

EUnetHTA Joint Action 2 Stakeholder Forum meeting

November 18, 2014, 13:00 – 15:00 CET

E-meeting

Organised by EUnetHTA Secretariat
Danish Health and Medicines Authority, Denmark



Participants:

Alric Ruether, IQWIG - Chair
Anne Raahauge, DHMA (EUnetHTA Secretariat), Denmark
Christoph Künzli, SNHTA, Switzerland
Claudia Wild, LBI, Austria
Elisabeth George, NICE, UK
Finn B. Kristensen, DHMA (EUnetHTA Secretariat), Denmark
Francois Meyer, HAS, France
Gintare Miksiene, VASPVT, Lithuania
Inge M. Skov, DHMA (EUnetHTA Secretariat)
Ingvil Sæterdal, NOKC, Norway
Julia Chamova, DHMA (EUnetHTA Secretariat), Denmark
Kristian Lampe, THL, Finland
Lisa Krüger, ZIN, the Netherlands
Luciana Ballini, ASSR, Italy
Marianne Klemp, NOKC, Norway
Marina Cerbo, AGENAS, Italy
Nathalie Merle, HAS, France
Sonja Scheffel, HVB, Austria

Stakeholder Forum Representatives:

Francois Houyez, EURORDIS – Co-Chair
Constance Colin, CPME
George Sarelakos, AESGP
Geoffrey Wilson, COCIR
Ilaria Passarani, BEUC
Isabella Notarangelo, HOPE
Jacques de Haller, CPME
Karianne Johansen, EFPIA
Marie-Astrid Libert, COCIR
Pieter Dylst, EGA
Rosa Giuliani, ESMO
Victoria Wurcel, EDMA
Yves Verboven, EUCOMED

European Commission:

Flora Giorgio

Agenda

A. General information and updates

1. Overview of action points (last E-meeting) and their status (*written status overview in the background documents*)
2. EUnetHTA Interim Reporting - Year 2
3. Permanent EU cooperation on HTA
 - a. HTA Network update
 - b. EUnetHTA Recommendations
4. HTA 2.0 Europe – Teaming up for value – update
5. EUnetHTA Stakeholder training Oct 2014 - update

B. Other issues

1. Next EUnetHTA Stakeholder Forum meetings
 - SF F-t-F meeting in Brussels, 26 February, 2015
 - SF E-meeting 12 May, 2015 13-15 CET
 - SF E-meeting 8 September, 2015 13-15 CET
 - EUnetHTA PA in Copenhagen 28-29 May 2015
2. Input to Newsletter

Francois Houyez (EURORDIS) Co-Chair of the Stakeholder Forum welcomed all meeting participants and the agenda was approved with no further amendments.

A. General information and updates

1. Overview of action points (last E-meeting) and their status (*written status overview in the background documents*)

Anne Raahauge (EUnetHTA Secretariat, DHMA) updated the Stakeholder Forum on the status of the action points from the last meeting.

SLIDE:

Status of action points – E-meeting 27 May

#	Action Point	Responsibility	Status
1	Minutes from Conference programme Committee meetings to be shared in the Stakeholder Forum area.	EUnetHTA Secretariat	Done right after the meeting

The EUnetHTA Secretariat had also received a list of questions from EDMA, which the Secretariat is still working on with the relevant Lead Partners in question. EDMA is informed and the answers will be shared with them shortly.

2. EUnetHTA Interim Reporting – Year 2

Julia Chamova (EUnetHTA Secretariat, DHMA) informed the Stakeholder Forum about the Stakeholder Feedback on the Interim Report.

SLIDE:

Stakeholder Forum was invited to comment on the draft interim reports – 2 weeks for responding to the request.

No input from Stakeholder Forum.

Key comments and discussion / decision points:

- It was highlighted from the EUnetHTA Secretariat that it is important for EUnetHTA to receive feedback and input from the Stakeholder Forum preferably within timelines given, but as it is a priority to hear from and include Stakeholders in the processes feedback is always welcomed.
- There was a general feeling among the Stakeholder Forum, that a period of 2 weeks for commenting on such kind of extensive document was too little. EUnetHTA Secretariat informed the Forum that the timeline given for the Interim Reporting is set by the Commission and only 2 months are given for the whole technical and financial reporting process, so this is a tight schedule for all partners involved. The Secretariat welcomed the suggestions on finding other ways of commenting on important documents and informing in good time about upcoming important deadlines in order to help the planning on the Stakeholder side.
- It was asked by EDMA if the quality assurance tool used in EUnetHTA could be shared with the Forum. There is no single quality assurance tool used across all Work Packages. In the Interim Report each Work Package has described how they assure quality in their work. The EUnetHTA Secretariat will follow up with EDMA to clarify and respond concretely on this request.

Action Points:

- EUnetHTA Secretariat to follow up and clarify with EDMA regarding the quality assurance process used in EUnetHTA's different work packages.

