

EUnetHTA Joint Action 2
Stakeholder Forum meeting
June 4, 2013, 13:00 – 15:00 CET



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

Participants:

Meeting Chair: Finn Børlum Kristensen, DHMA, EUnetHTA Secretariat

Stakeholder Forum Representatives:

Christine Dawson, ESIP
Edith Frénoy, EFPIA
Karsten Berndt, EDMA
Christian Peters, ESIP
Pascale Brasseur, EUCOMED
Magda Kalata, EDMA
Jacques de Haller, CPME
Liuska Sanna, EPF
Eva Münster, AESGP
Panagiotis Petrou, HIO
Constance Colin, CPME
Paolo Morgese, EuropaBio
Isabel Klinnert, EGA

EUnetHTA Executive Committee Representatives:

Alric Rüter, IQWiG, Germany
Anna Zawada, AHTAPol, Poland
Cari Almazán, CAHIAQ, Spain
Claudia Wild, LBI, Austria
Francois Meyer, HAS, France
Ingrid Wilbacher, HVB, Austria
Julia Chamova, DHMA, Denmark, EUnetHTA Secretariat
Julie Lange, DHMA, Denmark, EUnetHTA Secretariat
Kristian Lampe, THL Finland
Marianne Klemp, NOKC, Norway
Marina Cerbo, AGENAS, Italy
Mathias Christiansen, DHMA, Denmark, EUnetHTA Secretariat
Nicola Vicari, AGENAS, Italy
Patrice Chalon, KCE, Belgium
Sonja Scheffel, HVB, Austria
Wim Goettsch, CVZ, Netherlands

European Commission

Flora Giorgio, DG SANCO
Jerome Boehm, DG SANCO

AGENDA

A. General information and updates:

1. Overview of action points (last e-meeting) and their status
2. JA2 WP updates
3. EUnetHTA Conference Rome 2014 (October) – theme, organisation, etc
4. JA2 SAG activities – update
5. Discussion of the implementation of Co-Chair function in the Stakeholder Forum
6. Article 15 permanent network – update

B. Other issues:

1. Next EUnetHTA Stakeholder Forum e-meeting – September 17, 2013.

Finn Børlum Kristensen (DHMA, EUnetHTA Secretariat) welcomed the participants to the meeting and apologized for the technical problems before the meeting. Finn also gave a general briefing about the general state of SABA and the e-meetings.

A. General information and updates:

1. **Overview of action points (last e-meeting) and their status**

Julia Chamova (DHMA, EUnetHTA Secretariat) gave an overview of actions points from the last meeting and their status.

SLIDE:

#	Action Point	Responsible	Status
1	<i>Implementation of Co-Chair function in the Stakeholder Forum. Indication on wish for such a function and the process and timeline.</i>	<i>Stakeholder Forum</i>	<i>Update later in this meeting</i>
2	<i>Development of SAG for WP7</i>	<i>Secretariat / HAS</i>	<i>Not done – lack of information from WP7 LP</i>
3	<i>Information send to Stakeholder Forum on WP7 SG1 request for ideas from the Stakeholders for the choice of condition(s) for disease specific guideline(s)</i>	<i>Secretariat / HAS</i>	<i>Done</i>
4	<i>Overviews of SAG, Public Consultations and Surveys in Joint Action 2 shared with Stakeholders in the SH area on the Public Website</i>	<i>Secretariat</i>	<i>Done</i>
5	<i>WP7 SG4 request for input to the development of the 1st draft submission template. To be shared with all industry groups</i>	<i>HAS / NICE</i>	<i>On-going</i>

6	<i>Update on the development of the EUnetHTA-Roche and Medtronic EUnetHTA-pilot project on use of the HTA Core Model for companies' information repositories</i>	<i>Secretariat/THL</i>	<i>Update later in this meeting</i>
7	<i>All stakeholders to create an account under "My account" on the website and secretariat to follow-up and provide access to the Stakeholder Forum area</i>	<i>Secretariat/SF members</i>	<i>On-going</i>

Key comments and discussion:

- The action points will be a recurring item on agenda in future meetings.
- Julia Lange gave a presentation on the Stakeholder Forum area on the public website, and how to get access to it.

