EUnetHTA Joint Action 2
Stakeholder Forum meeting

Brussels, Belgium
January 15, 2014, 10:00 – 17:00 CET
Organised by: EUnetHTA Secretariat and KCE
Address of the meeting venue: Pacheco Centre, (entrance at the side of the Finance Tower) Boulevard Pacheco 13, 1000 Brussels
Mobile: +45 7222 7975 – Anne Raahauge, EUnetHTA Project Manager

Summary Report

Agenda

Coffee, light snack upon arrival	*09:30 – 10:00*
1. Opening and presentation of participants	10:00 – 10:15
2. Progress report from WPs	10:15 – 12:30
Lunch	*12:30 – 13:30*
3. EUnetHTA and HTA Network • Update on recent developments and interaction • Open discussion: EUnetHTA contribution to the HTAN 'Position Paper'	13:30 – 14:30
4. EUnetHTA Conference HTA 2.0 Europe – Stakeholders input	14:30 – 15:00
Coffee break	*15:00 – 15:15*
5. Other issues and closing of the meeting • How EUnetHTA reaches groups/experts for input to EUnetHTA activities on EDs, disease guidelines etc? • JA1 technical report – lessons learned from JA1 and how are challenges tackled by JA2?	15:15 – 16:00

1. Opening and presentation of participants

Alric Rüther (IQWIG) newly appointed Chair of the Stakeholder Forum (SF) welcomed the participants and expressed his appreciation of having this opportunity to inform and discuss with stakeholders face-to-face about the activities and developments in EUnetHTA. Francois Houÿez (EURORDIS) Co-Chair of the SF joined Alric Rüther in welcoming the participants and informed the meeting that he as Co-Chair would organise a meeting with the SF stakeholder groups in order to know their specific concerns and issues. Both chairs looked forward to leading the Stakeholder Forum during the next period.

Following the introductions and presentation of agenda and meeting participants, Finn Børlum Kristensen and Julia Chamova (DHMA, EUnetHTA Secretariat) gave the SF an overview of the accomplishments of EUnetHTA in the first year of JA2

SLIDE:
JA2 Year 1 at a Glance

- *Range of scientific outputs, tools, operational support structures/processes, external collaborations*
- *Year of transition: clarification of the EUnetHTA and HTAN synergistic existence and cooperation*
    - *EUnetHTA ensuring the scientific and technical cooperation on HTA in Europe with a purpose of supporting production of HTA information*
- *Further development of stakeholder involvement practices with a focus on scientific and technical cooperation*
- *Strengthened focus on (project) management; new communication media (social networks)*

JA2 Year 1- report from the Coordinator

Scientific Output:

- *1st Core HTA completed and 2nd started (WP4)*
    - *First drafts of the MSPs (Methodological Standard and Procedures);*
- *2 rapid Core HTAs (1-pharma, 1- non-pharma) completed; 2 more started (1 in each strand) (WP5)*
    - *Procedure manuals, templates for assessments and evaluation surveys developed for both strands of rapid pilots*
- *Local (national/regional) HTA report piloting: drafts for procedure (WP4); several countries are planning adaptation of the Core HTAs (WP4/WP5), 1 national report produced based on a rapid Core HTA (WP5)*
- *6 pilot Early Dialogues (EDs) finalised on medicinal products (WP7SG1)*
- *Template for a disease specific guideline produced, concept paper delivered, first draft being developed (WP7SG1)*
- *Literature review on the AEG (Additional Evidence Generation) performed (WP7SG2)*
- *3 guidelines are being drafted (WP7SG3)*
    - *Guideline elaboration process, templates for guideline concept and working manual*
- *1st draft of the submission template for pharmaceuticals developed (WP7SG4)*

Scientific Output - TOOLS:

- *2nd release of EVIDENT Database (+maintenance) (WP6)*
- *POP Database further development (+maintenance) (WP6)*
- *IMIS (Information Management Infrastructure and Services) development (new intranet, public website, re-design of the centralized authentication system, upgrade of EUnetHTA Aggregator, Toolbar, identification of technical options for e-learning platform, review of evolution needs for the Common Standards, evaluation of*

interoperability options; various support activities for JA2 operations management (financial/tech reporting; stakeholder involvement supporting tools, etc) (WP6)

- *Updated contents and applications of the HTA Core Model® (WP8)*
- *Updated Policy and License (commercial license) (WP8)*
- *Upgrading of the HTA Core Model Online Service (WP8)*
    - *All done with feedback from the ongoing pilots*
- *Development of the tailored trainings and learning material for the EUnetHTA members and stakeholders (WP2)*

THE FIRST HALF YEAR OF JA2 OVERLAPPED WITH FINALISING AND REPORTING JA1…….

