

EUnetHTA Joint Action 2
Stakeholder Forum meeting
April 9, 2013, 13:00 – 15:00 CET



E-meeting

Organised by EUnetHTA Secretariat
Danish Health and Medicines Authority, Denmark

Participants:

Meeting Chair: Julia Chamova, DHMA, Denmark EUnetHTA Secretariat

Stakeholder Forum Representatives:

Christine Dawson, ESIP
Edith Frénoy, EFPIA
Francois Houyez, EURORDIS
Frank Bongers, EGA
George Yiangou, AESGP
Karsten Berndt, EDMA
Liuska Sanna, EPF
Panagiotis Petrou, HIO
Paolo Morgese, EuropaBio
Pascale Brasseur, EUCOMED
Tsveta Schyns-Liharska, EMSP

EUnetHTA Executive Committee Representatives:

Anna Zawada, AHTAPol, Poland
Anne Raahauge, DHMA, Denmark, EUnetHTA Secretariat
Francois Meyer, HAS, France
Inge Merete Skov, DHMA, Denmark, EUnetHTA Secretariat
Ingvil Sæterdal, NOKC, Norway
Julie Lange, DHMA, Denmark, EUnetHTA Secretariat
Kristian Lampe, THL Finland
Marianne Klemp, NOKC, Norway
Marina Cerbo, AGENAS, Italy
Mathias Christiansen, DHMA, Denmark, EUnetHTA Secretariat
Mirjana Huic, AZZ, Croatia
Nicola Vicari, AGENAS, Italy
Patrice Chalon, KCE, Belgium
Sonja Scheffel, HVB, Austria
Wim Goettsch, CVZ, Netherlands

European Commission

Flora Giorgio, DG Sanco

AGENDA

A. General information and updates:

1. EUnetHTA Plenary Assembly meeting 21-22 March, 2013, Zagreb
2. Joint Action 2
 - a. Discussion of implementation of Co-Chair function in the Stakeholder Forum
 - b. Update Stakeholder Advisory Group (SAG)
 - i. Confidentiality Agreement
 - ii. Current and planned activities (per WP)
 - c. WP2: update on feedback on topics for Stakeholder Training courses
 - d. WP7: Opening of EVIDENT
 - e. WP8: Brief update on the issue of HTA Core Model and structuring of stakeholder information repositories
 - f. Presentation of Stakeholder Forum Area on website.
 - i. Information on how to sign up etc.

B. Other issues:

1. Brief update on the Article 15 permanent voluntary HTA network
 - a) ECORYS report about the permanent network

Julia Chamova welcomed the participants to the meeting and apologised on behalf of the Executive Committee Chair Bert Boer (CVZ) who could not participate in the meeting due to family circumstances. The agenda was adopted.

A. General Information and Update

1. **EUnetHTA Plenary Assembly meeting 21-22 March, 2013, Zagreb**

Julia Chamova (DHMA, EUnetHTA Secretariat) updated the meeting on the Plenary Assembly which was the first PA in Joint Action 2. The vast majority of EUnetHTA partner organisations were represented, Industry and Providers Groups from the Stakeholder Forum were represented – due to illness the Payers Group had to cancel their participation and due to other commitments the Patients Group could not identify participants for the meeting.

- The meeting had a high degree of consensus on the way forward and the main highlights from the meeting were:
 - EUnetHTA 3-year Work Plan endorsed (public availability via website – May 1, 2013)
 - EUnetHTA Elections to the Executive Committee – 2 new members were elected: Catalan Agency for Health, Information, Assessment and Quality (CAHIAQ), Spain (represented by Cari Almazán) and Agency for Health Technology Assessment in Poland (AHTAPol), Poland (represented by Anna Zawada) ran for the second term in the committee.
 - EUnetHTA Conflict of Interest policy endorsed – available on the public website upon finalisation and is already being applied in the work in JA2.
 - EUnetHTA External Collaborations
 - EUnetHTA will develop a joint position (relevant for European Commission public consultations)
 - Stakeholder involvement modalities – presented and discussed in the meeting.
 - EUnetHTA new online platform – presented in the meeting.