Action Point: all Stakeholders are to create an account on EUnetHTA public website and indicate to the Secretariat that they wish to be part of the Stakeholder Forum area on the EUnetHTA website.

2. JA2 WP updates

WP2

Patrice Chalon (KCE, WP2 Co-lead Partner) gave an update on WP2.

SLIDE:

Activity	Status
<i>3-year work plan</i>	<i>Published on EUnetHTA website</i>
<i>Reporting</i>	<i>Not started</i>
<i>Production of learning material for the EUnetHTA tools and methods</i>	<ul style="list-style-type: none"> • <i>Training needs among EUnetHTA members and Stakeholders have been identified (E-mail questionnaire to Stakeholders (presented on previous e-meeting), Survey from JA1, discussions within WP2).</i> • <i>Ongoing discussions within WP2 on learning material.</i> • <i>Input on learning material from Stakeholders in September/October 2013.</i>
<i>Communication strategy</i>	<i>WP2 members have commented on the strategy. Secretariat will send to ExCom for approval on June 26th.</i>

<i>Promotion of national HTA reports based on Core HTA</i>	<i>«Output» on website. Work on how to provide a workflow to catch the relevant information from the EUnetHTA members is ongoing.</i>
<i>E-learning about EUnetHTA tools and methods</i>	<i>Identify e-learning platform: Ongoing</i>
<i>Face-to-face training course</i>	<ul style="list-style-type: none"> • <i>Training needs among EUnetHTA members and Stakeholders have been identified (E-mail questionnaire to Stakeholders (presented on previous e-meeting), Survey from JA1, discussions within WP2).</i> • <i>Ongoing discussions within WP2 on training activities.</i> • <i>Training course in January 2014 in Brussel (in connection with the SH Forum ftf meeting).</i>
<i>Support HTA Capacity Building</i>	<ul style="list-style-type: none"> • <i>Training needs among Stakeholders is identified</i> • <i>Discussed the learning path at the WP2 face-to-face meeting in Oslo</i> • <i>Update «EUnetHTA Handbook on HTA Capacity Building», 2008</i>

Key comments and discussions:

- The lead partner for WP2, NOKC, has contacted EUPATI (European Patients Forum). NOKC is participating in their advisory board to facilitate possible coordination between EUnetHTA and EUPATI in their individual efforts in the area of training provision to patients.
- Liuska Sanna (EPF) expressed her surprise that comments shared at last e-meeting were “ignored” by the lead partner of WP2. Julia Chamova urged Liuska Sanna to elaborate on this subject and share it with the lead partner (NOKC), who was not participating in the e-meeting, for them to reply. The Secretariat will bring it forward to the WP2 lead partner.

Action Point: Secretariat to follow up with WP2 on the lack of response to EPF

WP3

Sonja Scheffel (HVB) gave a brief update on the work of WP3.

- Since last e-meeting WP3 the yearly survey of WP3 has been sent out to the individuals from the SF member organisations and EUnetHTA member organisations to fill in. The aim of the survey is to evaluate the EUnetHTA Joint Action 2 project. The survey is sent out only to the main contact person, as WP3 only needs one answer per SF member organisation. The deadline for response is June 30.

Action Point: Stakeholders to reply to the WP3 Survey

WP4

Marina Cerbo (AGENAS) gave the update on WP4:

SLIDE:

State of the art

- 3 years work plan finalized ✓
- Protocol for the 1st Core HTA ✓
 - SAG feedback within May 25th – revision ongoing (end of June)
- Methodological standards & procedures crafting ongoing (1st draft in finalization, completed by the end of May 2013)
- National pilots (volunteers for National Report production identified: Austria (HVB), Bulgaria (NCPHA), Portugal (Infarmed), Romania (NSPH MPD) and Sweden (SBU)) – production should start with final version of protocol and 1 st draft of MSP
- Next f-t-f meeting planned for October 2013

SAG Involvement - Core HTA 1 Protocol feedback:

- Protocol draft send to SAG members on May 8th
- Feedback deadline set on May 25th
- 7 answers received (some after the deadline)

SAG Involvement - Core HTA 1 Protocol feedback - Results:

General comments on the protocol:

- comprehensive and well described
- ...well focused and very detailed...
- ...protocol leaves the actual HTA methodology undefined to a large extent...
- additional clarity could be achieved by use a consistent nomenclature
- ...minor suggestions are related mostly to the need to use and design and editing...
- Domain related comments are under evaluation by each domain team and, if relevant, the protocol will be amended accordingly

Key comments and discussion:

- Nicola Vicari (AGENAS) informed that the next SAG activity in WP4 will be in August and September.
- The SAGs will receive the final draft of the Core HTA report for review.

WP5

Simone Warren gave an update on WP5. (CVZ)

SLIDES:

STRAND A

- Expression of interest by pharmaceuticals company
 - First pilot started in February 2013
 - Second pilot started in April 2013
- Expression of interest by WP5 partner
 - List with pharmaceuticals under EMA assessment sent to WP5 partners
 - Responses from WP5 partners are expected by the end of May 2013

STRAND B

- Call for collaboration
- POP database

STRAND A - Ongoing pilots:

Pilot 1: Zostavax for the prevention of herpes zoster (HZ) and herpes zoster related post herpetic neuralgia (PHN) in individuals of 50 years of age or older

- started in February 2013
- First author: CVZ (NL); Co-author: A Gemelli (IT)
- Dedicated reviewers: HAS (France), DPA/MHEC (Malta), RIZIV-INAMI, KCE (Belgium), BIQG/GÖG (Austria), MoH Cz Rep (Czech Republic), Regione Veneto (Italy), DGCF MSSSI (Spain)
- Scoping meeting on February 26
- Submission file received April 12
- 1st version of pilot assessment was sent to reviewers on 22nd of May 2013
- Final assessment report is expected in August 2013

Pilot 2: Canagliflozin

- Started in April 2013
- Authors: Fimea (FI), AZZ (HR), Regio de Veneto (IT)
- Scoping meeting on May 6
- Submission file expected in June 2013

STRAND B - Ongoing pilots:

Pilot 1: Endobarrier

- Author: LBI-HTA; Co-author: AAZ
- Dedicated reviewers: GYMESZI, HVB, GYMESZI, ISCIII, MoH (Czech Republic)
- Draft Project Plan consultation: WP5 SAG; Public consultation; Manufacturer
- Next Steps: Finalisation of the final project plan, writing of first version of pilot rapid assessment, selection of external reviewer(s)

Pilot 2: Symplicity RDN System

- Author: NOKC ; 2 co-authors: Avalia-t, CR.DK
- 5 dedicated reviewers: Healthcare Improvement Scotland , Finohta/THL , AHTAPol, GYEMSZI, IQWiG
- Draft project plan: May 2013

Procedure Manual:

- **Objective of the manual:** to guide the production of pilot rapid assessments
- Strand specific procedure manuals has been developed
- Comments from strand members have been discussed at f-t-f meeting (14&15 Feb)
- SAG consultation ended in April 2013
- Final version of STRAND B manual is ready, manual of STRAND A will be ready by the end of May 2013
- Final versions published on the EUnetHTA website BUT changes still possible based on the experience during the JA2

Development of templates:

- Project plans for pilots >> Strand specific templates

- *Included: scoping, methods (selection of assessment elements, data retrieval and abstraction) and detailed timelines*
- *To be used for first pilots*
- *Project plans are drafted during scoping phase and should be finalised before start of assessment phase*
- *Assessment template >> Strand specific templates*
- *Template for reviewers>> Strand specific templates*
- *Other templates >> evaluation forms and surveys for pilot producers, WP5 members and MAH*

All templates and surveys were consulted with WP5 members and based on their comments were finalised in Strand B, and will be ready by the end of May in Strand A

Key comments and discussion:

- EFPIA asked when manufacturers of the list of products which WP5 is consulting would be contacted?
The date is not yet set, but would most likely be after June 16, 2013. The responses from WP5 member should first be collected. EUnetHTA is in contact with EFPIA and discussing ways of facilitating the involvement of the pharma companies. The next step vis-à-vis the companies will not be taken before discussing with EFPIA.
- EGA commented that further involvement of the industry group as a whole would be greatly appreciated and EuropaBio emphasized that the priority should be the manufacturers of the products and then industry for consultations.

