
- During the expert meetings it was evident that experts are unanimous in the opinion that the permanent network should provide for support of a scientific collaboration between HTA organisations in Europe, allow varying degree of involvement in activities, and have an organisation of the network that allows productive, enhanced interaction between the policy and scientific levels in the HTA processes. Building on the experience of EUnetHTA was strongly supported.
- The permanent network should provide a mechanism for an appropriate stakeholder consultation

Other issues and closing of the meeting

- The EUnetHTA JA2 Plenary Assembly meeting will be held on March 21.22, 2013 in Zagreb, Croatia. Stakeholder Forum representatives (1 from each of the stakeholder groups) can participate as observers.

  Action point: Each Stakeholder Forum group should nominate a representative and inform the Secretariat of his/her name by March 5, 2013.
  Travel and accommodation expenses of patient/provider group representatives will be reimbursed by EUnetHTA (as per the rules applied to the SF meeting participation).

- The Secretariat clarified that organisations representing stakeholder groups at the national level are eligible for participation in the Stakeholder Forum. However, European umbrella organisations are given precedence
- When the work plans are finalised and approved, the timelines of stakeholders input in various work packages and in the overall EUnetHTA will be made available to the stakeholders via a dedicated section of the EUnetHTA website.
- Transparency in the processes and final outcomes of the work is important to ensure
- The avenues for stakeholder involvement in EUnetHTA are available – the stakeholder organisations need to find ways of providing input to the processes. With regards to the issue of limited resources, it is important to indicate each organisation's interest in participating in specific stakeholder involvement activities. Challenges (financial, competence) should be specifically stated in advance in order for all involved (EUnetHTA, the Commission, stakeholder organisations) to find concrete solutions to concrete problems.
- AIM (payers stakeholder group) seconded by EuropaBio (industry stakeholder group) raised a question with regards to the necessity of confidentiality agreements to be signed by each individual nominated by the SF member organisation to represent and bring this stakeholder group's opinion/input on the issues under consideration by the SAG

  Action point: The issue is to be discussed by the EUnetHTA Executive Committee at its next e-meeting (February 20, 2013).

The meeting was adjourned at 16:30.

Participants List

EUnetHTA Stakeholder Forum

Attendee	E-mail	Organisation
Frank Münchberg	Muenchberg@bah-bonn.de	AESGP (Association of the European Self-Medication Group)
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European Commission – DG SANCO

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