- EUnetHTA and permanent European network for HTA – substantial time was used on discussing this topic (see agenda point below under ‘other issues – update on Permanent HTA network)
- External collaborations were discussed at the Plenary Assembly. To ensure success and relevance of the EUnetHTA activities and their outcome, EUnetHTA pays regular attention to the Policy processes and relevant scientific developments in Europe and elsewhere.

EUnetHTA is engaged in the initiatives and activities in:

European Union:

- EU Institutions: DG SANCO, DG R&I, EMA
- Projects supported by EU grants:
 - EUCERD Joint Action and PARENT Joint Action – *contacts via the JAs’ Coordinators*
 - 4 FP7 projects (AdHopHTA, MedTechHTA, Integrate-HTA, Advance_HTA) – *EUnetHTA represented on the Advisory Boards*
 - IMI (Innovative Medicines Initiative) projects (EUPATI) – *presence on the Advisory Board*

Beyond Europe:

- HTAi (HTA Glossary, GPC)
- Asian and Latin American regional HTA networks
- INAHTA (MoU)
- Tapestry Networks

Challenges and way forward in relation to these external collaborations:

- Ever increasing number of requests for EUnetHTA involvement
- Ad hoc, spontaneous requests to provide input
- EUnetHTA is a network
 - Common position of 44 Partners from 27 EU MS, 2 EEA countries, and Croatia.
- Limited staff and time availability both at coordination level and individual partner level.

EUnetHTA Executive Committee – policy for EUnetHTA’s involvement. Activities should have a:

- ✓ Strategic priority for EUnetHTA
- ✓ Potential to contribute value to already existing tasks (JA2)
- ✓ Resources available which are necessary for a sustainable quality input from EUnetHTA

Ways to look into streamlining and ensuring the predictability of EUnetHTA’s external engagement:

- ✓ Agreement on a 1/multi-year realistic work plans with recurrent collaborators (e.g. EMA)
- ✓ Development of Memorandum of Understanding (Terms of Reference)

The above should be aligned with/contributing to reaching the objectives of and implementation of the EUnetHTA JA2 work plan.

It was agreed at the Plenary Assembly to pursue the development of a common position of EUnetHTA in cases of relevant public consultations run by the EC.

- The development of the permanent European voluntary network on HTA was discussed at the Plenary Assembly, and the main issues and comments brought forward by EUnetHTA were regarding: Membership, Financing mechanism and Organisational structure (discussed later in the agenda also)

2. Joint Action 2

a. Discussion of implementation of Co-Chair function in the Stakeholder Forum

Julia Chamova followed up on the discussion from the Face-to-Face meeting in Brussels regarding the introduction of a Co-Chair function in the stakeholder forum.

- The Co-chair function should provide a practical opportunity for continuous involvement and influence on the discussions (SF-Executive Committee meeting agenda development etc.)

The process and identification of an individual to perform the function is in the hands of the Stakeholder Forum and the Executive Committee encouraged the stakeholders to take the time needed to organise and make the choice of an individual representative for the post. If the Stakeholder Forum would find it useful and appropriate, the secretariat would offer to support the process and participate in a task force if needed.

Key comments and discussions:

- The main tasks of the Co-chair would be the same as the chair i.e. in collaboration with the Secretariat preparing meetings and in between meetings raise relevant issues and submitting them. A majority of stakeholders indicated their support to the idea of implementing the Co-Chair function.

