

# **EUnetHTA Joint Action 2 Stakeholder Forum meeting**

**May 27, 2014, 13:00 – 15:00 CET**

## **E-meeting**

Organised by EUnetHTA Secretariat  
Danish Health and Medicines Authority, Denmark



## **Participants:**

### **Stakeholder Forum Representatives:**

Francois Houyez, EURORDIS – Co-Chair

Constance Colin, CPME  
Christian Peters, ESIP  
George Yiangou, AESGP  
Jacques de Haller, CPME  
Karsten Berndt, EDMA  
Pascale Brasseur, EUCOMED  
Rosa Giuliani, ESMO  
Thibaut Du Favet, EuropaBio  
Yves Verboven, EUCOMED

### **EUnetHTA Executive Committee Representatives:**

Alric Ruether, IQWiQ - Chair

Anne Raahauge, DHMA, EUnetHTA Secretariat  
Claudia Wild, LBI  
Finn Børlum Kristensen, DHMA, EUnetHTA secretariat  
Gintare Miksiene, VASPVT  
Johannes Tvilling, DHMA, EUnetHTA Secretariat  
Julia Chamova, DHMA, Denmark, EUnetHTA Secretariat  
Kristian Lampe, THL  
Nathalie Merle, HAS  
Nicola Vicari, AGENAS  
Mairin Ryan, HIQA  
Patrice Chalon, KCE  
Sarah Kleijnen, ZIN  
Sonja Scheffel, HVB

### **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. JA2 WP updates including JA2 SAG activities update (*shared in advance, only clarifying questions*)
3. Permanent EU cooperation on HTA
  - a. HTA Network update from meeting 7 April, 2014
4. Update from EUnetHTA PA in Madrid 10-11 April, 2014
  - a. Next steps in developing EUnetHTA recommendations regarding the design and management of the future EU HTA cooperation.
5. HTA 2.0 Europe – teaming up for value – update
  - a. Status on Programme
6. EUnetHTA Expert meetings
  - a. Follow-up from meeting with Med Dev 8 May, 2014
  - b. Follow-up from meeting with EFPIA 9 May, 2014

## B. Other issues

1. The General EUnetHTA Power Point Presentation
2. Next EUnetHTA Stakeholder Forum e-meeting – 16 September, 2014 13-15 CET
3. Next EUnetHTA Newsletter issues – July 1, 2014 (deadline for input – 16 June, 2014)

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Alric Ruether chaired the meeting and started the meeting by welcoming everybody. The agenda was adopted with no 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 4 March**

#	Action Point	Responsibility	Status
1	Share with the SF the preliminary results of the ED survey that were presented at the EMA meeting	WP7 LP	Pending
2	SF Co-Chair and team to contact EUnetHTA Secretariat and WP3 if they come up with a relevant question for the WP3 yearly survey for Stakeholders.	SF Co-Chair and team	Not done.
3	WP4 to share the final protocol with the SAG members after the public consultation	WP4	Will be done after public consultation

4	<i>Sharing information on national uptake of the pilots maybe on EUnetHTA website</i>	<i>EUnetHTA Secretariat and WP5</i>	<i>On-going</i>
5	<i>WP7 Survey response rate for the survey for participating HTA bodies and manufactures to be shared with the Stakeholder Forum.</i>	<i>WP7</i>	<i>Pending</i>
6	<i>Stakeholder training Evaluation report to be shared with the Stakeholder Forum</i>	<i>WP2</i>	<i>Shared 22 May</i>
7	<i>All stakeholder groups to indicate the name of the participant for the PA meeting</i>	<i>Stakeholder Forum members</i>	<i>Done. Participation at the PA by all SF Groups</i>
8	<i>Stakeholders to inform EUnetHTA Secretariat if they are interested in receiving a few copies of the conference announcement flyer.</i>	<i>Stakeholder Forum members</i>	<i>Secretariat has sent 30 flyers per SF organisation</i>
9	<i>Stakeholders to inform EUnetHTA Secretariat if they are interested in having 1 item (several copies) of printed material per SF at display at the Conference.</i>	<i>Stakeholder Forum members</i>	<i>Deadline 6 June 2014</i>
10	<i>EUnetHTA Secretariat to share the request of the SF to have a representative from each of the SF groups in the Conference Programme Committee</i>	<i>EUnetHTA Secretariat</i>	<i>Done. The SF Co-chair and his team are members of the programme committee</i>
11	<i>Stakeholder Forum organisations interested in participating in the meeting as observers should send the name of the person and affiliation (contact details) to EUnetHTA Secretariat and EUCOMED Secretariat</i>	<i>Stakeholder Forum members</i>	<i>Done. Meeting held 8 May</i>