Output: SERVICE – OPERATIONS AND Project MANAGEMENT (tools and support):

- *EUnetHTA JA2 3-year Work Plan, Consortium agreement, SOP, various templates (WP1, Secretariat)*
- *Established and functioning SF and SAGs, public consultations structure and function (SI PROCESS SUPPORT) (WP1, Secretariat)*
- *Electronic timesheets (for the purpose of the financial reporting AND for calculation of efficiency gains) (WP1,WP3, Secretariat)*
- *Surveys and interviews to audit the progress and to capture specifics of the cross-border collaboration activities (WP3)*
- *Internal and external communications support (e.g., newsletters, coordination and facilitation of presentations at various events, news service, social media presence (Secretariat, WP1)*

External collaborations:

Policy developed to govern involvement with external parties

- ***EMA:** 3 year Work Plan; 2 joint meetings per year; input in a number of workshops; coordinated EUnetHTA input to one of EMA's public consultations; presence in ENCEPP*
- ***PARENT JA**: participation in the workshops, review/input to their deliverables; regular updates on developments*
- ***4 FP7 projects**: coordinating meeting held; contacts established between relevant EUnetHTA WPs/activity lines and FP7 projects*
- ***EUPATI:** EUnetHTA participates in the Advisory Board*

New developments:

- *EUnetHTA Position (process & procedure; 1 EUnetHTA Position developed)*
- *Clarifying synergistic co-existence and cooperation with the HTAN*
- *EUnetHTA partners cooperation to form SEED (further conditions for synergy to be clarified)*
- *Stakeholder Involvement:*
    - *Co-Chair function in the SF*
    - *Expert meetings with stakeholders becoming an integral part of the "production" WPs' working processes (August 29, 2013 (pharmaceuticals); planned – May 8, 2014 (medical devices)*
    - *Review of the EUnetHTA JA2 Technical Interim Reports by the SF*
    - *Framework for collaboration with EFPIA*
    - *ToR with Roche on exploring the application of the HTA Core Model in the internal company's processes*

Key comments and discussion / decision points:

- The issue of making the POP and EVIDENT databases publicly available was raised by the Stakeholders. EUnetHTA will discuss this further during the spring and move practically on this

– potentially bring it to the agenda for the Plenary Assembly in April.

***Action Points*:** EUnetHTA Secretariat to follow up with LPs on making the POP and EVIDENT databases publicly available.

2. Progress report from WPs

WP4

Marina Cerbo (Agenas) updated the meeting on the status and developments in the activities of WP4.

SLIDES:

Activity	***Due date / Milestone***	***Status***
1st Core HTA Fecal Immunochemical Test (FIT) versus guaiac-based fecal occult blood test (FOBT) for colorectal cancer screening.	*M14 (Nov '13)*	- *SAG Feedback on Core HTA 1st draft received (3 respondents out of 15, from 2 organisations)* - *Final version of Core HTA 1 ready by the end of Jan '14* - *Public consultation will start by the end of Jan '14 and last 1 month*
Methodological Standards & Procedures	*M15 (Dec '13)*	*Ready and published (intranet) by Jan '14*
2nd Core HTA	*Sep '14*	• *Topic selected: "Intravenous immunoglobulins for Alzeheimer's disease including Mild Cognitive Impairment."* • *New timelines developed as there is no evidence on the use of the technology* • *Project in the On-line tool created*
National Pilots	*M 36*	*On-going* - *"Volunteers" identified* - *Production on-going in some cases (Austria)*

WP4 National Report Piloting

Slovenia	*March 2014*	*A report based on Core HTA 1 (CRC screening) for all domain*
Croatia	*2nd half of 2014*	*National HTA Report using the final available Core HTA information*
Austria (GÖG and HVB)	*2nd half of 2014*	*National HTA Report using the final available Core HTA information on gFOBT/FIT (colorectal cancer screening)*

Finland	*TBD*	*National HTA Report using the final available Core HTA information on gFOBT/FIT (colorectal cancer screening)*

Other partners shown interest in production national/local report: Romania, Sweden, Portugal, Bulgaria

WP4 - Stakeholder involvement timeline 2014	
Jan	*Core HTA 1 Public Consultation* *Core HTA 2 Protocol to SAG for comments*
Feb	*Core HTA 1 final vers.* *Core HTA 2 finalized protocol*
Mar	
Apr	
May	
Jun	
Jul	*Core HTA 2 1st Draft to SAG comments* *Core HTA 3 Topic selection*
Aug	*Core HTA 2 Public consultation*
Sep	*Core HTA 2 final vers.*
Oct	
Nov	*Core HTA 3 Protocol to SAG for comments*
Dec	

Key comments and discussion / decision points:

- Feedback on how the comments submitted by the SAG members were handled by WP4 was requested. Stakeholders would appreciate to get replies as they do in WP5. WP4 LP informed the SF that feedback is still being collected and analysed and should be finalised at the end of January 2014.