Action Point: Stakeholder Forum should indicate to the secretariat if and when this function could be implemented – it was suggested to happen before the next SF e-meeting in June, 2013.

b. Update Stakeholder Advisory Group (SAG)

Julia Chamova updated the meeting on the developments of the use of confidentiality agreements in EUnetHTA and the SAGs

i. Confidentiality Agreement

- Stakeholders had at the meeting in Brussels in February, 2013 encouraged EUnetHTA to look into the possibility for SAG members to consult with peers in cases where further expertise and input from peers is needed. This has been discussed and accommodated by the Exec Comm and the new procedure was clarified and stipulated in an email shared by the Secretariat on March 11, 2013.

Documents marked confidential should still be treated as such however in cases where input from peers is needed; documents can be shared with identified individuals who will also need to sign an additional SAG Counsel confidentiality agreement. The new process introduced should be quickly to manage. Documents are available in the Stakeholder Forum Area on EUnetHTA's Public Website.

Key comments and discussion:

- The SAG for WP7 has not yet been developed. As WP7 consists of 4 sub-groups but only one SAG, stakeholders raised a concern about the workload of the SAG members. It was agreed that the SAG for WP7 would be flexible in terms of the use of SAG Counsels which the new Confidentiality agreement and procedure also takes into consideration.

Action Point: Secretariat will (with input from WP7 LP) start developing the SAG for WP7 and send out detailed description on what input and competences are required for the first tasks of the SAG in WP7.

- As the SAG for WP7 has not been developed the task from WP7 Sub Group 1 on proposing choice of condition(s) for disease specific guideline(s) was, upon acceptance from the Stakeholder Forum, given to the Stakeholder Forum with deadline end of May, 2013.

Action Point: Secretariat will (with input from WP7 LP) send out information to the Stakeholder Forum regarding the process and criteria for suggesting ideas for the choice of condition(s) for disease specific guideline(s). Soon after the meeting.

- The issue of personal liability as private persons signing the EUnetHTA Confidentiality Undertaking was taken up by EDMA and EDMA requested that this topic should be revisited and solved by lawyers.
However, EUnetHTA needs the Confidentiality undertakings signed by individuals who receive confidential documents, and the issue of who is holding the liability is a question between e.g. EDMA and the individual member organisations. Confidential documents will only be shared with people who have signed an confidentiality undertaking.

ii. Current and planned activities (per WP)

Anne Raahauge (DHMA, EUnetHTA Secretariat) gave an overview of the SAG Tasks planned in the first EUnetHTA JA2 Project year from October 2012- September 2013 (See slide 15 for details).

Key comments and discussion:

- An overview of the SAGs, Public Consultations and Surveys planned in Joint Action 2 will be shared in the Stakeholder Forum Area on the Public Website. These overviews and dates are guiding and can be subject to changes following the changes of activities in the 3-year work plan.

Action Point: Secretariat will upload the overviews.

- WP7 SG4: input into the development of the 1st draft submission template is restricted to the industry group. Some of the industry members had not yet received this request from NICE (Leader of SG4).

Action Point: WP 7 lead to follow up with NICE and ensure that all relevant industry partners receive the requests and will be able to provide input to the process and activity.

c. WP2 update on feedback on topics for Stakeholder Training courses

Ingvil Sæterdal from NOKC (WP2 LP) updated the meeting on the WP2 request to Stakeholders on training courses.

- An email was sent in March 2013 to the Stakeholders asking for preferences on:
 - **Topics** for the training courses
 - Preferred **format** of training courses
 - **Type** of learning material

Replies were received from: AESGP, CPME, EDMA, EFPIA, EPF, Eucomed, EuropaBio and HOPE.

The topics for courses were (prioritised listing):

1. Use of HTA for decision making
2. Introduction to systematic reviews and critical appraisal
3. EUnetHTA methodological guidance
4. Key principles of HTA
5. The usefulness of HTA reports
6. General introduction to EUnetHTA
7. Information about EUnetHTA tools
8. EUnetHTA terminology
9. Introduction to quality of life assessment
10. Ethical and social considerations of HTA

The preferred format for training courses (prioritised listing):

1. Workshops
2. Group work
3. Small plenaries
4. Webinars

The preferred type of learning material (prioritised listing):

1. Slides, electronic and printed
2. Recorded presentations / webinars (YouTube)
3. Booklets (electronic and printed)
4. Access to databases and methodological guidelines

- Inputs from stakeholders will be included in the work within WP2 and discussed at the face-to-face meeting in Oslo, April 25-26. The first training course for Stakeholders is planned in January 2014 and the learning material for the first training course will be created during 2013.

