

EUnetHTA Joint Action 2 Stakeholder Forum meeting

September 16, 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)
Christoph Künzli, SNHTA
Finn B. Kristensen, DHMA (EUnetHTA Secretariat)
Francois Meyer, HAS
Inge M. Skov, DHMA (EUnetHTA Secretariat)
Ingvil Sæterdal, NOKC
Johannes Tvilling, DHMA (EUnetHTA Secretariat)
Julia Chamova, DHMA (EUnetHTA Secretariat)
Kristian Lampe, THL
Lidia Becla, DHMA (EUnetHTA Secretariat)
Lisa Krüger, ZIN
Luciana Ballini, ASSR
Marina Cerbo, AGENAS
Nicola Vicari, AGENAS
Patrice Chalon, KCE
Sonja Scheffel, HVB
Wim Goettsch, ZIN

Stakeholder Forum Representatives:

Francois Houyez, EURORDIS – Co-Chair
George Sarelakos, AESGP
Jacques de Haller, CPME
Karianne Johansen, EFPIA
Karsten Berndt, EDMA
Pascal Garel, HOPE
Rosa Giuliani, ESMO
Victoria Wurcel, EDMA
Yves Verboven, EUCOMED

European Commission:

Jerome Boehm

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. JA2 WP updates including JA2 SAG activities update (*shared in advance, only clarifying questions*)
3. Permanent EU cooperation on HTA
 - a. HTA Network update
4. EUnetHTA Recommendations
5. HTA 2.0 Europe – teaming up for value – update
 - a. Status on Programme
 - b. Activity Stations
6. SEED and EUnetHTA Early Dialogues – update
7. Stakeholder input to interim report JA2 year 2

B. Other issues

1. New staff in EUnetHTA Secretariat
2. Next EUnetHTA Stakeholder Forum meetings
3. Next EUnetHTA Newsletter – October 1, 2014 (deadline for input 22 September, 2014)

Alric Ruether 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*)

SLIDE:

Status of action points – E-meeting 27 May

#	Action Point	Responsibility	Status
1	Stakeholder Forum to be updated on the SAG involvement in WP7 – HAS to share an updated slide on SAG involvement.	WP7	Done right after the meeting
2	Notes from EUnetHTA PA to be shared with the Stakeholder Forum and the HTA Network Working Group.	EUnetHTA Secretariat	Done. Can be found on EUnetHTA public website

3	<i>HTA Network Secretariat to share the draft strategic paper with the Stakeholder Forum</i>	<i>HTA Network Secretariat</i>	<i>Done</i>
4	<i>The PA evaluation report to be shared with the Stakeholder Forum upon finalisation</i>	<i>EUnetHTA Secretariat</i>	<i>Done. Can be found on EUnetHTA public website</i>
5	<i>Stakeholder Forum members to provide names for the Conference free of charge attendees</i>	<i>Stakeholder Forum members</i>	<i>A few still missing. EUnetHTA Secretariat in direct contact</i>
6	<i>The content of the programme for the upcoming training for the Stakeholder Forum members to be shared with the SF</i>	<i>WP2</i>	<i>Done. Email 27.06.14</i>
7	<i>Summaries of the meetings with EFPIA and Med Dev to be shared on EUnetHTA's public website and the Stakeholder Forum to be notified when they are uploaded.</i>	<i>EUnetHTA Secretariat</i>	<i>Done. Can be found on EUnetHTA public website</i>
8	<i>EUnetHTA Stakeholder Forum members to give input to the next EUnetHTA Newsletter</i>	<i>Stakeholder Forum members</i>	<i>Done. No input</i>

2. JA2 WP updates including JA2 SAG activities update (shared in advance, only clarifying questions)

SLIDE:

WP Updates – shared in advance

Any clarifying questions from Stakeholders?

Any additional information from LPs/CoLPs?