- Consultation on the final version of the protocol should be shared in due time. It was noted that coherence needs to be ensured with regards safety domain and effectiveness domains (e.g. literature sources were not consistent in different chapters of the same domain leading to different outcomes). It was suggested that the specific scientific questions regarding specific Core HTAs should be discussed as a part of the SAG input and the communication between the project team and SAG.

- The procedure of selecting the topic for the second core HTA was asked into. The topic was selected through two rounds among Partners, Stakeholders and the European Commission.

- The public consultation for the 2nd core HTA is planned during August and it was suggested to postpone this as August is a vacation month for many.

WP5

Wim Goettsch (CVZ) updated the meeting on the activities in WP5.

SLIDES:

Activity/Activity steps	***Due date / Milestone*** *(Since last e-meeting)*	***Status/Clarification of delays***
Procedure manual including evaluation forms (Strand A & Strand B)	*M7: Apr '13*	• *Strand A Procedure Manual finalised in May 2013 (delay due to additional input EMA)* • *Strand B: Finalised in April 2013*
Coordinating and supporting the joint pilots of rapid assessments of pharmaceuticals (strand A) and other technologies (strand B) *Discussion and evaluation of on-going pilots at f-t-f meeting in Vienna*	*M9: Jun '13*	*Continuous.* *Finalized in M14, delayed because f-t-f meeting in Vienna was held in November 2013 (M14).*
Discussion and evaluation of on-going pilots at f-t-f meeting	*M21: Jun '14*	*Expected delivery on time*

Status on Pilots:

Pilot nr.	***Topic***	***Status/Clarification***
Strand A		
1.	*Herpes zoster vaccine (Zostavax®)*	☑ *Final assessment was published on the EUnetHTA website on 23 August 2013* ☑ *Uptake in local/national reports: Austria (twice, 2013), NL (2014), 2 potential other countries*
2.	*Canagliflozin (Invokana®)*	☑ *Scoping phase completed* ☑ *Authors currently writing 3rd draft – ready Jan 13th* ☑ *Final assessment planned to be ready by 13 Feb 2014*
Strand B		
1.	*Duodenal-jejunal bypass sleeve (EndoBarrier®)*	☑ *The final assessment has been published on the EUnetHTA website on 9 August 2013* ☑ *Uptake in local/national reports: planned 2014 CVZ, AAZ, Czech Republic, NOKC, HIQA*
2.	*Renal denervation systems*	☑ *Final assessment was published on 19 December 2013* ☑ *Uptake in local/national reports: HIS, CVZ, ??*

<u>Next Pilots:</u>

Strand A:

To be determined

Reluctant engagement of pharma companies

- *Risk averse*
- *Need more time to prepare for participation*
- *More pilots expected in 2nd half of 2014*

- Workshop with EFPIA planned

Strand B:

2 – 3 pilots planned in 2014, 1st expected to start early 2014

Potential topics (TBC) next pilots:

1) *Closure of patent foramen ovale or of left atrial appendage*
2) *Percutaneuous mitral valve repair using MitraClip or Balloon eustachian tuboplasty*

Stakeholder involvement in Strand A:

Previous:

- *stakeholder consultation of procedure manual and evaluation forms in March 2013*
- *Involvement (scoping and consultation) of MAH in the two pilot assessments*
- *Workshop with EFPIA at ISPOR meeting in November 2013*

Upcoming:

- *expert meeting in 2014*
- *Workshop with manufacturers on the involvement in pilots (early 2014)*
- *It is to be explored whether other stakeholders can be included in the scoping and/or consultation phase of the pilots.*

Stakeholder involvement in Strand B:

Previous:

Stakeholder advisory group (SAG):

- *consultation of the Procedure Manual (March 2013) and on draft project plans of first 2 pilots*
- *suggestion of External Reviewer, identification of patient/consumer representative*

Others:

- *manufacturers: consultation on draft project plans and pilot assessment drafts of first 2 pilots, provision of evidence*
- *medical experts, patient/consumer representative consultation on first/second pilot assessments*

Upcoming:

- *notification/consultation on further draft project plans*
- *Expert meeting (COCIR, EDMA, EUCOMED): May 2014 (TBC)*
- *Exploration of scoping meeting with manufacturer(s) and other stakeholders*

Other activities:

Activity/Activity steps	***Due date / Milestone*** *(Since last e-meeting)*	***Status/Clarification of delays***

Core model challenges meeting	*20 Nov '13*	• *Change required to Rapid Model as there is to much workload and the three-layer structure is prone to inconsistencies and errors* ➢ *Assessment elements will be integrated in domain reports* ➢ *Reduction of overlap (change in assessment elements)*
Discussion and evaluation of on-going pilots at f-t-f meeting in Vienna	*M14: Nov '13*	• *The meeting was held on 21&22 November 2013. For most relevant topics see next slides*

F-t-f meeting in Vienna (21&22 Nov '13):

Most relevant topics:

- *lessons learned from pilots first 4 pilots*
  - *Authors are enthousiastic about producing the pilots*
  - *Experiences are rather similar for different pilots. Main challenges:*
    - *Tight timeline*
    - *A lot of overlap in information due to overlap of assessment elements and triple layer structure (summary – domain reports – result cards)*
    - *Processing comments from reviews is most time consuming and challenging task*
- *Discussion to simplify rapid model/templates*
- *National report production*

Relevant conclusions of meeting:

- *WP5 member organisations are dedicated to joint production of assessments*
- *Local report production based on pilot assessment is feasible*
- *Assessment template will be changed and piloted in next pilots*
  - *Assessment elements will be included in domain reports instead of separate result cards*
  - *Ready for use in first quarter of 2014*
- *Model for Rapid REA will be updated in first half of 2014 instead of 2015*
  - *reduction of overlap of assessment elements (use HTA Core Model 2.0 for update)*

Submission template (WP7 SG4):

Strand A:

- *Currently working alongside NICE in the development of a manufacturer's submission template.*
- *'1st Draft Submission Template for WP5 piloting' was completed in October*
  - *WP5 will test the use of this template in the upcoming pilots*
  - *consultation on the draft submission template (pharmaceuticals) with EUnetHTA partners, agencies receiving submissions and Industry in Jan-March 2015 (awaiting confirmation)*
  - *2nd draft submission template, and feedback from that can be included in the development of the final draft submission template over the summer 2015.*

Strand B: submission file template under development – first draft available in May 2014

Key comments and discussion / decision points:

- Too which extent the guidelines from JA1 were used in the pilots was raised as a question. The JA1 guidelines are still an important part of and reference for the work in JA2

- How and when EUnetHTA is exchanging information with the stakeholders was asked into. In WP5 Strand B, the draft project plans have been put on the EUnetHTA website for public consultations, shared with SAG and manufactures for input. Such a three-winged way of sharing and receiving responses was too time consuming and confusing. From now on, there will only be one public consultation on the website, for all to comment on.

- Regarding national uptake it was highlighted by the SF that there need to be some clarification and possibly guidelines for when and how countries can take information from EUnetHTA. It was commented that taking only one line from the EUnetHTA full report and call it information from a full EUnetHTA report would be misleading. More experience needs to be collected on national adaptation – EUnetHTA follows this very closely to gather lessons learned for adapting and guiding the process into the future.

WP7

Francois Meyer (HAS) updated the particpants on the developments in WP7.

SLIDES:
WP7-SG1 Early Dialogues Update Nov.13-Jan.14

SG1 Activity	***Due date / Milestone***	***Status***
Pilot early dialogues for drugs (n=3) and medical devices (n=1)	*Last two FTF meetings: Nov.'13*	• *8 EDs for drugs completed* • *1 ED for medical device to be completed in Q1/2015*
Survey to participating HTA bodies, EMA, manufacturers and other stakeholders on ED process	*Oct.'13*	*Responses from all HTAs (11), EMA and companies (8) obtained;* • *Complete analysis is finished. Results to be presented to next FTF WP7 meeting 22 and 23 Jan. 14* • *Proposal of revised procedure is ongoing*

WP7-SG1 Disease Specific GuidlinesUpdate Nov.13-Jan.14

SG1 Activity	***Due date / Milestone***	***Status***
Choice of condition: *Osteoarthritis (author OSTEBA)* ***Templates*** *for concept paper and guideline* ***Concept paper:*** *publication on EUnetHTA website*		*Finished*
Guideline: *1st draft to be released by author*	*Oct.13 - Jan.14*	*Ongoing*