3. Permanent EU cooperation on HTA

a. HTA Network update

Flora Giorgio (DG Sanco/HTA Network Secretariat) updated the Stakeholder Forum on the last meeting in the HTA Network.

SLIDES:

HTA Network 3rd meeting – main outcome

- *Unanimous adoption HTA Network Strategy paper*
- *Set up of WG to "re use of joint work in national activities" – stakeholders will be invited ad hoc*
- *WG meeting 16 December 2014 (TBC)*
- *HTA Network meeting 23 March 2015 (focus on MD)– Oct TBD*

EU Cooperation on HTA – next steps

- *WG Mandate:*
Based on experience gathered so far, and in view of the directions set by the HTA Network Strategy, the WG should develop a draft reflection paper on the conditions to facilitate take up and re-use at national level of HTA production including information and joint assessments (ie "joint work")

HTA Network 3rd meeting – main outcome

- *Discussion on synergies between Regulators and HTAs*
- *Discussion on work of EUnetHTA and Medev Hepatitis C assessment*
- *Discussion on HTA for eHealth*

Joint Action 3 – Timing (indicative subject to adoption of current WP and establishment of new EC)

- *Informal meeting with MS representatives*
- *Adoption WP 2015 → 1st Q 2015 (TBC)*
- *Informal meeting with MS representatives*
- *Letter from CHAFEA to MS to declare interest/appoint → 8/12 weeks (TBC)*
- *Meeting(s) with appointed MS representatives*
- *Submission for Negotiation → 3 months after deadline for appointment*

Summary of discussion

- *Close involvement of national HTA bodies*
- *Link between HTA Network and Scientific cooperation*
- *Focus on "Joint production"*
 - *Simpler processes and outputs*
 - *Selection process to respond to national needs*
 - *Importance to keep medical devices but recognize specificity*

Key comments and discussion / decision points:

- The Stakeholder Forum was represented in the HTA Network meeting by Francois Houyez, Jacques de Haller, Irina Odnoletkova, Andrea Rappagliosi and Nicola Bedlington. For the first time SF were invited to stay throughout the whole meeting.
- It was emphasised by the Commission that despite the fact that medical devices have different regulatory processes than pharmaceuticals it is important that medical devices should not be kept out of the scope of the European cooperation on HTA. The HTA Network meeting in October had a strong focus on pharmaceuticals with the presentation from EMA, so it has been decided that the next meeting in March 2015 should have medical devices e.g. update on the legislation etc, on the agenda.
- It was brought up, that the presentation at ISPOR in Amsterdam on joint participation by EUnetHTA partners and industry in EUnetHTA's pilots had been very interesting (link to presentations: <http://ispor.org/Event/ReleasedPresentations/2014Amsterdam>) and the possibility of having stakeholders presenting and sharing their experiences with their joint work with EUnetHTA at one of the upcoming Stakeholder Forum meetings was suggested.
- The Stakeholder Forum was informed by WP7 that WP7 is considering planning either a F-t-F or E-meeting to present and discuss the ED Surveys. More information will come at a later stage.

Action Points:

- EUnetHTA Secretariat following up on the idea of having stakeholders presenting their experiences with joint work with EUnetHTA in one of the upcoming SF meetings

b. EUnetHTA Recommendations

Julia Chamova (DHMA, EUnetHTA Secretariat) updated the Stakeholder Forum on the development of the EUnetHTA Recommendations which has now been endorsed and will be shared with the Commission together with the Interim Report.

SLIDES:

EUnetHTA Recommendations

The recommendations provided by the EUnetHTA SF members were taken into consideration in the development of the final version of the Recommendations for endorsement by the EUnetHTA PA.

The EUnetHTA JA2 Recommendations were endorsed by the EUnetHTA Plenary Assembly (42 Partner organisations explicitly endorsed the document).

Document was distributed at the HTA Network meeting on Oct 29 and at the HTA 2.0 Europe conference October 30-31 in Rome.

Reference document for developing JA3 proposal.

Key comments and discussion / decision points:

- The Recommendation is a Deliverable of JA2 and will be used for developing a JA3 proposal. All comments from the stakeholders have been taken into consideration. If stakeholders would like feedback on how their comments have been taken into consideration, they were invited to contact the Secretariat for further clarifications.

4. **HTA 2.0 Europe – teaming up for value – update**

Julia Chamova (DHMA, EUnetHTA Secretariat) gave the Stakeholder Forum members an update on the Conference.