WP2 – Dissemination and capacity building

WP3 – Evaluation and data collection on costs and efficiency

WP4 – Core HTA

WP5 – Apply(ing) the HTA Core Model in Rapid Assessment for national adaptation and reporting

WP6 – Information Management Infrastructure and Services

WP7 – Methodology development and evidence generation: Guidelines and pilots production

WP8 – Maintenance of HTA Core Model infrastructure to support shared production and sharing of HTA information

Key comments and discussion / decision points:

- Agenas the Lead Partner in WP4 informed the Stakeholder Forum, that they had been contacted by EDMA for some clarification and discussion regarding the first Core HTA on Colorectal Cancers screening tests available. A meeting has been organised between EDMA and Agenas the Lead Partner in WP4, and the Stakeholder Forum will be kept updated on the outcome of the meeting.
- It was brought up by members of the Stakeholder Forum that the overview of SAGs is not updated. This will be done in connection with the interim reporting and the amendment of the work plan for the last year.

3. Permanent EU cooperation on HTA

a. HTA Network update

Jerome Boehm (DG Sanco/HTA Network Secretariat) updated the Exec Comm on the developments in the HTA Network, the survey on 'Products on EU cooperation' and the developments of the strategy paper.

SLIDES:

2nd Meeting HTA Network – FOLLOW UP

WG June 12 to:

- Discuss possible priority areas of cooperation → questionnaire (WHAT)
- Discussion on chapter 3 (HOW) – Governance and funding post Health Programme

WHAT "Products on EU cooperation"

PHARMA

- Q1 which you consider can be most useful to be addressed by European cooperation (use column "European cooperation") and
- Q2 for which you identify greatest potential to be re-used at national level (use column "potential for reuse at national level") .

WHAT "Products on EU cooperation" II

12 respondents (14 MS in WG)

Q1 (priority for EU cooperation?)

- 1) ED (6)
- 2) REA (5)
- 3) Guidelines/Methodologies (4)
- 4) Full HTA (3)

WHAT "Products on EU cooperation" III

12 respondents (14 MS in WG)

Q2 (potential of reuse at national level?)

- 1) REA
- 2) Guidelines/Methodologies
- 3) Full HTA
- 4) ED

WHAT "Products on EU cooperation": Next steps

- Complete responses and further analysis
- Share with HTA Network at HTA Network next meeting.
- Take into account for next steps (JA + ...)

HTA Network Draft strategy paper – next steps

- Sent to HTA Network and observers 11 July – deadline for comments 26 August
 - 5 Member States
 - Several stakeholders: consolidated responses by patients, providers, payers and industry+ several individual responses
- Secretariat revising draft for circulation to HTA Network and observers by end September

HTA Network next meeting possible Agenda item

- Adoption of strategy paper
- Discussion on priorities of possible JA 3
 - Results of "joint work" for national activities –strategic discussion
 - Results questionnaire –national priorities
 - Recommendations of EUnetHTA
- Upcoming items:
 - HTA for eHealth
 - Hepatitis C

EU cooperation on HTA – key dates

- EPSCO informal Council – 22-23 September 2014, Milan
 - Strategic discussion on cooperation at EU level on HTA

- **HTA Network meeting, 29 October 2014, Rome**
 - Discussion and adoption (TBC) Strategy paper
 - Discussion on priorities for possible next Joint Action
- **EUnetHTA Conference " Europe HTA 2.0 teaming up for Value", 30-31 October 2014, Rome**

EU cooperation on HTA – Next steps

- Reflection on involvement of Stakeholders in HTA cooperation
 - @ strategic and technical/scientific level – post JA 2
- Implementation of HTA Network strategy
 - Reflection paper on the conditions to facilitate take up and re-use at national level of joint HTA production including information and joint assessments – planned Spring 2015

Process for Joint Actions

- **Indicative timing for WP 2015 (possible 3rd JA HTA)**
 - 2nd Quarter 2015 - first submission
 - 3-4th Quarter 2015- Closing negotiations
 - <http://ec.europa.eu/chafea/health/actions.html> Relevant to 2014 Work Programme but process and conditions expected to be the same

Key comments and discussion / decision points:

- As the future involvement of the Stakeholders in the two layers of the HTA cooperation is still unclear a concern was brought forward by the Stakeholder Forum. As it is indicated so far, the stakeholder participation is intended to bring scientific and technical input to the HTA cooperation, but some of the Stakeholder members like CPME are political organisations with no resources for the scientific work and such organisations should in future also be part of the stakeholders in the HTA cooperation. The EUnetHTA Secretariat informed that, in the EUnetHTA Recommendations these concerns will be considered and the intent is to see how it will be possible to adjust the modality of the involvement of the stakeholders at the scientific and technical level in order to bring the most value of expertise from each stakeholder group gained in JA1 and JA2. The HTA Network emphasised that if stakeholder organisations are only to be at the strategic level of the HTA cooperation they will not be so much involved in the long run.