WP6

Patrice Chalon (KCE) presented the activities of WP6

SLIDES:

Activity	Due date / Milestone	Status
<i>3-year work plan</i>	<i>M5</i>	<i>Delivered on time</i>
<i>Implementation of a new Public site</i>	<i>M4</i>	<i>Delivered on time (1st Jan 2013)</i> <ul style="list-style-type: none"> • <i>Includes Stakeholder forum area</i> • <i>Includes SAG areas</i> • <i>some adjustments to occur</i>
<i>Implementation of a new intranet (including "work rooms")</i>	<i>M4</i>	<i>Delivered on time</i> <ul style="list-style-type: none"> • <i>with some delay for some administrative functionalities</i> • <i>some adjustments occur</i>

<i>Implementation of a Newsletters diffusion tool</i>	<i>M4</i>	<i>Delivered at M6 some adjustments to occur</i>
<i>Planned and On-going Projects database operation</i>	<i>M4-M36</i>	<ul style="list-style-type: none"> • <i>Release 2 functionalities revised (planned 09/13)</i>
<i>Centralized authentication system (EUnetHTA ID)</i>	<i>M4-M36</i>	<i>Deployment release 2 in progress</i>
<i>EUnetHTA Toolbar</i>	<i>M4-M36</i>	<i>Updated according to websites changes</i>
<i>“e-learning “ platform</i>	<i>M7-M9</i>	<i>Needs assessment: ongoing</i>
<i>Surveys of users</i>	<i>M6-M8</i>	<i>Questionnaire preparation: delivered on time</i>

WP7

Francois Meyer (HAS) gave an update on WP7

- The WP7 SAG creation has been delayed due to a number of reasons (complexity of the structure of WP7 (several subgroups), short of staff resources for coordination at the LP). Should be resolved by the end of the month.

Update from subgroups:

- Subgroup 4: Francois Meyer informed the forum that all stakeholders involved in the subgroup's work have been contacted specifically about the templates. Clarification on participation of the individual SF members in the work has been clarified (ie, contact to EDMA was made and explanation provided (work on templates will not focus on diagnostics)).
- Subgroup 3: Alric Ruether (IQWiG) commented that subgroup 3 have chosen the main topics for the guidelines (first 3 topics: internal validity of non-randomised studies and interventions; meta-analysis of diagnostic tests accuracy studies; economic evaluation), identified main authors for each of the topics, formed the working group for each topic; each working group has already had exchange and agreement on the concept phase. The process (including timing) for guideline development and its review has been agreed (Process= topic selection, prioritisation, creation and maintenance including stakeholder involvement in it). Work on first drafts has commenced, which will then go to stakeholder consultation. The topics for the second group of guidelines: personalised medicine; information retrieval and study registries, bibliographic databases; medical devices (WP7 SG3 is in contact with a FP7 project MedTechHTA to avoid duplication and facilitate cooperation on the subject).

Stakeholder consultation is scheduled for no later than January 2014.

- EUnetHTA is exploring the possibilities of cooperating with the WG on HTA of ENCePP (first face-to-face meeting of the WG on HTA of ENCePP will take place later in June). Later in the process EUnetHTA will conduct pilots in cooperation with the industry. The stakeholders will be consulted for advice on a choice of technologies for the database on the additional evidence generation (later in 2013 (around October 2013)).
- In Subgroup 1, an e-meeting on disease specific guidelines will be held later this week. Pilots are on-going (Pilots of early dialogue). One in June and one in September. A call for tender has been issued by the European Commission on April 9 for the conduct of 10 early dialogues. The deadline for submission of the proposal for tender is June 7.