WP7-SG1 ED SAG involvement: Upcoming

SG1 Activity	*Timing initially planned*	*Status*
Expert meeting (or e-meeting) to present • *results of the survey,* • *proposals for improvement of the procedure*	*Jan. 14*	*Expert meeting to be postponed?* • *After last ED on MD: to be performed in 2015?* • *At the end of the 10 EDs for SEED, in 2015?* • *Before public consultation?*
Review of draft consolidated procedure for ED for drugs and non drugs	*Mar. 14 - Jun. 14*	• *Results of the survey and proposals for improvement of the procedure to be provided to SAG for comments*
Public consultation of consolidated procedure for ED for drugs and non drugs	*Jul 14 - Sept. 14*	*To be postponed?* • *At the end of the 10 EDs for SEED, in 2015*

WP7- SG1 DSG SAG involvement : Upcoming

SG1 Activity	*Timing*	*Type of input*	*Purpose of SAG's involvement*
Review of the 1st draft of guideline	*May '14 - Jun '14*	*Comments*	*Improvement of document*

WP7-SG2 Update Nov.13– Jan.14

SG2 Activity	*Due date / Milestone*	*Status/Clarification of delays*
1st survey on the possibilities and conditions for performing harmonized ADC	*Survey circulated July '13;* *last responses received Oct '13*	*Response rate: APs: 18/19; CPs: 7/10 + 9 responses from partners outside WP7.*
Development of the 1st draft of guidelines/position paper	*Postponed due to late survey responses*	*Partners that expressed an interest, confirming adequate resources to participate in this task, were contacted in Dec '13; scoping of the documents will be discussed at the 2nd ftf meeting in Jan '14.*
Pilot of a common core protocol for additional data collection: SG2 SAG consultation	*Rescheduled for mid-Jan '14*	*SG2 SAG consultation: to participate in the choice of the technology of interest for the pilot and suggest up to 3 candidates*
• *EVIDENT training session* • *EVIDENT query update*	*Jan'14* *Dec'13*	• *Increase use and familiarity with the use of the database; training the trainees for the individual agencies on EVIDENT's objectives, functionalities and use* • *Partial responses from only 9 agencies to the 14 EVIDENT queries observed (Nov'13). Action point (Dec'13): partners to complete as many remaining Minimal Set of Information forms as possible and, at minimum, the one for MELODY (Transcatheter Pulmonary Valve); analysis in progress*

• *EVIDENT functionality update* • *EVIDENT maintenance*		• *MESH tree improvement with addition of a search functionality, simplification of the query response for users…* • *Continuous maintenance of technical and functional aspects of the database*

<u>WP7-SG3</u> Update Nov.13– Jan.14

SG3 Activity	***Due date / Milestone***	***Status/Clarification of delays***
Elaboration of new general methodological guidelines	*May ´14 (planned finalization of the first three guidelines following WP7 work plan)*	• *Three guideline teams at work:* 1. *Internal validity of non-randomised studies (NRS) on interventions: (Collaboration with Cochrane NRS-Group, systematic literature search finished, work on the 1st draft version started)* 2. *Economic evaluations: (collection of national guidelines nearly completed, information extraction form developed, systematic analysis in divided work)* 3. *Meta-analysis of diagnostic test accuracy studies: (first draft version under internal review)* *Continue…next slide*
Elaboration of new general methodological guidelines	*May ´14 (planned finalization of the 1st three guidelines following WP7 work plan)*	*…continue.* • *Minor delays (≈ 4 months) for the 1st two guidelines* • *2/3 designated first authors of the next three guidelines (8/2014 – 9/2015) already agreed on an earlier start of the elaboration process (i.e. ≈ May 2014)* • *SAG consultation on the draft guideline versions: Start of March 2014 (1 Guideline), Start of June (2 Guidelines)* • *Public consultations on the draft guideline versions: Mid-March 2014 (1 Guideline), Mid-June (2 Guidelines)*
Review of existing JA1 methodological guidelines	*-*	*Ongoing phase of using the JA1 guidelines for the work in WP4 / 5 – no critique or internal requests for updates until now*
Process description for the future methodological guideline elaboration and maintenance in EUnetHTA	*M36 - Sep´ 15*	*SG3 working manual (1st draft) under internal review; working manual will be one basis for the final process description at the end of JA2*

