

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

**Sep 8, 2015, 13:00 – 15:00 CET**

### **E-meeting**

Organised by EUnetHTA Secretariat  
Danish Health and Medicines Authority, Denmark



### **Participants:**

Alric Ruether, IQWiG, Germany – Chair  
Anne Raahauge, DHMA (EUnetHTA Secretariat), Denmark  
Christoph Künzli, SNHTA, Switzerland  
Ingvil Sæterdal, NOKC, Norway  
Julia Chamova, DHMA (EUnetHTA Secretariat), Denmark  
Julia Mayer, LBI-HTA, Austria  
Lidia Becla, DHMA (EUnetHTA Secretariat), Denmark  
Luciana Ballini, ASSR, Italy  
Marianne Klemp, NOKC, Norway  
Nageen Højbjerg, DHMA (EUnetHTA Secretariat), Denmark  
Nick Crabb, NICE, United Kingdom  
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  
Constance Colin, CPME  
Deniz Kocas, EGA  
Edith Frenoy, EFPIA  
Isabella Notarangelo, HOPE  
Katrina Perehudoff, BEUC  
Marie-Astrid Libert, COCIR  
Nicole Denjoy, COCIR  
Pascale Brasseur, EUCOMED  
Rosa Giuliani, ESMO  
Valentina Strammiello, EPF  
Victoria Wurcel, EDMA

### **European Commission:**

Sevala Malkic, 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. Survey on National uptake and adaptation
4. Finalising JA2
  - a. Outstanding tasks
  - b. Timeline for Technical Reporting
5. Permanent EU cooperation on HTA
  - a. JA3 and HTA Network update incl. feedback on stakeholder proposals to HTA Network on Stakeholder involvement in JA3.

### B. Other issues

1. Input to Newsletter (1 October issue)

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Alric R  ther (IQWIG) and Francois Hou  yez (EURORDIS) Chair and Co-Chair of the Stakeholder Forum welcomed all meeting participants to the last Stakeholder Forum meeting of JA2. The agenda was approved with one additional point – under other issues, it was requested to get some more information on programme and registration for the conference in HAS at the end October.

### 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 12 May**

#	Action Point	Responsibility	Status
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	The report is being reviewed by the Exec Comm until end Sep. Will be shared with SF in the beginning or mid of November
2	Each Stakeholder Group to prepare 2 slides with key messages on suggestions for JA3 for the upcoming 3 <sup>rd</sup> JA3 informal preparatory meeting and as previous agreed 2 slides with lessons learned for the EUnetHTA PA.	Stakeholder Forum	Done and presented at the PA
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	Presented in this meeting

4	<i>SF members to send written input to SEED on the future model of Early Dialogues in Europe before 24 May.</i>	Stakeholder Forum	<i>Done and input presented at the PA</i>
5	<i>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.</i>	Stakeholder Forum	?

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

- A debriefing e-meeting was held among Industry group.

## 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:

- WP2
  - Completed all Face-to-Face trainings courses in JA2 F-t-F and published the material from the training on the EUnetHTA website. In these slides it is possible to find the link to a YouTube video on the guideline on clinical endpoints.
    - It was questioned how the upcoming EUnetHTA training strategy is taking the synergy with other training activities into consideration - like the EUPATI patients academy. The current training strategy is only focusing on trainings for EUnetHTA partners but WP2 would recommend that a future training strategy in the possible JA3 should take the aspect of trainings for Stakeholders into consideration.
- WP3
  - Finalised the 2015 survey report which will be uploaded in the SF area by the Secretariat. Further WP3 is working on interviews with WP4 and WP5 on national uptake and adaptation, collaboration and topic selection. Results are to be shared in the final report from WP3
- WP4
  - The Second Core HTA has now been completed and a professional medical writer is going through the document. The third Core HTA has been a little delayed due to the holiday season and some clarifying issues with the domain teams. The draft is planned to be ready mid-September for the SAG consultation. The second version of the Methodology Standards and procedures document is being finalised after it has gone through a consultation with the SAG and other WPs.