Key comments and discussion:

- With the WP7 SAG still not established it is difficult to follow how stakeholders are going to be involved in the activities of WP7 and individual subgroups. With a creation of a SAG it will be easier to follow developments.
- There will be different timelines for the templates. The work on the template on pharmaceuticals will continue as planned while the submission template for devices will be worked on later. Finn (DHMA) commented that there is much more existing evidence and well established knowledge coming out of regulatory processes from companies on pharmaceuticals. When things are becoming more clear regarding the template on pharmaceuticals, we will continue with the template on devices.

WP8

Kristian Lampe (THL) updated the stakeholder forum on WP8.

SLIDES:

HTA Core model update

- *Progressing as planned*
- *Currently 2nd draft in a quick internal review by WP4, 5 and 7 + WP8 Stakeholder Advisory Group*
- *WP8 face-to-face meeting 5-6 June in Helsinki*
- *3rd draft by the end of June -> review by all EUnetHTA agencies + WP8 SAG*
- *September: final modifications*
- *HTA Core Model Online:*
 - *Rapid REA Model included in the tool, testing phase*
 - *Working on upload results feature*

Policy update

- *Policy for the HTA Core Model and core HTA information*
- *Developed within JA1, now review*
- *EUnetHTA agencies mostly agree with the policy*
- *Stakeholders more critical*
 - *partly misunderstandings,*
 - *access to HTA Core Model Online production features for commercial companies?*

Commercial license

- *Allows use of the HTA Core Model for commercial purposes*
- *Few limitations, just some principles to prevent e.g. use of EUnetHTA brands for marketing purposes*

- Draft being reviewed by WP8 + some key WP leads + legal check
- Executive Committee in June

Industry Collaboration

- With Roche and Medtronic
- HTA Core Model in internal processes
- Preparing a MoU / ToR
- Introduction of the system to participants, consideration of feasibility

Key comments and discussion:

- It was clarified, that any use that is aimed toward private monetary compensation (making money of its use) is commercial use.
- The draft commercial license will be send to the SAG for review.
- The secretariat will be happy to facilitate in the process of preparing for the Executive Committee meeting June 26, that there will be time for WP8 to involve the SAG in the review of the HTA Core Model policy, so the executive committee will also have the input of WP8 in the light of SAG comments.

Action Point: WP8 LP will send asap a draft Policy document for the WP8 SAG to provide input in order to prepare a draft Policy for review by the Executive Committee

3. EUnetHTA Conference Rome 2014 (October) – theme, organisation, etc

Julie Lange (DHMA) gave a short presentation of the title, focus and scope of the EUnetHTA Conference in Rome 2014.

SLIDE:

Conference title: HTA 2.0 Europe: teaming up for value

Focus and scope:

- To present and discuss our own (EUnetHTA) achievements, work in progress, etc etc in a larger and more complex/multi-layer/multi-faceted (geographically, content-wise, etc) context of the current developments in HTA, health policy/decision-making with the view to the future → thus, “HTA 2.0”
- To allow effectively work with the stakeholders to be a part of the programme
- To allow/explore ways of collaborating with FP7 research projects, EMA, bringing relevant “best” European research and other input from the scientific societies on the conference programme → thus, HTA 2.0 Europe
- To bring a positive, action message of “working concertedly together” (“who” “together” – to be defined (however, going beyond just the immediate EUnetHTA network partners/associates) → thus, “teaming up”
- “sustainability”, “change”, “action/implementation”, “value”, “network”, “sharing” are key, operative words to further define the objectives

EUnetHTA (through the EUnetHTA Secretariat) holds the copyright for "HTA 2.0 Europe"

Key comments and discussion:

- The specific date in October 2014 is still to be announced, and will depend on further planning with the local conference provider.
- The EUnetHTA secretariat will keep the Stakeholder Forum updated and involved in the preparations of the conference.

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

Edith Frenoy, EFPIA presented the main discussion point from the stakeholder group on the implementation of the Co-Chair function.

- The stakeholder group informed that a meeting was held on May 13 where the implementation of a Co-Chair function was discussed.
- The stakeholders find that the role of the co-chair should include:
 - Preparing the meeting of the SF, the e-meetings and F-t-F meetings, and co-chair the meetings as such.
 - Represent the Stakeholder Forum in other EUnetHTA activities.
 - The Co-Chair could have a role in discussing the future permanent HTA network, in collaboration with EUnetHTA, ensuring stakeholder involvement in the process.