<u>WP7-SG4</u> update Nov.13– Jan.14

SG4 Activity	***Status/Clarification of delays***
Draft submission template for pharmaceuticals	• *Draft questionnaires created to gather feedback on use of template in WP5 pilots from manufacturers and WP5 partners* • *Publication on national European evidence requirements for pharmaceutical under development* • *Collaboration with WP7 SG3 over evidence requirements on cost or cost effectiveness data for pharmaceuticals (for inclusion in 2nd draft submission template)* • *Liaison with WP8 over industry piloting of the Core model where it relates to industry submissions*

Development of submission template for medical devices	• *Final response to request for evidence requirements from 27 out of 31 national agencies responsible for medical device assessment* • *Templates received from 12 national agencies, 9 confirmed no templates and 6 confirmed same templates for devices and pharmaceuticals* • *Liaison with industry stakeholders for information and collaboration* • *Liaison with WP5B over timeframe for piloting draft template* • *Contact with WP7 SG4 partners over contribution to develop devices template (interest from LBI and GYEMSZI)* • *Stakeholder involvement with device industry about the development of the device template : Meeting currently being organised by secretariat for Spring 2014* • *Stakeholder consultation: rescheduled to Jan-March '15, awaiting confirmation*

SAG and public consultations: summary:

Subgroup	***Activity***	***Due date / Milestone***
SG1	• *SAG consultation: review of the 1st draft of disease specific guideline* • *Public consultation of consolidated procedure for ED for drugs and non drugs*	• *May 14 - Jun. 14* • *Jul 14 - Sept. 14*
SG2	• *SAG consultation : choice of the technology for the pilot of a common core protocol for additional data collection* • *SAG consultation : review of the 1st draft of guidelines/position paper for AEG* • *Public consultation : 2nd draft of guidelines/position paper for AEG*	• *Rescheduled for mid-Jan '14* • *Initially scheduled for March-May '14 : a two-month delay is expected (due to delayed start)* • *Initially scheduled for Oct '14 - a two-month delay is expected (due to delay in start)*
SG3	• *SAG consultation on the draft guideline versions* • *Public consultations on the draft guideline versions*	• *Begin of March 2014 (1 Guideline), Begin of June (2 Guidelines)* • *Mid of March 2014 (1 Guideline), Mid of June (2 Guidelines)*
SG4	• *Stakeholder involvement with device industry about the development of the device template* • *Stakeholder consultation*	• *Meeting currently being organised by secretariat for Spring 2014* • *Rescheduled to Jan-March '15, awaiting confirmation*

Key comments and discussion / decision points:

- Stakeholders asked whether or not medical devices in diagnostics would be included in WP7. JA2 is not focusing on draft templates for diagnostics as they are not so generic across Europe and it would difficult to have a common template for these technologies.

- A timeline for the public consultations on guidelines was requested.

- Sharing the survey results from the Early Dialogue surveys with the Stakeholder Forum was requested, and WP7 agreed to that the results will be shared with the SF and WP7 SAG. Due to the lack of interest in Early Dialogues from the medical device industry, WP7 is further considering making a survey among non-drug companies in order to uncover the reasons behind this lack of interest and to find out possible difficulties faced by the non-drug companies in relation to the Early Dialogues.

- Sharing the survey on EVIDENT with partners and survey manufactures was discussed. It would be of benefit to the manufactures to have an insight in what kind of additional evidence is collected and descriptions of technologies suitable for common protocol. The survey is focusing on capacity within HTA bodies to participate in EVIDENT work, and other actors can have useful information on what happens in real life on data-collection. Such an exchange will be welcome.

***Action Points*:** WP7 to share the results of the Early Dialogue surveys with the Stakeholder Forum and SAG

WP8

Kristian Lampe (THL) updated the meeting on activities and developments in WP8.

SLIDES:

Activity	***Due date / Milestone***	***Status***
Piloting of HTA Core Model for internal processes of technology manufacturers (Roche + Medtronic)	*M15 – Dec 2013*	*Terms of Reference document developed and signed the Secretariat and Roche. E-meeting in Dec with Roche and relevant EUnetHTA partners. Another e-meeting scheduled for 3 Feb to discuss more details.*
Update of the HTA Core Model, including expansion of rapid REA model into a core HTA model	*M12 – Sep 2013*	*Delivered in Nov.* • *Legal domain not yet updated at all, due to lack of primary investigator. Work will most likely commence soon, aim to be ready by April 2014.*
Upgrade HTA core Model Online to support production of rapid HTAs and local reports	*M14 – Nov 2013*	*Differences between production of core HTAs and rapid HTAs, and related challenges discussed in a meeting in Nov 2013. New features to support rapid HTA production will be implemented early 2014.* *Development of local report functions started, first pilot features in Feb 2014.*