SLIDES:

EUnetHTA Conference – update

Thank you to

- *all Stakeholders who provided promotion material on their organisation's work for display in the Networking Area*
- *all Stakeholders who participated in the conference and joined the discussions and the networking!*

FINAL conference participants in total: 443

Division of participant groups registered (in %) and participants per country (in numbers) – SEE SLIDES

HTA 2.0 Europe – Teaming Up for Value

Highlights of the discussion

- *Network collaborations have created value (they give value to participants)*
 - *We can show positive national results of European cooperation*
 - *Synergies between policy making, HTA and regulation have materialised at EU level – they facilitate national synergies*
 - *Getting effective technologies faster to the patients – pathways are emerging, with shared strategies still to be developed*
- *The HTA cooperation mechanism is here*
 - *Europe now has an official HTA Network Strategy and*
 - *EUnetHTA has issued Recommendations on the implementation of the scientific work*
- *We can continue delivering value through network alliances*
 - *Europe is moving into HTA 2.0!*

Key comments and discussion / decision points:

- Links to audio of all presentations and copies of presentations are available through the website of EUnetHTA.
- Written feedback on the conference content from the group of participants from patients with rare diseases is being collected by EURORDIS and Francois Houyez indicated that this feedback will be shared with the Stakeholder Forum and EUnetHTA Secretariat. Overall the conference had been a good help for this group of patients in order to understand the work and issues in HTA. It was good to have time for networking which is important for a context with so many stakeholders. For future conferences it would be better to have even more engagement with the people at the activity stations presenting posters. EUnetHTA Secretariat is already evaluating with the people who were managing the activity stations in order to find out how to improve this interaction for the future.

- Local Italian media were present at the conference and the Conference were covered in the Italian media.

Action Point:

- EURORDIS to share with the EUnetHTA Secretariat the written feedback on the conference content from the group of conference participants representing the patients with rare diseases.

5. EUnetHTA Stakeholder training Oct 2014 – update

Ingvil Sæterdal (NOKC) gave the Stakeholder Forum a preliminary evaluation on the training for the Stakeholders, which were held by WP2 on the day before the Conference in Rome. A final report will be shared after the deadline for the evaluation.

SLIDES:

Evaluation:

- Invitations sent out by e-mail the day after the course
- Questionnaire published on EUnetHTA website until on November 21
- 12 questions assessing content, format and practical arrangements
- 13 of the 23 attendees have replied
- Results to be presented as a brief slide show and a descriptive summary

Feedback:

How would you assess the usefulness of the course overall?

6 very good

7 quite good

0 quite bad

0 very bad

Positive Feedback:

- *Practical sessions on a EUnetHTA pilot: understand which are the real critical points of the assessment*
- *The presenter of the topic Key principles of HTA was excellent.*
- *Interactivity during the presentations*

Suggestions for improvement

- **Organisational:** *more information in advance, bigger room, more time*
- **Format:** *more interactivity and small group working sessions*
- **Topic:** *include a pharmaceutical pilot example*
- **Material:** *produce material that are useful for training others*

Key comments and discussion / decision points:

- The material from the trainings is available for the participants and they are encouraged to share this at national level and inform/teach their colleagues.

B. Other issues

1. Stakeholder experiences with EUnetHTA
 - As discussed previously in the meeting, Stakeholders were encouraged to share their experiences from their joint work with EUnetHTA.
2. Next EUnetHTA Stakeholder Forum meetings:
 - 26 February, 2015; F-t-F meeting in Brussels
 - 12 May, 2015; E-meeting 13-15 CET

- 8 September, 2015; E-meeting 13-15 CET
- EUnetHTA Plenary Assembly 28-29 May 2015, Copenhagen

Key comments and discussion / decision points:

- There have been different activities and progress on the issue of public and stakeholder access to the POP and EVIDENT database and it was requested by the Stakeholder Forum to put an update on this work on the agenda for the Stakeholder Forum F-t-F meeting in Brussels on 26 February, 2015.
- The Stakeholder Forum members were encouraged to share input to the F-t-F agenda – to be sent to araa@sst.dk already from now on. Draft agenda will be shared in the beginning of February.

Action Point:

- EUnetHTA Secretariat to put the issue of public access to POP and EVIDENT database on the agenda for the F-t-F meeting in Brussels 26 Feb, 2015.
- SF members to share input for the draft agenda for the F-t-F meeting in Brussels

3. **Next EUnetHTA Newsletter issues** – January 9, 2015 (deadline for input – 15 December, 2014 sent to jula@sst.dk)

#	Action Point	Responsible	Deadline
1	EUnetHTA Secretariat following up on the idea of having stakeholder presenting their experiences with joint work with EUnetHTA in one of the upcoming SF meetings	EUnetHTA Secretariat	Before next meeting
2	EURORDIS to share with the EUnetHTA Secretariat the written feedback on the conference content from the group of conference participants representing the patients with rare diseases.	EURORDIS	Upon finalisation
3	EUnetHTA Secretariat to put the issue of public access to POP and EVIDENT database on the agenda for the F-t-F meeting in Brussels 26 Feb, 2015.	EUnetHTA Secretariat	Before beginning of February
4	SF members to share input for the draft agenda for the F-t-F meeting in Brussels 26 Feb, 2015	SF members	Before beginning of February