Key comments and discussions:

- As topics very much depends on the stakeholder group, the objectives of the trainings will be more specifically targeting the recipients of the training. During the WP2 Face-to-Face meeting in April all inputs from the feedback will be taken into consideration and objectives of the trainings will be more defined based on all inputs. WP2 will also at a later stage develop a SAG and the SAG will be continuously consulted on these issues also so the need of the Stakeholders continuously is taken into consideration.

d. **WP7 Opening of EVIDENT**

Julia Chamova on behalf of Claudia Wild from LBI (WP5 Co-LP) and Francois Meyer from HAS (WP7 LP) informed the meeting of the possibilities of opening POP database and EVIDENT database to the public.

- It is in principle possible to open the access to the POP database for certain aggregated information through EUnetHTA channels; this will need to be discussed in more details.
- The EVIDENT database consists of information which are confidential i.e. information on technologies at the time they are being accessed by HTA

bodies/EUnetHTA partners. But also some information which could be made public. As the database initially has not been developed in order to allow publication of data it will technically be difficult to open up for the non-confidential data and this will take time, but in HAS will look into this.

Key comments and discussions:

- EDMA encouraged the opening of the EVIDENT database. Giving the public at least partial access to the EVIDENT database would be a high impact leverage for increasing the efficiency of allocation in healthcare as health information and knowledge would be disseminated quicker and the healthcare industry would have better and timelier information about what innovation would be valued by health technology assessment agencies and payers. Thus the health care industry could generate further evidence when necessary in a more timely fashion with positive effects for the health care system and for society. This would propel access to high value health care technologies and increase certainty for investment in healthcare.

e. WP8 Brief update on the issue of HTA Core Model and structuring of Stakeholder information repositories

Julia Chamova and Kristian Lampe from THL (WP8 LP) briefly updated the Stakeholder Forum on the pilot project which EUnetHTA together with Roche and Medtronic is engaging in, regarding the use of the HTA Core Model for Stakeholder's internal information repositories improvement.

- The first e-meeting has been held between the partners and the meeting confirmed several possibilities for the companies to mirror and use the Core Model in producing HTA information in the organisations and in this way improve the quality and timeliness of providing the information necessary for the HTA processes.
- It was agreed in the next phase to organise a sessions on the HTA Core Model in order for the partners to get familiarise with the model and also start working on the development of a MoU between EUnetHTA and Roche and Medtronic.

Action Point: An update on this activity to be put on the agenda for the next Stakeholder meeting.

f. Presentation of Stakeholder Forum Area on website.

Julie Lange informed the meeting participants about the Stakeholder Forum Area which is available on the public website. Here similar areas for the SAGs will also be formed, but information on this will follow at a later stage.

- The purpose of the Stakeholder Forum Area is:
 1. To share and store important and relevant SF documentation
 2. To provide SAG updates relevant to all members in the SF
 3. To provide up-to-date individual contact info (SF, Secretariat, Executive Committee, SAG-responsible in the WP LP/Co-LP)

This will achieve a reduction in heavy e-mails with large attachments. It was however stressed, that the daily communication with the Secretariat on more regular issues still will be through e-mails, i.e. e-meeting invitation and registration

- As of the time of this meeting, there are four folders in the Stakeholder Area:
 1. **Meeting** folder – Background documents, agendas and participants list (from face-to-face meetings) will be shared here. Draft minutes will also be shared here for your comments, while final minutes will be posted on the public website – a link to this post will be provided in the meeting folder under the respective meetings

2. **General documents** – documentation which are only for the Stakeholder forum members and not for the public will be shared here, e.g. SABA guide, information regarding confidentiality undertaking.
3. **SAG Updates** – On-going updates on whatever information that is necessary for the Stakeholder Forum to have i.e. SAG overview etc
4. **Contact information** – list of individual contacts as explained above.