WP8 Stakeholder involvement in 2014:

- *Public consultation of Model version 2.0 will commence during January*
  - *Aim: gather feedback to improve the Model*

- *HTA Core Model Online: features to support local report production – SAG to be consulted regarding suggested approach during March/April 2014*
  - *Aim: to ensure that the suggested processes and tools take into account stakeholder views.*

Key comments and discussion / decision points:

- There was a question how the Core model 2.0 would be published – in one or several documents. At the moment it looks as if it will be application-specific documents, like e.g. REAs, but this will be discusses and WP8 is open for suggestion if it all should be in one document.

WP6

Patrice Chalon (KCE) updated the meeting on the developments in WP6.

SLIDES:

Activity	***Due date / Milestone***	***Status***
Implementation of a new Public site	*M4*	*Addition of SAG WP2 area (2013-11)*
Implementation of a new intranet (including "work rooms")	*M5-36*	*EUnetHTA ID renewal ongoing (2014-01) Evaluation of change requests planned (2014-01)*
Planned and On-going Projects database operation	*M4-M36*	*Release 2 functionalities delayed (planned 04/2014) 1212 projects from 46 partners (23 countries)*
Centralized authentication system (EUnetHTA ID)	*M4-M36*	*Deployment release 2 in progress*
"e-learning " platform	*M7-M9*	*Needs assessment delayed (planned 02/2014)*
Common standards & interoperability	*M36*	*Conference call planned with CRD regarding interoperability POP database and HTA database (2014-01)*
Reporting Y1	*M14*	*Interim report Y1 adjusted following comments (2013-12)*
"Aggregated" Newsletter	*M13-M18*	*Delayed (2014-06)*

WP2:

Marianne Klemp (NOKC) updated the meeting on the activities in WP2.

SLIDES:

Activity	***Due date***	***Status***
Reporting	*M12-Sep'13* *M14 Nov'13*	*Finalized Nov '13*
Production of learning material for the EUnetHTA tools and methods	*M16-Jan'14*	• *Production of learning material for the first training course for Stakeholders*
Face-to-face training course	*M13-Oct'13* *M16 – Jan'14*	• *According to schedule* • *Training course in January 14 (EUnetHTA partners and associates) Content: HTA Core Model, POP, EVIDENT, methodological guidelines, Intranet* • *Training course in January 16* ***Stakeholders.*** • ***Content****: How to use HTA for decision making, patient involvement in the HTA process, HTA Core Model and methodological guidelines*
Organise one workshop for the Community of Practice	*M13-Oct'13*	• *Identification of CoP participants* • *Planning of a webinar with potential CoP participants* • *Planning of the workshop* • *Workshop will take place in connection with the EUnetHTA conference in Rome, Oct 2014*

SAG Tasks

- *Provide input and suggestions for improvement on the feedback we receive from the first training course.* ***February, 2014.***
- *Give input on topics and format of second training course.* ***May 2014***

Key comments and discussion / decision points:

- The Second Stakeholder Training will be held in Rome on 29 October, 2014 in connection with the EUnetHTA Conference. Plans include having seats for up to 50 participants in this training.

- It was raised why payers were not invited to participate in the first stakeholder forum training and whether they would be invited in the future. The main focus in the WP2 work plan is on patients and providers but payers will be invited in the future. The content of the training will continuously focus on the needs of patients and providers but payers and industry will be invited depending on the seat availability and with the understanding that the content of the trainings are focusing on patients' and providers' needs.

WP3

Sonja Scheffel (HVB) updated the meeting on the developments in WP3.

SLIDES:

Activity/Activity steps	***Due date/ Milestone***	***Status/Clarification of delays***