#### Key comments and discussion / decision points:

- On the two pending action points from WP7, the Stakeholder Forum was informed that the survey made by HAS (LP in WP7) had a very high response rate. Feedback was received from all eleven HTA organisations, from the observer and from eight out of the nine companies. The high response rate has enabled HAS to make solid conclusions and to propose modification to the procedure for EUnetHTA early dialogues. HAS is in the process of exchanging the respective surveys with EFPIA and EuropaBio following which the Stakeholder Forum will be further informed about the survey results.
- The WP7 SG3 guideline on Meta-analysis announced for March has been delayed for about 2 months and will be shared with the SAG for review end of May/beginning of June.

**Action point:** WP7 will share an updated slide on SAG involvement (see below in the minutes – update from WP7)

## 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**

**WP 2, 3, 4, 5:**  
There were no clarifying questions for WP 2, 3, 4 and 5

**WP 6:**

**Key comments and discussion / decision points:**

- On the activity update on the second release of the POP Database and the dissemination level request, it was questioned whether or not there will be a consultation with the Stakeholder Forum on which type of information that will be considered confidential and which type of information which the Stakeholder Forum can access?
  - It is not planned to have a consultation with the Stakeholder Forum as it will be the EUnetHTA partners who will identify which information will be public or not. As a default in the system all project descriptions have been set at a restrictive dissemination level meaning only EUnetHTA Partners and Associates can access the information. All EUnetHTA organisations have now been asked to inform which dissemination level their projects should have. EUnetHTA is collaborating with the CRD (UK) HTA Database through which EUnetHTA will provide public access to the relevant entries in the EUnetHTA POP Database.

**WP7:**

**Key comments and discussion / decision points:**

- The updated slide on WP7 SAG/Public consultation was shared with the Stakeholder Forum after the meeting together with the other slides from the meeting – also inserted here in the minutes.

**WP7-SAG/Public Consultation Update May 2014**

<b>SG1</b>	<b>Due date / Milestone (Since last e-meeting)</b>	<b>Status/Clarification of delays</b>
<i>Early Dialogues (ED): survey to participating HTA bodies, EMA, manufacturers and other stakeholders on ED process</i>	<i>To be decided</i>	<ul style="list-style-type: none"><li>•Exchange between EUnetHTA, EFPIA and Europabio under discussion with regard to the sharing of respective surveys</li><li>•SAG consultation on revised ED procedure pending above discussion</li><li>•Aspects requiring clarification: 1) target of the consultation (All SH? Industry only?) 2) Format for exchange (e-meeting?)</li></ul>

**WP7-SAG/Public Consultation Update May 2014**

<b>SG2</b>	<b>Due date / Milestone</b> (Since last e-meeting)	<b>Status/Clarification of delays</b>
SAG consultation on the first draft of position papers <sup>1</sup>	M20 (May)	•Ongoing. First 2 drafts of the position papers will likely be delayed. The SAG consultation date will be updated accordingly.
SAG consultation on topic selection for the common core protocol (round 1 - topic notification)	M16-M18 (Jan-Mar)	•Further to additional clarifications from the LP, 2 SAG members provided feedback on criteria to select technologies for the pilot

#### **WP7-SAG/Public Consultation Update May 2014**

<b>SG3</b>	<b>Due date / Milestone</b> (Since last e-meeting)
1. Meta-analysis of diagnostic accuracy...	May-June 2014
2. Int. validity of NRS	ca. Nov-Dec 2014
3. Economic evaluations	ca. Oct –Nov 2014
4. Information Retrieval	ca. Oct-Nov 2014
5. Medical Devices	ca. Apr-May 2015
6. Personalised Medicine	unclear

### **3. Permanent EU cooperation on HTA**

#### **a. HTA Network meeting 7 April, 2014 – update**

Flora Giorgio (HTA Network Secretariat) gave the Stakeholder Forum an update on the outcome and next steps following the HTA Network meeting on 7 April.