All feedback and comments on the structure and content of the Stakeholder Forum area are very welcome and appreciated.

i. Information on how to sign up etc.

Patrice Chalon from KCE (WP6 LP) demonstrated for the meeting participants how to get access to the Stakeholder Forum area.

To create an account on the public website: Please go to the upper right hand corner and press “my account”. Here you will find the “create an account” tab. Click on this tab and create the account by filling in the blank spaces with your personal information. Once your account is approved by the Secretariat, you will receive an e-mail with your username and password. The password can always be changed subsequently.

- The Stakeholder Area and the SAG areas are part of the public website, but functions as a kind of ‘backroom’ of the website, where only people with access can enter. The areas are like silos, so there are no connections between them, and only the people given access to the respective SAG areas can see the content in here. The personal access for the Stakeholder area will also be the access for the SAG areas.

Action Point: All Stakeholders to create an account under ‘My account’ on the website and Secretariat to follow-up and provide access to the Stakeholder Area.

B. Other issues

1. Brief update on the Article 15 permanent voluntary HTA network
1. ECORYS report about the permanent network

Flora Giorgio from the European Commission updated the Stakeholder forum on the developments on Article 15 and the establishment of the permanent voluntary HTA network.

- Objective of the network (art. 15.2 of Directive 2011/24)
 - Cooperation between voluntary national authorities or bodies
 - Provision and exchange of information on relative efficacy and effectiveness of health technologies
 - Analysis of the nature and type of information that can be exchanged
 - Avoid duplication of assessments.
- Governance of the network
 - Experts’ meeting January-February 2013.
 - Key line:
 - 2 levels of structure: the political /strategically and the operational. The two levels should complement each other.
 - Political level in charge of the overall strategic issues
 - Operational scientific independent level
 - Lessons to be learnt from EUnetHTA governance

- Ecorys: Benefits / limits of HTA cooperation
 - Bottlenecks identified
 - Insufficient resource dedicated to coordination and strategy in EUnetHTA and HTA bodies.
 - Insufficient stakeholder involvement
 - Diverging methods and national decision making processes
 - Heterogeneity of HTA capacities; with less appetite for cooperation from 'big' institutions

Findings from the Ecorys study will be taken into consideration in the development of the permanent network. It is up to the commission and the network to address these bottlenecks and see what can be done.

- Preparation of the legal framework
 - Art. 15.4: Adopt necessary measures for the **establishment, management and transparent functioning of the network** – started
 - Art. 15.5: Arrangements for granting aid, the conditions to which it may be subject and the amount of the aid - TO BE STARTED (2nd half 2013/2014)

The Commission is now working on the first step. The question on financing is not yet clear as the negotiation of the financial framework and provision is still on-going and DG SANCO will have to wait for this to be finalised. However, in the legal framework / the directive there is a provision saying that aid should be granted to this network, which is good.

- Implementing Act on Establishment, management and transparent functioning of the network – Process in the Cross-Border Healthcare Committee
 - 22 Oct 2012 CBHC meeting: introduction and the first round of comments
 - 16 Jan and 1 Feb 2013: HTA expert group to discuss substance on the HTA network.
 - 11 March 2013: CBHC meeting discussion on the draft IA
 - 30 March 2013: MS deadline for further comments on the draft IA
 - 3 June 2013: Vote on the draft
 - Adoption within the transposition date of the Directive – 25 Oct 2013
 - Adoption of the rules of procedures by the HTA network
- Financing Provisions
 - Permanent network... without permanent funding, according to Directive 2011/24.
Principle of the funding in the upcoming health programme 2014-2020, but amount unknown.
Provision of the programme will apply (joint action?)
The HTA network should send clear signal on the amount needed and duration
SANCO explores H2020 provisions for funding specific activities
- Next Steps
 - EC internal process for finalising IA (April/May)
 - Vote in CBHC (3 June)
 - Launch EC Adoption procedure (June/July)
 - Send invitation to MS for appointments (summer 2013)
 - First meeting in HTA network (September 2013)