- WP5
  - Strand A: the first 5 REAs from strand A are now available on the EUnetHTA website and the project plan for the 6<sup>th</sup> Pilot on Hepatitis C is now finalised – 180 comments were received in the public consultation. Now the 6<sup>th</sup> Pilot is in the assessment phase and the public consultation on the draft is tentatively planned for 14 Oct – 2 Nov. On 7 October there will be an expert meeting with EFPIA focusing on lessons learned from the 5 first pilots and discussion of the process of joint assessments in the future.
    - A question was raised whether the Patient Groups which were contacted to participate in the consultation actually did so. WP5 Strand A informed the SF that they reached out to a lot of the patient groups and got replies back from about 3-4 groups. It is hoped that more patient groups will comment on the public consultation in October-November.
    - It was shared in the meeting that some of the results from the discussion on lessons learned and future assessments from the WP5 Face-to-Face meeting in Dublin will be shared at the expert meeting with EFPIA on 7 October.
  - Strand B: 4 rapid assessments published and 2 are ongoing. The 5<sup>th</sup> assessment is in the phase of development of the 3<sup>rd</sup> draft and the publication is planned for end of September. The 6<sup>th</sup> pilot is in the development of the first draft and the publication is planned for December.
- WP6
  - WP6 will continue to support the public website, intranet, newsletters until the extended deadline of the JA2 i.e. until March 2016.
  - The second release of the POP database has been in place since July. It is now possible to export the description of project marked level 1 dissemination and have interoperability with others. WP6 would be interested to get feedback from Stakeholders on this new function and interested Stakeholders should send an email to Patrice Chalon at KCE [Patrice.Chalon@kce.fgov.be](mailto:Patrice.Chalon@kce.fgov.be).
- WP7
  - HAS, the LP of WP7, was not present in the meeting. The WP7 Co-LP IQWIG stated that WP7 should be in line with the information shared in the activity updates.
    - At the EUnetHTA PA in Copenhagen, Denmark in May, WP7 had shared the information that a meeting/scientific advice session with the EUnetHTA PA members would be planned in order for the members to give input the EUnetHTA and SEED experience with Early Dialogues. It was questioned in the Stakeholder Forum whether or not this meeting would still happen. The EUnetHTA Secretariat is working on following up with HAS the WP7 Lead Partner on the matter as HAS has not yet shared any information or dates for this meeting. Taken into consideration that all activities in JA2 are to be finalised by November 2015 it was stated that the scientific input probably at this stage would have to be given through a written procedure.
    - The WP7 Sub Group 3 paper on personalised medicine was initially planned as a guideline but is now a Reflection Paper. A Reflection Paper is a new product in EUnetHTA and has been discussed in the EUnetHTA Exec Comm. Definition of what reflection paper is will be included in the draft document on personalised medicine. The position paper on Personalised Medicine is planned to undergo both a SAG and Public Consultation.

Out of the 9 Guidelines from JA1 being updated in JA2, 8 Guidelines were updated by 3 different EUnetHTA Partners each before being sent to Public Consultation. EDMA/IV manufactures informed the Exec Comm and WP7 that EDMA would like to

support the process of updating the Guidelines in order to ensure that the updates have the specificities and modalities needed to expand the scope of these important Guidelines.

- SG4WP7 is on time with the finalisation of the submission template.

#### Action Point:

- Stakeholders interested in giving feedback to WP 6 on the new features in the POP database should write to Patrice Chalon (KCE Lead Partner in WP6) [Patrice.Chalon@kce.fgov.be](mailto:Patrice.Chalon@kce.fgov.be)

### 3. Survey on National uptake and adaptation

Julia Mayer (LBI-HTA) gave the Stakeholder Forum an update on the results from the first round of the survey on National uptake and adaptation.