#### **SLIDES:**

##### **2<sup>nd</sup> Meeting HTA Network – outcome**

- Agreement Chapter 1 and 2 Strategy paper (WHAT) + discussion with stakeholders
- Preliminary discussion Chapter 3 (HOW) – EMA and or other EU agencies considered as an option for long term sustainability of cooperation

##### **EU cooperation in HTA – VISION**

- New phase of cooperation → from "agreeing on " to "doing and learning together" → PILOTS
- Up take of joint work in national activities → MAINSTREAM
- "Life cycle" approach to health technologies → More synergies with regulators and payers → DEFAGMENTATION
- From "projects" to "permanent" cooperation → SUSTAINABILITY  
**HTA Network DRAFT Strategy Paper**

##### **2<sup>nd</sup> Meeting HTA Network – next steps**

- 10 June 2014- Consultation meeting with HTA Network SAF representatives – Chapter 3
- 12 June 2014 - WG meeting on– Chapter 3 "Sustainability and implementation"
  - Discuss and propose priorities on WHAT
  - Develop HOW (type of activities; funding etc)
- July-August 2014 – HTA Network Consultation on Chapter 3
- September 2014 - EUnetHTA recommendations on next steps (WHAT and HOW)

##### **3<sup>rd</sup> Meeting HTA Network (TBC)**

- *Adoption of strategy paper*
- *Discuss and agree on priorities for JA 3*
- *Follow up discussion on long term sustainability*
- *Preliminary discussion on conditions to facilitate take up and re-use at national level of joint HTA production*

#### Key comments and discussion / decision points:

- The notes from the EUnetHTA Plenary Assembly will be shared by 2 June and it was strongly recommended and re-emphasised by the HTA Network Secretariat and the Stakeholder Forum Co-Chair that the Stakeholder Forum members should familiarise themselves with the notes as they would also serve as a good preparation for the next HTA Network consultation with the Stakeholder Forum members on 10 June, 2014.<sup>1</sup>
- There will be a consultation with the Stakeholder Form representatives before the next HTA Network meeting as was done previously. In the actual HTA Network meeting there is little time to discuss the Stakeholders' input as the stakeholders are invited only to the part of the HTA Network meetings according to the Rules of Procedure, and it is therefore thought benefitting for the HTA Network to know the position of the Stakeholders on the different issues in advance.
- On the issue of financial sustainability, the concern was raised in the Stakeholder Forum that the countries with small and less experienced HTA agencies would have difficulties in contributing to the financing of the technical cooperation as they might not be able to generate the savings by sharing work, participating in joint assessment and adapting national reports from core reports. This would not be a big issue for the well-established and big agencies in other countries. The HTA Network Secretariat is aware of this and it is something that needs to be thought through carefully when the business model is being developed.

#### Action Point:

- Notes from EUnetHTA PA to be shared with the Stakeholder Forum and the HTA Network Working Group.
- HTA Network Secretariat to share the draft strategic paper with the Stakeholder Forum.

Julia Chamova (DHMA, EUnetHTA Secretariat) informed the Stakeholder forum, that the EUnetHTA Secretariat, in the process of developing the recommendations, is looking at all the input received from the Stakeholder throughout the years.

#### SLIDES:

##### **EUnetHTA Secretariat**

##### **Stakeholder comments (SH meeting with DG Sanco, July 8, 2013):**

"... the HTA Network may become a duplication of EUnetHTA if profiles are not differentiated. ..."

- **EUnetHTA Plenary Assembly meeting, April 10-11, 2014 (SF representatives attended and provided input)**  
*Work started to define and differentiate between remits, tasks and mandates of the scientific and technical mechanism (EUnetHTA) and the strategic level (HTA Network) of the European cooperation on HTA*  
  
 Scientific level:  
 - *Intellectual independence of scientific/technical level in deciding the specific assessment topics and methods*

<sup>1</sup> The PA summary report is now available at <http://www.eunetha.eu/outputs/eunetha-plenary-assembly-meeting-april-10-11-2014-madrid-spain-report>

- The HTA Network has its focus on high-level objectives of and priorities for the European cooperation on HTA while the scientific and technical cooperation level is in charge of and define **how the objectives are implemented** into scientific and technical work
  - Eg, HTA Network: discuss, clarify the role of HTA in the MS healthcare systems; define priority areas for the EU cooperation on HTA, HTA and regulation EUnetHTA: concrete implementation of cooperation between HTA agencies respecting the voluntary nature and the principles of subsidiarity via value-added (to the national/regional HTA production processes) activities in prioritised areas

