

EUnetHTA Joint Action 2 Stakeholder Forum meeting

May 12, 2015, 13:00 – 15:00 CET

E-meeting

Organised by EUnetHTA Secretariat
Danish Health and Medicines Authority, Denmark



Minutes

Participants:

Alric Ruether, IQWiG, Germany – Chair
Anna Nachtnebel, LBI, Austria
Anne Raahauge, DHMA (EUnetHTA Secretariat), Denmark
Christoph Künzli, SNHTA, Switzerland
Gintare Miksiene, VASPV, Lithuania
Ingvil Sæterdal, NOKC, Norway
Johannes Tvilling, DHMA (EUnetHTA Secretariat), Denmark
Julia Chamova, DHMA (EUnetHTA Secretariat), Denmark
Kristian Lampe, THL, Finland
Leonor Varela, AVALIA-t, Spain
Luciana Ballini, ASSR, Italy
Nageen Højbjerg, DHMA (EUnetHTA Secretariat), Denmark
Nicola Vicari, Agenas, Italy
Patrice Chalon, KCE, Belgium
Simone Warren, ZIN, Netherlands
Sonja Scheffel, HVB, Austria
Wim Goettsch, ZIN, Netherlands

Stakeholder Forum Representatives:

Francois Houyez, EURORDIS – Co-Chair
Christine Dawson, ESIP
Deniz Kocas, EGA
Edith Frenoy, EFPIA
George Sarelakos, AESGP
Ilaria Passarani, BEUC
Isabella Notarangelo, HOPE
Marie-Astrid Libert, COCIR
Paolo Morgese, EuropaBio
Pascale Brasseur, EUCOMED
Rosa Giuliani, ESMO
Tsveta Schyns, EMA
Valentina Strammiello, EPF
Victoria Wurcel, EDMA

European Commission:

Jerome Boehm, DG Sante, EU

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
 1. HTA Network update
 4. JA3 preparations
 5. Update on evaluation from SF training course April
 6. Finalising JA2
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B. Other issues

1. Letter to DG R&I on research to be considered for Horizon2020 call
 2. Next EUnetHTA Stakeholder Forum meetings
 3. Input to Newsletter
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Alric R  ther (IQWIG) and Francois Hou  ez (EURORDIS) Chair and 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 – Meeting 26 February

#	Action Point	Responsibility	Status
1	The SF is to inform the EUnetHTA Secretariat by April 20, 2015 on the names of individuals who will attend the PA meeting in Copenhagen (May 2015).	SF members	Industry: Victoria Wurcel Providers: Jacques de Haller Patients: Valentina Strammiello Payers: Menno Arnout

2	<i>SF members to provide written input on lessons learned and concrete suggestions for improvement of the stakeholder involvement processes in the European cooperation on HTA. Deadline: end of April.</i>	<i>SF members</i>	<i>Feedback from: Joint Industry, Joint Providers, Joint Payers, BEUC, EURORDIS (supported by EMSP)</i>
3	<i>EUnetHTA Secretariat to inform the SF when the national uptake webpage will be accessible.</i>	<i>EUnetHTA Secretariat</i>	<i>Done. Email sent 9 March. More information will be shared on the website on an ongoing basis</i>

Key comments and discussion / decision points:

- Francois Houyez (EURORDIS) confirmed that he will also participate in the Plenary Assembly in his capacity of Co-Chair of the Stakeholder Forum.

2. WP Activity update slides – shared in advance

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:

- In the version 2.1 of the HTA Core Model the comment from stakeholders were not included, so it was questioned when version 3.0 including comment from Stakeholders will be available. WP8 informed the meeting that the version 3.0 will be ready in May/June.
- It was questioned when the report on calculation of efficiency gains and added value, will be available for the Stakeholders. There were no participation in the meeting from WP3, so the question will be shared with them and an update will follow.
- It was highlighted from EDMA that any changes in the parts related to diagnostics in the Core Model should also be reflected in the update on the HTA Core Model for Rapid REA. There should be an alignment between the two documents and a note in the Rapid REA update reflecting any future changes following updates in the Core Model.
- It was brought forward that the process of informing stakeholders on public consultation is not the same in all WPs; information on the ongoing public consultation on the 'position paper on study design' has not been shared.'

Action Point:

- WP3 to inform the Stakeholder Forum on when the report and information on the efficiency calculation will be available to the Stakeholder Forum.