EUnetHTA comments Draft strategy paper

3.1 Governance, second paragraph: *Including organisations in the scientific and technical cooperation that are "using HTA" is a too wide criteria which will lead to inclusion of too many organisations that cannot contribute actively to the scientific and technical work – and actively use its output. The participating organisations in the scientific and technical cooperation will need to have competence and explicit mandate to do HTA.*

Annex 2: General: *The annex would benefit from a more strategic, higher-level consideration going beyond mentioning specific, currently ongoing projects as the target of cooperation.*

Scientific societies: *There is no MoU between the HTAi Board and the EUnetHTA Executive Committee.*

Projects: *While it is important to emphasise cooperation with already ongoing projects it is useful - for a strategy paper - to suggest structured / regular cooperation with DG R&D to ensure relevance of call topics and logistics of cooperation when the projects are developed and implemented.*

4. EUnetHTA Recommendations

Julia Chamova (DHMA, EUnetHTA Secretariat) updated the Stakeholder Forum on the development of the EUnetHTA Recommendations which is now in the final development stage.

SLIDES:

EUnetHTA Recommendations (I)

- *Version 1.0 was restructured if compared to the initial version – to focus more on "scientific and technical" aspects, including organisation of work*
- *Recommendations are developed in parallel with the development of the HTA Network strategy paper (now in its final developmental stage).*
- *Comments received from 13 SF organisations (industry -6, patients/consumers – 3, payers – 2, providers – 2) and from 14 Partner organisations. Monday, Sept 15, made available to the Executive Committee.*
- *Constructive comments (thank you)*
- *Need to balance the scientific and technical nature of the activities the recommendations are developed for with sometimes highly political nature/focus of the SF members' comments.*
 - *Some chose to approach commenting from the point of view of the European cooperation on HTA as a whole, and not with a specific focus and scope of the scientific and technical cooperation level for which the recommendations are for.*
- *The recommendations are developed with the fundamental understanding of the MS's responsibility for the definition of their health policy and for the organisation and delivery of health services and medical care, including allocation of resources assigned to them.*

EUnetHTA Recommendations (II)

General Observations:

- *the 2-layer structure of the European cooperation on HTA is a given (Implementing Act, Rules of Procedures, etc).*

However, a lot of explanatory work – coupled with further detailed development of the structure - needs to be done both inside the European community of HTA agencies themselves as well as with the stakeholders on the implementation of 2 levels in the structure (1 – strategic and 2 – scientific and technical) to convince that such a structure is effective, makes sense and can contribute to supporting "good governance" and "effective management" in the European cooperation on HTA.

- *Governance: Questioning of the membership in each (the same bodies?)*
- *Organisation: is it "lean"? Can it be less complicated?*
- *Tasks: which questions to direct to which level?*
- *Requests for further clarifications of operational aspects of the stakeholder involvement at each level – strategic and scientific and technical*
- *Requests to safeguard against a two-tier or fragmented and complex system with varying Levels of engagement.*

EUnetHTA Recommendations – Timeline – (III)

- Aug 28 - Version 1.0 review and commenting by the PA and SF (deadline for comments Sept 11, 2014, end-of-business (eob))*
- Sept 17 - comments received and specific areas for further clarifications based on the comments received to be sent as a background document for discussions in the FTF meeting in CPH on Sept 24-25*
- Oct 3 - final document delivered to PA for adoption (deadline for response – October 15, 2014, 10:00CET); shared with the SF for information*
- (Sept 29 - the Strategy paper for adoption by the HTA Network)*
- Oct 30-31 - Recommendations presented at the Rome conference*

Key comments and discussion / decision points:

- It was clarified that the strategy paper will be distributed on 29 September – one month before the HTA Network meeting in Rome.

5. HTA 2.0 Europe – teaming up for value – update

Julia Chamova (DHMA, EUnetHTA Secretariat) updated the Stakeholder Forum members on the development of the programme for the Conference.