#### SLIDES:

##### Overview

- Web-based survey via SurveyMonkey (April 2015)
- 69 main representatives (Collaborating Partners & Associate Partners)
- Response time: 2.5 weeks & 4 reminders
- Gain insights into the
  - national adaptation of Joint Assessments
  - national uptake of other outputs
- Obtain a broad overview of the barriers and challenges of using the Joint Assessments

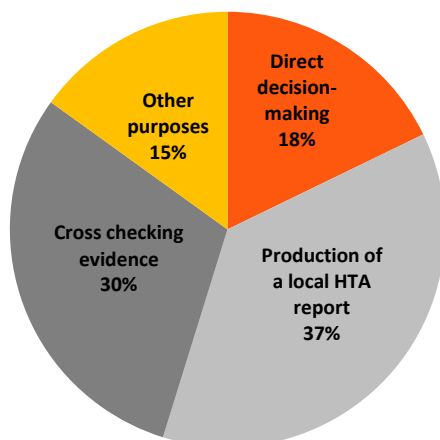
#### Main results

Response rate = 53.6% (n=37/69) from 25 different European countries responded

##### Use of

Joint Assessments = 58.3% (n=21/36)  
POP Database = 70.7% (n=22/31)  
EVIDENT Database = 35.5% (n=11/31)  
HTA Core Model = 67.7% (n=21/31)  
Rapid Model = 54.8% (n=17/31)  
Guidelines = 64.5% (n=20/31)

#### Purpose of using Joint Assessments



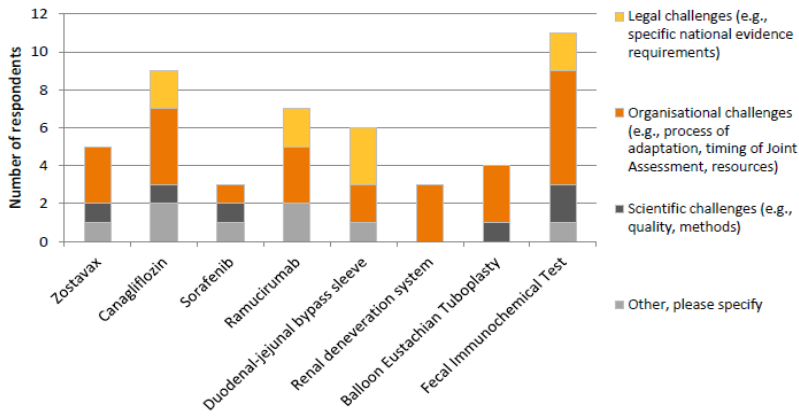
N = 19/21

Joint Assessment	Total number of usages		Purposes of usage							
			Production local HTA report		Direct decision making		Cross checking evidence or methods		Other purposes	
	n=	%=	n=	%=	n=	%=	n=	%=	n=	%=
Zostavax	5	20.0	2	40.0	1	20.0	2	40.0	-	-
Canagliflozin	11	45.5	5	45.5	1	9.1	4	36.4	1	9.1
Sorafenib	5	20.0	1	20.0	2	40.0	2	40.0	-	-
Ramucirumab	6	23.1	3	50.0	1	16.7	1	16.7	1	16.7
Duodenal-jejunal bypass sleeve	13	50.0	5	38.5	2	15.4	3	23.1	3	23.1
Renal denervation system	14	53.8	2	14.3	4	28.6	5	35.7	3	21.4
Balloon Eustachian Tuboplasty	9	34.6	4	44.4	2	22.2	2	22.2	1	11.1
Fecal Immunochemical Test	10	38.5	5	50.0	-	-	3	30.0	2	20.0