3. Permanent EU cooperation on HTA

1. HTA Network update

Jerome Boehm (DG Sante/HTA Network Secretariat) informed the Stakeholder forum about the current work in HTA Network. No slides.

Key comments and discussion / decision points:

- Minutes from the previous meeting in the HTA Network on 23 March will be posted in the coming week together with the reflection paper on Re-use of joint production at national level. Jerome will make a more thorough presentation at the EUnetHTA Plenary Assembly end of May.
- At the Second Preparatory meeting on JA3 the HTA Network Secretariat was given the green light by the participants to liaise with the Stakeholders on the preparation for the JA3. A meeting was held on 7 May where the suggested governance structure and WP titles was discussed with the Stakeholders. The Stakeholders had contributed with valuable input and it was a good exercise to involve the Stakeholders in the initial phase of preparation of JA3. Summary minutes from the meeting will be circulated within a couple of days. Jerome will report on this meeting at the EUnetHTA Plenary Assembly and at the 3rd preparatory meeting on 12 June.

Action Point:

- Each Stakeholder Group to prepare 2 slides with key messages on suggestions for JA3 for the upcoming 3rd JA3 informal preparatory meeting and as previous agreed 2 slides with lessons learned for the EUnetHTA PA.

4. JA3 Preparations

Julia Chamova (DHMA, EUnetHTA Secretariat) shortly updated the Stakeholders on the processual steps of the preparation for JA3.

SLIDE:

JA3 preparations – EUnetHTA JA2

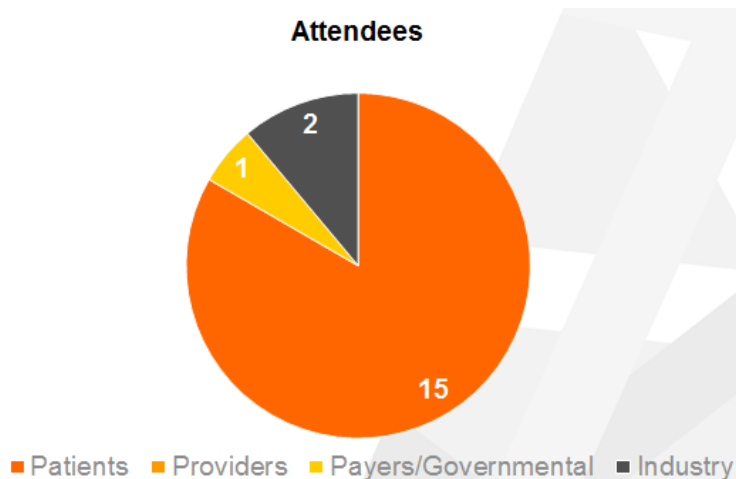
- *E-mails with the updates on the Health Work Programme development and support to possible JA3 are regularly sent to the EUnetHTA MoH-nominated partners*
- *EUnetHTA Secretariat participated in 2 informal preparatory meetings convened by the European Commission (DG SANTE) and will participate in the 3rd meeting (June 12 2015).*
- *Time is set aside to discuss the priorities, potential objectives and activities in JA3 at the upcoming JA2 Plenary Assembly meeting (May 28-29 2015) in Copenhagen.*

5. EUnetHTA Stakeholder training Apr 2015 – update

Ingvil Sæterdal (NOKC) gave the Stakeholder Forum an update on the SF training held in April.

SLIDES:

Training course for Stakeholders



Method and results

- Invitations sent out by e-mail the day after the course
- Questionnaire published on the EUnetHTA website
- 12 questions assessing content, format and practical arrangements
- 9 of the 18 attendees have replied so far
- Results to be presented as a brief slide show and a descriptive summary

Overall usefulness of the course

7 very good

2 quite good

0 quite bad

0 very bad

- «The day exceeded my expectations»

Topics that were liked well

- Importance of HTA for decision making for patients and providers
- Understand the work done by WP5 (rapid REA) and how to contribute
- Understand the assessment process works
- Understand the evidence requirement for the HTA production
- The submission template

Topics that were liked less well

- Submission template – not so useful to patient representatives
- How patients could contribute – patients need to be involved in all stages
- Session on devices, not too relevant – however still useful
- «I liked all the topics», «There wasn't a topic I did not like»

Organizational issues

Practical support and information given in advance: Very good ☺

Lunch and refreshments: Very good (7), quite good (2)

Suggestions for improvements:

Difficult to find the right entrance of the building

Start later (possible to fly in and out on the same day)

Positive feedback

- <<I would just like to thank the organizers for the initiative and for organising such an interesting meeting>>
- <<Thanks for the welcoming atmosphere and the openness>>
- <<A very enjoyable and interesting day>>
- <<Thank you for giving me this opportunity to participate, I found it very useful and informative for my work>>

Suggestions for improvements

- Include a session on EUnetHTA website where all public information can be found

6. **Finalising JA2**

Julia Chamova (DHMA, EUnetHTA Secretariat) updated the Stakeholder Forum on the remaining activities in JA2 which will also be discussed at the PA in Copenhagen end of May.