Key comments and discussions:

- EUnetHTA appreciates the effort in clarifying the details and the cooperation with DG SANCO and the possibility to provide inputs from EUnetHTA. A deliverable in JA2 is to provide recommendations to the setup of the permanent HTA network and EUnetHTA is ready to provide such input and have already done so also – inputs based on the empirical fieldwork developed over the past 6 years in EUnetHTA. In the Plenary Assembly in Zagreb 3 issues which need to be clarified further were shared with Jerome Boehm from DG SANCO:
 - **Membership**
 - Concept of the ‘network members’?
 - Formal mechanism of interaction/delegation of ‘operational’ responsibilities to EUnetHTA from the permanent network?
 - 2. **Financing mechanism** – the issue is not only the amount and duration of the financial aid but also under which mechanisms it will be provided, how and when it will happen in order to provide adequate support.
 - **Financing of permanent network in 2014-2015** – relationship with EUnetHTA JA2?
 - **Financing mechanism 2016-2020?** Joint Action mechanism as of now is not adequate (eg. JA budgeting) Timing of applying for EU funding
 - **Financing mechanism 2020+?** Permanent financing should be (eventually) made available via EU formal mechanism.
 - 3. **Organisational structure**
 - **2 layer structure** – lean, efficient, effective responsibility and accountability division between governing bodies.
 - **Network Assembly, Network Forum and Exec Comm:** Accountability for strategic direction and implementation at operational level – coherent, effective structure holding each body accountable vis-à-vis each other and in general main function of each.
 - **Coordinating facility:** Assignment of functions supporting efficiency and coherence of the whole structure
 - **Ability to receive funds and handle issues of Intellectual Property Rights (IPR)** making contracts with external providers etc (legal entity ‘abilities’)

All comments have been well taken on board by DG SANCO and are planned to be used in the development of Rules and Procedures of the permanent network.

- A debrief call was arranged by the Industry Stakeholder Group after the Plenary Assembly, so this group is updated on the development of the permanent network. But concerns were raised that other Stakeholder groups, from this presentation, might not understand the situation and the issue that the likely scenario is another joint action.
 - Flora Giorgio from the European Commission informed the Stakeholders that it at the moment is too early to say anything concrete about how the operational /scientific level will be financed. It is likely that it will be through a Joint Action instrument, but DG SANCO is at the moment looking into different options and also into ways to modify the Joint Action instrument to better address the work.

2. Stakeholders input to the news

Julie Lange (DHMA, EUnetHTA Secretariat) encouraged and invited the Stakeholders to send input for news to be considered to be included in EUnetHTA’s newsletter and LinkedIn group ‘HTA in Europe’. Content type should be HTA-relevant, EUnetHTA

relevant and available on the web (i.e. something on stakeholder's website).

- The newsletter will be send out quarterly and an email reminder about deadlines will also be send out. Deadlines are:
1 July issue – deadline 15 June, 2013
1 October issue – deadline 15 September, 2013
1 January issue – deadline 15 December, 2013

For the LinkedIn group input can be send on an on-going basis.

All inputs should be send to Julie Lange, jula@sst.dk

3. Project management routines

The Secretariat has been requested to improve project management routines regarding details/communication of instruction information and sharing non-confidential information with the SAGs.

- The Secretariat will of course take this into consideration and be more clear on brining deadlines up front e.g. in email subject lines. And also make sure, that any non-confidential information shared with the SAGs are also shared with the Stakeholder Forum.

4. Next SF e-meeting – 4 June, 2013