#### **EUnetHTA Secretariat**

1) Input to the HTA Network's strategy paper work is continuously provided (last time after the May 7 Executive Committee e-meeting)

2) EUnetHTA to deliver by October 2014 – after a drafting process that will also include the Stakeholder Forum

*Recommendations on the implementation of a sustainable European network for HTA*

*(Deliverable 1 of the EUnetHTA JA2 Grant Agreement 2011 23 01)*

#### **4. Update from EUnetHTA in PA Madrid 10-11, April 2014**

##### **a. Next steps in developing EUnetHTA recommendations regarding the design and management of the future EU HTA cooperation**

Anne Raahauge and Julia Chamova (EUnetHTA Secretariat) gave the Stakeholder Forum an update on the evaluation of the Plenary Assembly and a highlight of the way forward in the development of the Recommendations on the implementation of a sustainable European network for HTA also as the way to prepare for possible JA3.

#### **SLIDES:**

##### **Follow-up PA 2014: Evaluation results**

84,2% response rate. Overall very positive feedback – improved a lot from last year

100% indicated that the meeting objectives were met (the most successful meeting to-date)

##### Best /worst thing about content of the meeting:

- Good strategic discussions in plenary and groups and good structured and balanced programme.
- Tight programme/heavy agenda

##### Best / worst thing about organisation of meeting

- Preparations for the meeting/guiding document, good venue and meeting setup, networking
- Meeting setup/sitting too tight, traffic during bus trip

##### Leadership of meeting, relevance, networking

- Leadership of meeting (Good: 55,3%, Very good: 40,4%)
- Relevance of discussions (Good: 39,6%, Very good: 60,4%)
- Networking opportunities (Good 43,7%, very good 52,1%)

*Final report will be shared with the Stakeholder Forum*

#### **Details on the PA Madrid discussions**

*Focus: mid-term (2015-2020) and long-term (2020+) development with lessons learned to inform adjustments (where possible) in the remaining short-term (2014-2015).*

*Final report from the meeting to be available on 2 June (intranet and SF website area).*

#### **Follow-up PA 2014: Next steps in developing EUnetHTA recommendations**

*DG SANCO general timelines/steps of preparing the JA 3 opportunity:*

- Nov/Dec 2014 – publishing of the Work Programme 2015 of the Health Programme and shortly after – Call for Proposals issued
- March/April 2015 – deadline for submitting JA proposals

EUnetHTA informs the mid-term (2016-2020) and the long-term (post 2020) discussions (ie, development of Recommendations (D1 of JA2)

- priority is to clarify further details of implementation in MID-TERM (details of JA3 development)

#### **Follow-up PA 2014: Next steps**

EUnetHTA input in JA3 development:

- 1) requirements (based on the concrete experience from the first 2 JAs) for the conditions to implement any next steps in developing and testing a permanent structure and processes of the European cooperation on HTA

- see already provided input to DG SANCO on necessary adjustments in the formal mechanism of joint actions

1. possible activities, supporting structures for the processes, etc. in JA3 (also informed by the needs from the long term perspective (post 2020)).

Focus and scope on the technical and scientific cooperation mechanism and its corresponding remit for activities

#### **Next steps (mid-term) – development of Recommendations (Deliverable 1)**

Week 19 - summary of discussions PA Madrid

May – June - first draft of the Recommendations (Deliverable 1), to be developed by the Coordinator (Secretariat) (w.25 to be shared with the Exec Committee and **Stakeholder Forum\***) for discussions in the Executive Committee (June 25, w.26)

\*feedback will be invited to be sent by July 1, 2014

July – August - draft finalised for the 1<sup>st</sup> review round by the PA

Sept (w.36-37) - review and commenting by the PA **and Stakeholder Forum**

Sept (w.39) - Exec Comm discussing final adjustments to the draft (Sept 24-25) based on PA feedback

Oct (w.40-42) - final draft delivered to PA for adoption; **shared with the SF for information**

Oct 30-31 (w.44) - Recommendations presented at the Rome conference

#### **Key comments and discussion / decision points:**

- The Stakeholder Forum will be invited to comment on the recommendations according to the timeline, so attention should be paid to the dates indicated for the involvement of the Stakeholder Forum.

#### **Action Point:**

- The PA evaluation report will be shared with the Stakeholder Forum upon finalisation.