SLIDES:

EUnetHTA Conference – update

HTA Days in Rome

October 29:

- 3rd meeting of the HTA Network
 - discussion and endorsement of the strategy for the European cooperation on HTA
- EUnetHTA training for stakeholders
 - to increase understanding of HTA, promote awareness of EUnetHTA and HTA processes and the stakeholders' roles in these
- Workshop of the EUnetHTA Community of Practice (HTA dissemination specialists)
 - To discuss and identify best practices in disseminating HTA reports

October 30-31: HTA 2.0 Europe conference

October 31: Meeting between the FP7 HTA project coordinators and EUnetHTA representatives

HTA 2.0 Europe – Teaming Up for Value - 30-31 October 2014, Rome, Italy

2.0 – what is it?

Origins - from Web 2.0 concept:

- the new user-centred paradigm in which users are, at the same time, both producers and consumers of content and services
- Web 2.0 tools and services foster new modes of connectivity, communication, collaboration, sharing of information, content development and social organisation

Characteristics of "things 2.0" relevant to HTA – next page

BTW

2.0 is not only about Web or technology mediated communication or interaction (though it is a part of it)– it is about new current approaches to "doing things differently" and generally to organisational innovation ...

- Interaction, collaboration, participation
 - Work across silos/borders (organisational, geographical, "intellectual" (i.e., multidisciplinary approach to finding solutions))
 - Users as creators/contributors
 - Conversation vs. broadcast
 - Community vs. audience
 - Decentralisation through connectivity and interactivity
 - Networks as platforms
 - Standardisation (standard-based integration platforms)
 - Structure for usability (and re-usability)
 - Speed and continuous change in everything
 - Transparency and dynamic content
 - Data-driven environments and working processes
-
- **All 34 (except for 1) speakers confirmed their participation**
 - Speaker affiliations:
 - HTA agencies (technical experts and top management representatives (e.g., Directors/Presidents/CEO/Chair of the Board))
 - Senior level policy makers and payers (MoHs, national reimbursement committees)
 - Senior level industry representatives (CEO/Heads of global market access management teams)
 - Senior representatives of the European Commission and EU regulatory bodies
 - Representatives from the patient and professional stakeholder groups experienced and knowledgeable in the European cooperation issues
 - Representatives of the European research community (FP7 projects, EU JAs)
 - Varying roles on the programme:
 - E.g. Patient representative being a moderator of the panel discussion between HTA, regulatory representatives and industry

- **Interactive format of the conference**
 - 3 out of 5 sessions offering panel/round table discussion format with involvement of the audience (Q&A)
 - Excellent networking and learning opportunities:
 - EUnetHTA Activity Stations:
 - Comprehensive HTA
 - Rapid HTA
 - HTA Core Model® and Service
 - Evidence Generation
 - Methodology: EUnetHTA Guidelines and Templates
 - Building capacity for cooperation
 - FP7 HTA Projects Area (all 4 FP7 HTA projects represented)
 - AGENAS exhibition stand (incl. Information on the Italian HTA network)
 - Long(er) networking breaks between the sessions, reception Day 1
- **Online registration is open till the final week before the conference (October 24)**
 - Group discount: 20% off for groups of 5 and more people from the same registration category (e.g., private sector, non-for-profits/governmental organisations, EUnetHTA Partners and Associates, etc.)

Key comments and discussion / decision points:

- It was requested that the minutes from Conference programme Committee meetings should be shared with the Stakeholder Forum.
- The participation of stakeholder representatives at the activity stations was discussed. It will be the Lead Partners in EUnetHTA managing the stations and stakeholders will be very welcome to freely participate and engage in the discussions at the stations.

Action Point:

- Minutes from Conference programme Committee meetings to be shared in the Stakeholder Forum area.

6. **SEED and EUnetHTA Early Dialogues – update**

Francois Meyer (HAS) updated the Stakeholder Forum on the developments and status of the SEED project.