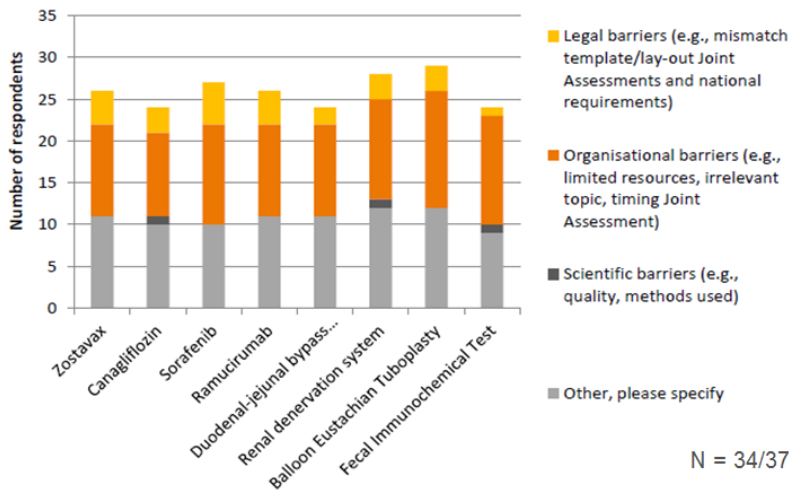
#### Published local HTA reports

Core HTA on Abdominal aortic aneurysm (AAA)	Austria	HVB
	Croatia	AAZ
	Norway	NOKC
Duodenal-jejunal bypass sleeve for the treatment of obesity with or without Type II Diabetes Mellitus (Published on July 2013)	Austria	LBI-HTA
	Netherlands	ZIN
	Spain	ISC III
Zostavax for the prevention herpes zoster (Published September 2013)	Netherlands	ZIN
	Austria	LBI-HTA
Renal denervation systems for treatment-resistant hypertension (Published December 2013)	-	-
Canagliflozin for the treatment of type 2 diabetes mellitus (Published February 2014)	Netherlands	ZIN
Fecal Immunochemical Test (FIT) versus guaiac-based fecal occult blood test (FOBT) for colorectal cancer screening (Published July 2014)	Austria	BIQG/GÖG and HVB
Pilot rapid assessment on Balloon Eustachian Tuboplasty for the treatment of Eustachian tube dysfunction (Published February 2015)		
Sorafenib for the treatment of advanced or metastatic, progressive differentiated thyroid cancer (Published March 2015)	UK	HIS
Ramucirumab in combination with Paclitaxel as second-line treatment for adult patients with advanced gastric or gastro-oesophageal junction adenocarcinoma (Published March 2015)	-	-

**Challenges while using Joint Assessments**

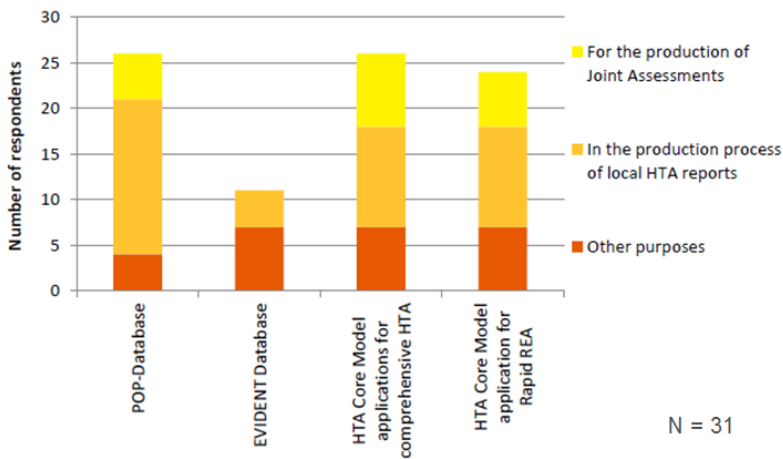


**Barriers for not using Joint Assessments**



N = 34/37

**POP, EVIDENT & HTA Core Model Purpose of usage**



N = 31

## Challenges using EUnetHTA tools

### POP Database:

- Mismatch of local HTA topics and projects of other organisations (n= 3)
- Incompleteness of POP Database (n= 1)
- Limited list of MeSH terms (n= 1)

### EVIDENT:

- Limited utility due to regulatory framework (n= 2)
- Time intensive process (n= 1)
- Incompleteness of data (n= 1)
- Practical relevance unclear (n= 1).