Key comments and discussion:

- More discussion is needed for the appointment of an actual person to fill out the Co-Chair role.
- The secretariat requested to receive the notes on the ideas and comments on the Co-chair function for further work.

Action Point: Edith Frenoy (EFPIA) will send a note on the SF ideas and comments on the Co-Chair function to the secretariat for further work.

5. Article 15 permanent network – update

Flora Giorgio (European Commission) updated the Stakeholder Forum on the latest developments on the permanent network.

SLIDES:

- **HTA Network - Art 15.1 of the Directive**
- **Support voluntary cooperation and the exchange of scientific information among Member States**
- **Members**
 - *national authorities or bodies responsible for HTA*
 - *designated by the Member States*
 - *contribute to the network's activities according to the MS's legislation*

- **Based on the principle of good governance**
 - transparency,
 - objectivity,
 - independence of expertise,
 - appropriate stakeholder consultations.
 - **Main conclusions Experts meeting January/February 2013**
 - **2 levels of activities**
 - Strategic → Governance, strategic direction, long term sustainability
 - Technical/scientific → production of HTA reports, methodologies, piloting etc
 - **In synergies but independent**
 - **Membership**
 - Strategic → 1/Alternate + 1 expert
 - Technical/scientific → as necessary according to expertise, including stakeholders
 - **Challenges in IA drafting:**
 - Procedural issues (avoid legal uncertainty, build on precedents)
 - Balance between comprehensiveness and flexibility → set the overall framework but not details
 - Refer to the two levels as connected but independent → one HTA Network + technical cooperation
 - **Challenges in IA II :**
 - Refer to the importance of science but do not give impression of duplication nor confusion in who is doing what → HTA Net does overall directions, Technical does Science
 - Give visibility to the technical cooperation but leave enough flexibility to organise its work and rules ... and financing.
- Art 4.2 "The rules of procedure shall facilitate appropriate stakeholder consultation and liaison with EU bodies, researchers and international organisations on the work of the Network."
 - Art 5.2 "The HTA Network shall be supported by a scientific and technical cooperation and it may initiate or participate in activities involving all or some of its Members, if such involvement contributes to the objectives of the HTA Network".
 - Art 6.4 "The HTA Network may invite European and international organisations to attend meetings as observers."

Key comments and discussion

- The member states will designate an institution to be part of the network. There should be one member and one alternate.
- Involvement of the stakeholders in the governance level will be discussed by the members of the permanent network.
- It would be helpful to have a clarification on the "exit rules" of the network. The European Commission will not put at specific length or and "expiry date" on membership of the network as it is a voluntary network. The member states are not obliged to be represented in the network, but every member state will have an opportunity.

6. Other issues

- The next EUnetHTA Stakeholder Forum e-meeting will be held on September 17.
- The next issue of the EUnetHTA Newsletter will be published on July 3. The secretariat welcomed inputs from the SF members to take into consideration for the newsletter. The deadline for the inputs is June 15. Julie Lange will send out the information on how to send in the inputs.
- EFPIA's annual meeting will be held in Brussels from June 24 - 25. Further information and registration is available online.

Action Point table:

#	Action Point	Responsible	Deadline
1	All Stakeholders are to create an account on EUnetHTA public website and indicate to the secretariat that they wish to be part of the Stakeholder Forum area on the EUnetHTA website	Stakeholders	On-going
2	Secretariat to follow up with WP2 on the lack of response to EPF	Secretariat	Within a month and before the next SF meeting
3	Stakeholders to reply to the WP3 Survey	Stakeholders	June 30, 2013
4	WP8 LP to send a draft HTA Core Model Policy for commenting by the WP8 SAG	WP8 LP	ASAP
5	Edith Frenoy (EFPIA) will send a note on the stakeholder groups ideas and comments on the Co-Chair function to the secretariat for further work.	EFPIA	ASAP