SLIDES:

SEED Partners – please see slide

The 10 Early dialogues

- 7 drugs and 3 Medical Devices (including IVD)
- Drugs:
 - 4 multi-HTA ED
 - 3 parallel EMA-SEED ED
- Different therapeutic fields: oncology, cardiology, haematology, etc.
- Orphan and non-orphan diseases
- Small and big companies
- 1st ED on May 2014 (drug) , June 2014 (MD)
- 1st EMA SEED parallel advice October 2014
- Last ED expected March 2015

Documents available on website

- Call for Tender http://ec.europa.eu/eahc/health/tenders_H09_2013.html
- Call for Expression of Interest http://www.has-sante.fr/portail/upload/docs/application/pdf/2013-12/appele_candidature_pour_les_early_dialogues_seed.pdf

- 3 Briefing Book Templates
 - Medical device <http://www.earlydialogues.eu/has/?p=35>
 - Drugs for multi-HTA <http://www.earlydialogues.eu/has/?p=51>
 - Drugs for Parallel EMA-HTA <http://www.earlydialogues.eu/has/?p=248>
- 2 Procedures
 - Parallel EMA HTA <http://www.earlydialogues.eu/has/?p=271>
 - Multi-HTA <http://www.earlydialogues.eu/has/?p=1>

How to manage the list of candidates

- More than 10 candidates
- Possible cancellations (for instance due to delays in product development)
- Waiting list for products
- To date: one delay, one cancellation, one product finally non eligible
- EARLY DIALOGUES ARE NOT PRE-SUBMISSION MEETING
- Change in development plans possibly affecting the appropriateness of an early dialogue (not sure anymore to conduct a phase III trial...)
- Request for “group submission” a priori not eligible

Diverse points to highlight

- National ED and/or SEED ED?
 - Company may seek for national ED in complement to SEED ED but no obligation
- Involvement of Stakeholders
- Questionnaire after each ED for partners and companies
- Production of a proposal for a permanent model to be submitted to EUnetHTA PA

Key comments and discussion / decision points:

- It was clarified that for participation in both EUnetHTA and SEED EDs a confidentiality agreement has to be signed by the external participants (experts, patient’s representatives...)
- The final results from SEED will be in the shape of a report to be delivered to the Commission by the end of August 2015. As the Commission is the owner of the report and information from the SEED activities, it is up to the Commission what to do and how to share the results from SEED.
- The results from the survey following the 10 Early Dialogues in EUnetHTA (JA1: 2 EDs, JA2: 8 EDs as of today) are ready but EUnetHTA is still waiting for the results of the ED surveys from EuropaBio, in addition to the already available EFPIA survey – upon their finalisation all three surveys should be presented and shared.

7. Stakeholder input to interim report JA2 year 2

Anne Raahauge (DHMA, EUnetHTA Secretariat) informed the Stakeholder Forum, that they again in this second year of EUnetHTA JA2 will be invited to comment on the Technical Interim report.

SLIDES:

Technical Interim report JA2 year 2

Timeline for the development of the report:

Timeline for the development of the 2nd Technical Interim Report	
When	What
15 October	LPs send Draft Technical Interim Report to Secretariat

20 October	Secretariat sends Draft Technical Interim Report to Stakeholders for comments - "high-level" comments - Confidential drafts, not for distribution
31 October	Stakeholders send comments to Secretariat
10 November	Secretariat send Stakeholders' and Secretariat's comments to LPs
17 November	LPs sends Final Technical Interim report to Secretariat
1 December	Secretariat sends Final Interim Reports to EC

B. Other issues

1. New staff in EUnetHTA Secretariat

SLIDES:

New Staff in EUnetHTA Secretariat:

Lidia Becla - Scientific Coordination Officer (limb@sst.dk)

Tasks:

- Task Force on the Col criteria
- HTA Core Model - cross WP coordination (WP4, 5, 7(SG4), 8)
- Cooperation with EMA
- Work with FP7 projects
- Following up on SEED developments (and consequent WP7 remaining tasks in EDs)
- Looking into improved modes of stakeholder involvement at scientific & technical level

2. Next EUnetHTA Stakeholder Forum meetings:

18 November, 2014; E-meeting 13-15 CET

26 February, 2015; F-t-F meeting in Brussels

12 May, 2015; E-meeting 13-15 CET

EUnetHTA Plenary Assembly 28-29 May 2015, Copenhagen

8 September, 2015; E-meeting 13-15 CET

3. Next EUnetHTA Newsletter issues – October 1, 2014 (deadline for input – 22 September, 2014 sent to jula@sst.dk)

#	Action Point	Responsible	Deadline
1	Minutes from Conference programme Committee meetings to be shared in the Stakeholder Forum area.	EUnetHTA Secretariat	After the meeting
2			
3			
4			

Appendix - WP activity update slides