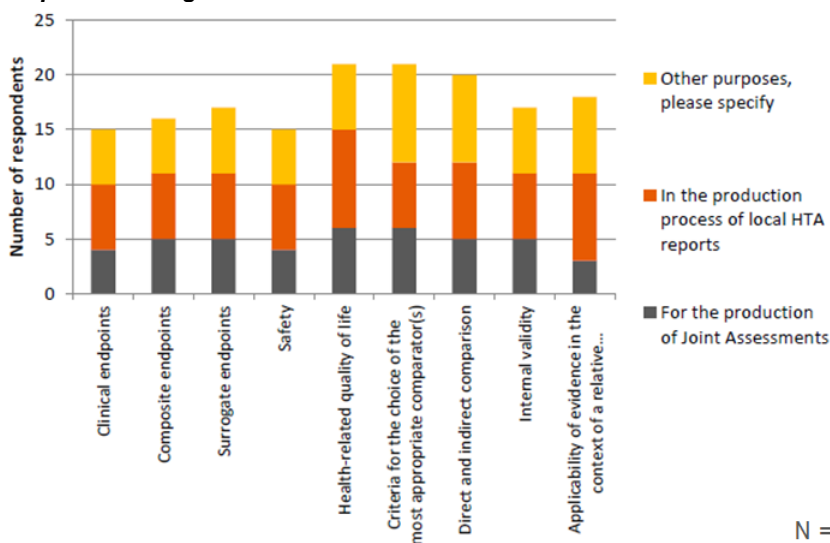
### HTA Core Model:

- Model is too extensive/complicated (n= 6)
- Overlaps between assessment elements (n= 2)
- Challenge to use for local HTA (n= 2)
- Patient issues not very well captured (n= 1)

### Rapid model:

- Absence of cost-effectiveness (n= 2)
- Clear methodological guidance is missing (n= 1)
- Structure not compatible with local HTA reports (n= 1)
- Not suitable for medical devices (n= 1)
- Too complex (n= 1)
- Overlap in assessment elements (n= 2).

## Purpose of using Guidelines



## Conclusion

- Rather low response rate - non-responders?
- EUnetHTA outputs were used by > 50% of responders
- Uptake/adaptation can still be improved
  - For assessments main barriers: topic selection, timing
- New survey sent out 4th of September

## Key comments and discussion / decision points:

- The complexities of the EUnetHTA tools and challenges in using them were mentioned in the survey as a reason behind lack of national uptake. All information from the survey has been shared with the



relevant WP. As part of the work on the challenges with the tools in EUnetHTA a task force has been set up to work on the challenges in using the HTA Core model with an aim of improving the model and streamline the Core Model in order to decrease overlaps and improve user-friendliness. Another task force has been set up to streamline the processes and procedures between the WPs working on comprehensive and rapid assessments in order to ensure consistency and coherence and this task force will also develop recommendations for JA3. Both task forces are led and coordinated by the EUnetHTA Secretariat.

#### 4. Finalising JA2

Julia Chamova (DHMA, EUnetHTA Secretariat) updated the Stakeholder Forum members on the remaining tasks and deliverables in JA2. And Simone Warren (Zin) informed the members about the final preparations for the meeting with EFPIA.

##### **SLIDES:**

##### **Finalising JA2**

###### **WP2**

GA Deliverable: Report on yearly training courses on EUnetHTA tools and methodology.

Remaining tasks: national uptake promotion, finalising development of e-learning/webinar training, Community of Practice activities.

*Final report to CHAFEA (task for all WPs!)*

###### **WP3**

GA Deliverable: Report on evaluation of project completion including assessment of impact on secondary users of HTA information.

Remaining tasks: finalisation of the efficiency gains report.

###### **WP4**

GA Deliverable: 3 full Core HTAs.

Remaining tasks: finalising 2<sup>nd</sup> and 3<sup>rd</sup> Core HTAs and methodological standard and procedure guide.

###### **WP5**

GA Deliverable: 12 pilot rapid assessments.