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

#### **a. Status on program**

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



**SLIDES:**

**EUnetHTA Conference – update**

[www.eunetha2014.it](http://www.eunetha2014.it)

*Programme update – end of this week (details on the objectives, format, titles and contributors to each of the announced sessions)*

*Programme Committee (SF representatives (ie, SF Co-Chair and his team) invited to participate and provide input):*

- *Advice on the programme content (eg, focus /content of the sessions, suggestions of speakers)*
- *Supported development of the content*
- *3 meetings held, continuous contact via e-mail*

*Payers and decision-makers as well as patients, industry and other stakeholders are included in the programme sessions.*

**EUnetHTA Conference – update**

- *Free of charge attendees – names to be provided by August 15, 2014 (deadline extended).*
- *Assistance with promotion and conference flyer distribution is welcome and appreciated.*

**Key comments and discussion / decision points:**

- EUnetHTA Secretariat has sent out conference flyers to all Stakeholder members and they were encouraged to share the flyers in their network and offices.
- There will be training for the EUnetHTA Stakeholder Forum members in connection with the Conference in Rome. The Stakeholder Forum kindly requested to be informed about the content of the training so it can be taken into the consideration of individuals' participation in the Conference.

**Action Point:**

- Stakeholder Forum members to provide names for free of charge attendees by 15 of August
- WP2 to share the content of the training programme with the Stakeholder Forum members.

**6. EUnetHTA meetings**

**a. Follow-up from meeting with Med Dev 8 May, 2014**

**b. Follow-up from meeting with EFPIA 9 May, 2014**

Finn Børlum Kristensen (DHMA, EUnetHTA Secretariat) informed the gave the stakeholders an update from the two meetings.

**SLIDE:**

**Expert meetings**

*Meeting with Medical Devices 8 May, 2014: report to be available within the next 2 weeks*

*Meeting with EUnetHTA-EFPIA Advisory Group e-meeting 9 May, 2014: meeting report is being finalised and will also be publicly available*

**Key comments and discussion / decision points:**

- The meeting with the medical device industry had been very fruitful and it was benefitting to have people from EUnetHTA and different areas of the device industry together discussing mainly issues of methodology. The summary of the meeting is being processed jointly by EUnetHTA and EUCOMED and will be available within the coming weeks.
- The meeting with EFPIA should have been a workshop focusing on methodology, but for practical reasons the workshop had to be postponed to after the summer break. The meeting discussed methodology and looked into how the uptake of EUnetHTA pilot outputs should be discussed in the upcoming workshop.

- There are no concrete plans for the next Expert meeting, but once the plans for the third year of Joint Action 2 has been adjusted, the Stakeholder Forum members will be informed.

**Action Point:**

- Summaries of both meetings to be shared on EUnetHTA's public website and the Stakeholder Forum should be notified when they are uploaded.

**B. Other issues**

**SLIDE:**

- *The General EUnetHTA Power Point Presentation is now available in the SF Area (including instructions on how to use it). here: <https://eunetha.fedimbo.belgium.be/general-eunetha-power-point-presentation>*
- *Next EUnetHTA Stakeholder Forum e-meeting – 16 Sep, 2014 13-15 CET*
- *Next EUnetHTA Newsletter issues – July 1, 2014 (deadline for input – 16 June, 2014 sent to [jula@sst.dk](mailto:jula@sst.dk))*

**Action Point:**

- EUnetHTA Stakeholder Forum members to give input to the next EUnetHTA Newsletter, by 16 June, 2014

#	Action Point	Responsible	Deadline
1	Stakeholder Forum to be updated on the SAG involvement in WP7 – HAS to share an updated slide on SAG involvement.	WP7	After the meeting
2	Notes from EUnetHTA PA to be shared with the Stakeholder Forum and the HTA Network Working Group.	EUnetHTA Secretariat	By 2 June
3	HTA Network Secretariat to share the draft strategic paper with the Stakeholder Forum	HTA Network Secretariat	Before 10 June
4	The PA evaluation report to be shared with the Stakeholder Forum upon finalisation	EUnetHTA Secretariat	By 13 June
5	Stakeholder Forum members to provide names for the Conference free of charge attendees	Stakeholder Forum members	By 15 of August
6	The content of the programme for the upcoming training for the Stakeholder Forum members to be shared with the SF	WP2	By end of July
7	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.	EUnetHTA Secretariat	Upon finalisation
8	EUnetHTA Stakeholder Forum members to give input to the next EUnetHTA Newsletter	Stakeholder Forum members	By 16 June

**Appendix**

**WP activity update slides**