SLIDES:

The updated Work Plan – Year 3 is available; certain small adjustments are being done while it is currently implemented (information about changes are provided)

- *Slight extension of the duration of JA2 till December 2015 (all deliverables to be submitted by December)*
- *Expert workshops with EFPIA (October 7, 2015) and Med Tech Industry (mid-October, date to be set) will be held. Representatives of the other stakeholder groups to be invited.*
- *Discussion of the remaining tasks is scheduled for the Plenary Assembly meeting on May 28-29, 2015 in Copenhagen*
 - *SF groups written input on learnings from JA2 are included in the background documentation for the meeting.*
 - *Invitation to make a brief presentation of main points from the learning reports at the meeting in Copenhagen.*
 - *SEED/EUnetHTA discussion – input*

Key comments and discussion / decision points:

- The scope of the workshop with EFPIA will mainly be discussions on lessons learned and experiences from the processes and the changes made to the processes during JA2 and also to look a little ahead and discuss further developments in light of the continuous focus on more collaboration in joint assessments.
- As part of the Plenary Assembly the SEED Consortium will present the input received on the future model for Early Dialogues in Europe. The list of topics will be shared as background documents for the PA and the Stakeholders are encouraged to be prepared to discuss the topic on the day of the meeting. Any written input prior to the PA is more than welcome. Comments to be sent to the SEED Coordinator. Deadline May 26 noon for written input.

Action Point:

- EUnetHTA Secretariat to share the content of the EFPIA and Med Tech Industry Workshops with the Stakeholder Forum, once the agendas have been developed.
- SF members to send written input to SEED on the future model of Early Dialogues in Europe before 24 May.

B. Other issues

1. Letter to DG R&I on research to be considered for Horizon2020 Call

Julia Chamova (DHMA, EUnetHTA Secretariat) briefly informed the Stakeholder Forum that EUnetHTA with the initiative of the Executive Committee has developed a letter to the Director of DG R&I on research topics to be considered for the Horizon2020 call to contribute the HTA methodology. The letter has been made public on EUnetHTA's website and can be found in the news section.

2. Next EUnetHTA Stakeholder Forum meetings

- EUnetHTA PA in Copenhagen 28-29 May 2015

- SF E-meting 8 September, 2015 13-15 CET

3. **Next EUnetHTA Newsletter issue** – July 1, 2015 (deadline for input – 15 June, 2015 sent to ins@sst.dk Cc eunetha@sst.dk)

Key comments and discussion / decision points:

- As the next SF e-meeting is in September the SF requested to have a debriefing meeting shortly after the EUnetHTA Plenary Assembly. The EUnetHTA Secretariat encourages the Stakeholder Forum to use the SABA facility to have such a meeting.

Action Point:

- Stakeholder Forum to arrange a debriefing e-meeting after the PA in order to update and all stakeholder forum members on the discussion at the PA.

#	Action Point	Responsible	Deadline
1	WP3 to inform the Stakeholder Forum on when the report and information on the efficiency calculation will be available to the Stakeholder Forum.	WP3	Before next meeting
2	Each Stakeholder Group to prepare 2 slides with key messages on suggestions for JA3 for the upcoming 3 rd JA3 informal preparatory meeting and as previous agreed 2 slides with lessons learned for the EUnetHTA PA.	Stakeholder Forum	Before end of May
3	EUnetHTA Secretariat to share the content of the EFPIA and Med Tech Industry Workshops with the Stakeholder Forum, once the agendas have been developed.	EUnetHTA Secretariat	ASAP
4	SF members to send written input to SEED on the future model of Early Dialogues in Europe before 24 May.	Stakeholder Forum	Before 24 May
5	Stakeholder Forum to arrange a debriefing e-meeting after the PA in order to update and all stakeholder forum members on the discussion at the PA.	Stakeholder Forum	After EUnetHTA PA