Remaining tasks: finalise 1 pilot (Strand A) and 2 pilots (Strand B), piloting of the submission template, finalise the update of the HTA Core Model for Rapid REA including feedback on the online tool; workshop with EFPIA on rapid REA pilots on pharmaceuticals;

###### **WP6**

GA Deliverable: Report on Information Management Infrastructure and Services.

Remaining tasks: support and maintenance of the EUnetHTA public website and Intranet; news aggregator update; e-learning platform support.

###### **WP8**

GA Deliverable: upgraded and updated application package of the HTA Core Model®.

Remaining tasks: training in the HTA Core Model, finalising update of the HTA Core Model and upgrade of the Online Service to support production of rapid HTAs and local reports.

###### **WP7**

GA Deliverables: guidelines and pilots to improve quality and adequacy of initial and additional evidence generation; Methodological guidelines and Templates to support production of core HTA information and rapid assessments.

Remaining tasks:

**SG1:** 1 ED and report on lessons learned on the disease-specific guideline development.

**SG2:** finalising common core protocol pilot,

**SG3:** 1 guidelines and 1 reflection paper to finalise; finalise update of JA1 methodological guidelines.

**SG4:** finalisation of submission templates, dissemination of results.

### **WP1/Secretariat**

**GA Deliverables:** Recommendations on the implementation of a sustainable European network for HTA; Final report from the JA.

**Remaining tasks:** monitoring national uptake, recommendations for coherent joint assessment production processes and procedures (SOP) across WPs (review of current guides, procedure manuals, etc.); reporting on implementing EMA-EUnetHTA cooperation (1 f-t-f meeting Dec'15); expert workshop with Med Tech industry (October 16); preparation of the EUnetHTA JA2 Final Technical and Financial Report; regular support in project management, administration and financial management of EUnetHTA JA activities (partner, WP and network levels).

### **Upcoming Stakeholder involvement**

WP	Date	
WP4	Sep	Core HTA 3 – first draft ready for SAG Consultation
WP4	Oct	Core HTA 3 – Public Consultation
WP5A	14 Oct - 2 Nov (tentative)	Public consultation of assessment draft of Hep C pilot
WP5A	Oct 7	Expert Meeting with EFPIA (by invitation only)
WP5B	Oct	Manufacturers will be invited to review the 2 <sup>nd</sup> draft version of the 6 <sup>th</sup> rapid assessment
WP7SG1	Sep (tentative)	SAG consultation - Report on Lessons learned and proposals for JA3 on developing the Disease Specific Guidelines
WP7SG1	Oct (tentative)	Public consultation - Report on Lessons learned and proposals for JA3 on developing the Disease Specific Guidelines
WP7SG3	End Sep	SAG/Public consultation on Guideline on Therapeutic Medical Devices
WP7SG3	Begin of Oct	SAG/Public consultation on Supplemented/adapted JA1 guideline “Safety”
WP7SG3	26 Aug - 9 Oct	SAG/Public consultation on Check of wording changes in 8 JA1 guidelines
WP8	Sep - Oct	SAG will be consulted regarding the processes for local reports
WP8	Sep – Oct	Review and revision of the policy for the HTA Core Model and core HTA information

### **Expert meeting with EFPIA**

Time	Agenda
10.30 – 10:45	<b>Welcome and objectives of the meeting</b> – W. Goettsch, ZIN (NL)/A. Rappagliosi, SP-MSD
10.45-11.15	<b>Overview of EUnetHTA joint assessments</b> Presentation by: (name tbc) EUnetHTA ❖ Presentation and explanation of EUnetHTA WP5 processes (the general pilot procedures and timelines, etc). ❖ Content and scope of joint REA, ❖ Evidence requirements, incl. EUnetHTA evidence submission template, ❖ Format of joint REA reports
11.15-11.30	<b>Q&amp;A</b>
11.30-12.30	<b>Experiences from first 5 pilots</b> These short presentations will focus on experiences and lessons learned from the first pilots. We will briefly discuss how these experiences influenced the changes in the structure/process of the subsequent pilots. Demonstration of the evolution of the pilot and implementation processes.

	<b>Industry experience with joint European assessments:</b> process, methods, outcomes and re-use. Tim Wilsdon, Charles River Associates <b>EUnetHTA experience based on 5 pilots</b> (presenter tbc)
12.30 – 13.30	LUNCH
13.30-15.00	Discussion of: <ul style="list-style-type: none"> <li>❖ improvements to pilot process,</li> <li>❖ improvements to input from industry</li> <li>❖ re-use of the evidence submissions on local level</li> <li>❖ national implementation and next steps,</li> <li>❖ ways to enhance REA processes</li> <li>❖ ways to enhance exchange and cooperation on national implementation</li> </ul> <b>Moderation:</b> Anne d'Andon (HAS)/ EUnetHTA (tbc), Ansgar Hebborn, Roche/EFPIA
15.00-15.15	Coffee Break
15.15-17.00	<b>Discussion on the future of joint European Assessment</b> <ul style="list-style-type: none"> <li>❖ JA3</li> <li>❖ HTA Network</li> </ul> <b>EUnetHTA views on the future:</b> Wim Goettsch (ZIN/EUnetHTA) / <b>Industry views on the future:</b> Andrea Rappagliosi, SP-MSD/EFPIA  <b>Moderation:</b> Jerome Boehm (DG Sanco) Including national implementation issues and next implementation steps in JA3; aim is to clarify how various discreet activities lead to a seamless process of joint assessment production geared towards meeting the national HTA needs that input into access decisions. Attention to the operational and technical issues of the process for the companies and HTA bodies to be prepared to effectively engage in the process; identify bottlenecks in the processes (joint and national) as well as internal processes in companies.

**Expert workshop with MedTech industry 16 Oct**  
**Draft agenda proposals from the MedTech industry:**

**TOPIC 1**

- EUnetHTA JA2 views on success factors within the JA2 collaboration for non-pharma technologies – HTA agency expert views
- Industry views on the value and impact of EUnetHTA JA2 collaboration - industry expert views

**TOPIC 2: The value and impact of EUnetHTA JA2 concrete work packages (learnings and proposal for improvement) – industry and HTA agencies expert views**

- REA on medical devices (WP5 strand B)
- Core HTA on Fecal Immunochemical Test (FIT) versus guaiac-based fecal occult blood test (FOBT) for colorectal cancer screening (WP4)
- Core HTA on “Structured telephone support (STS) for adult patients with chronic heart failure” (WP4)
- Early Dialogue (WP7)
- Methodological guidelines on medical devices (WP7)

**TOPIC 3: Teaming up for value - views on how the HTA cooperation could be of value and could be impactful in the next JA3 and beyond - HTA agencies and industry expert views**

- Concrete suggestions of approaches and activities in future JA3 Working Packages
- Stakeholder involvement modalities in JA3

**Finalising JA2 – Technical Reporting**

**Timeline for finalisation and commenting on the final JA2 Technical Report:**

When	What
15 Jan	LPs send 1 <sup>st</sup> draft WP Technical Report AND Financial statement AND timesheets for their respective organisation to the Secretariat
29 Jan	Secretariat sends comments on the 1 <sup>st</sup> draft of WP Technical Reports to LPs

10 Feb	LPs send 2 <sup>nd</sup> draft of WP Technical Reports to Secretariat
7 Mar	<b>Secretariat sends the consolidated overview of EUnetHTA JA2 activities and results to all EUnetHTA Partners and Stakeholder Forum for comments</b>
21 Mar	<b>Deadline for comments from EUnetHTA Partners and Stakeholders</b>
15 April	Secretariat shares final report with the EUnetHTA Partners for information and approval
25 April	Deadline for input from the EUnetHTA Partners
2 May	Secretariat sends Final Report (including financial) to CHAFEA

## 5. Permanent EU cooperation on HTA

### 1. HTA Network update

Sevala Malkic (DG Sante/HTA Network Secretariat) informed the Stakeholder forum about the current work in HTA Network and the Stakeholder involvement in future JA3.

#### SLIDES:

##### Summary of actions

- Mandate given on 24 March to Secretariat to liaise with stakeholders
- Meeting with stakeholders on 7 May
- Written input "lessons learnt" from stakeholders
- Distribution of input to MS
- Discussion in EUnetHTA PA, Copenhagen, 29 May
- Presentation of SH input and EC view on stakeholders involvement, 12 June
- Meeting with stakeholders on 9 July
- Distribution of input to MS(to be distributed)

##### Next step – for discussion

- Representation of all stakeholders in the HTA Network
- Status of stakeholders in JA3
- Stakeholder involvement in EUnetHTA
  - Stakeholder Forum
  - Stakeholder Advisory Group (Establishing dedicated stakeholder representatives at the WP level for purpose of addressing of specific topics at the WP level in SAG rather than SF,...)
  - Funding

## 6. JA3 Preparations

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

#### SLIDES:

##### JA3 preparations update - I

**June 2** – 2015 Work Programme approved; 12M€ allocated to support JA3 (constituting 60% of the JA3 budget)

**June 5** – official invitation to the official representations of the EU MS (and other eligible countries) to nominate JA participants (Associated Partners)

**June 12** – 3<sup>rd</sup> informal JA3 preparatory meeting organised by DG SANTE/HTA Network Secretariat.

**October 9, 2015** – deadline for nomination of the JA3 partners (by the MoHs)

**December 17, 2015** – deadline to submit JA3 proposal to CHAFEA

##### JA3 preparations update – II

- **In June 2015 JA2 the Coordinator took initiative to set up a JA3 Task Force**
  - information to the JA2 Plenary Assembly on June 17
  - follow-up communication to the Exec Comm June 18
  - Invited organisations were informed on the conditions and all confirmed their participation

### **JA3 TF Purpose and remit:**

- Further develops a structured input on organisation of JA3 activities, governance structure, etc following
  - the JA proposal requirements from the European Commission
  - Discussions and clarifications during the informal preparatory phase supported by DG SANTE
  - Previous discussions and clarifications re: JA3 by the JA2 Plenary Assembly, JA2 SF and Exec Comm
- Temporary group for a specific task; to be discontinued on the task completion (October 9)
- No formal decision-making power – hands over its input to the JA3 Consortium after October 9.

### **JA3 preparations update – IV**

- **JA3 TF mode of working:**
  - TF works in consultation and via involvement of the JA2 Executive Committee (that has been given a mandate by the JA2 PA to be “the voice of EUnetHTA” till the start of JA3)
  - Small teams around 5 identified WP focus areas (based on the discussions in the three informal preparatory meetings) to develop specific input for further deliberations in the Executive Committee
    - Joint Assessments - National Implementation
    - Quality Management and Process Support
    - Evidence Generation - Network Coordination
  - **TF teams have been encouraged to involve other TF members and OTHERS from the JA2 partnership of HTA organisations (eg, Executive Committee members, etc) and the HTA Network in the development process**
    - **To contribute input an organisation does not have to be a member of the Task Force**
    -

### **JA3 preparation update**

**June 25-Aug 25** – TF teams develop and share their input within the TF

**Sept 8** – next versions of WP draft descriptions shared with the Exec Comm and JA2 EUnetHTA partners

**Sept 16-17** – discussions in the Exec Comm

**By Oct 9** – TF finalises its work and hands over its input to the JA3 Consortium

## **B. Other issues**

1. **Next EUnetHTA Newsletter issue** – October 1, 2015 (deadline for input – 15 Sep, 2015 sent to [nmkh@sst.dk](mailto:nmkh@sst.dk) Cc [eunetha@sst.dk](mailto:eunetha@sst.dk))

#	Action Point	Responsible	Deadline
1	Stakeholders interested in giving feedback to WP 6 on the new features in the POP database should write to Patrice Chalon (KCE Lead Partner in WP6) <a href="mailto:Patrice.Chalon@kce.fgov.be">Patrice.Chalon@kce.fgov.be</a>	SF members	ASAP