Collection of routine data	*M13 Oct. 13* *M14 Nov. 13*	• *Collection of data (by WP1) through timesheets developed by WP3 in Excel* • *Including number of person days per individual and costs (expressed in relevant currency) – documentation on a WP & pilot level* • *Development of a cost-benefit model – preparation of concept for calculating efficiency gains (in Excel)* • *Development of a tool (in Access) for easy data extraction from the timesheets and for assurance of data quality* • *Adaptation of developed timesheet template and guidelines for project year 2* • *Pilot testing of adapted timesheet*
Survey report of EUnetHTA Partners/ Associates and Stakeholders	*M12 Sept. 13 – M13 Oct. 13*	• *Writing the interim survey report by WP3* • *Reporting the status and survey results for the European Commission* • *Feedback for all WPs*
Tool usage	*M12 Sept. 13*	• *Reporting the EUnetHTA tool usage (POP, EVIDENT, Core HTA) through the information from the log files (included in the observational report) & from the interview/survey answers* • *Writing the report of the information collected on EUnetHTA collaboration*
Quality assessment process/ deliverables	*M12 Sept. 13*	• *Evaluating the project progress and its timely attainment of milestones, deliverables, etc. (from observations and through structured interviews with LPs/Co-LPs – for quality assurance)* • *Reporting the process of qualitative assessment*
Interim report of 1st project year	*Delivered in M15 Dec. 13*	• *Survey report: methods, partners, stakeholders* • *Observational report (tools, surveys)* • *Quality report (LP/Co-LP interviews)* • *Internal review (by APs: NETSCC, GYEMSZI, and CP: SNHTA)*
Administrative tasks	*M13 Oct. 13*	• *Financial statement* • *Incl. delivery of timesheets per person, personnel salary costs, travel expenses, …*

Main results of Project Year 1 (I):

- ***Response rate of surveys***
  - *Partners' survey: 47% overall response rate (n=199 respondents),*
  - *Stakeholders' survey: 47% overall (n=9 respondents completed the survey, out of 19 Stakeholder Forum organisations)*

Results

- *Experience and attitudes*
  - *Partners learn to work together and produce in common within this project*
- *Report results differ by evaluation methods*
  - *Higher observed productivity than estimated and expected according to the survey answers (variations between observations vs. survey answers)*
- *Different views / focus reported*

- *Productive members: → report difficulties with resources*
- *Supporting members: → report project management aspects*
- *Stakeholders: → believe in achieving the goals*

Main results:

Collaborations & working together

- *WP tasks are mainly in time and according to the workplan*
- *Working together and operating as a network is successful → high willingness to contribute and collaborate together*
- *Positive expectations and feedback about the collaboration from partners*
- *The proposed activities in HTAs (pilots & national transfer) are achieved*

Measurement of real productivity in WP4, 5:

- *1 WP5 pilot (rapid assessment, Strand B) already published from JA2*
- *1 HTA Core in process from JA2*

Quality assurance process – information on activities of WPs (LP/Co-LP interview)

Observation of activity (attendance in e-meetings, f-t-f meetings)

- *Exec.Comm. meetings: 77-100% attendance rate (of Exec.Comm. members)*
- *SH meetings: 9-17 (47-89%) attendees/organisations (with a participation rate of 33-50% mainly industry)*

WP3 Plan for Stakeholder involvement:

2nd Project year (2013/14):

- *Stakeholder Survey*
  - *Answer WP3 survey of the EUnetHTA Stakeholders*
  - *M18 March 2014 - M19 April 2014 (preponed new deadline – instead of M19-M20)*
  - *Start of survey before the Plenary Assembly meeting*
  - *Comment on transparency and easy reading of correct details in the WP3 documents submitted to the Stakeholder Forum review*

Challenges in project year 1:

- *Administration: The overlap of JA1 and JA2 for 3 months was challenging*
- *Coordination: Unexpected time-extend in creating the 3-year workplan*
- *Technical challenges in using different IT software versions on an international level (Excel timesheet, SABA dropouts etc.)*
- *Challenges to provide a full-functioning timesheet*
- *Low survey-participation → room for improvement*

Outlook:

- *No further overlap of JA1 and JA2*
- *Workplan is finalised*
- *Higher awareness of different international software versions & IT challenges*
- *Adapted and improved timesheet version is already available*

- *WP3 is currently working on 2nd survey – additional reminder during PA meeting*

SEED - Multi-HTA Early Dialogues

Francois Meyer (HAS) presented the Stakeholder Forum for an update on SEED.

SLIDES:

EC Call for tender 2013:

- ***In addition to EunetHTA EDs***
  - *At least 10 EDs : 7 drugs and 3 medical devices*
  - *Conducted by a consortium of at least 10 HTA organizations*
- ***Consortium selected by the Commission***
  - *Call for tender published (April), deadline for submission (June), Selection by Commission (August), Contract signed (October).*
- ***Selected project : SEED consortium***

SEED consortium Additional EDs (2014):

SEED: Shaping European Early Dialogues

- *HAS (lead) + 13 partners*
- *Regulators, payers, patient representatives as observers.*
- *Sustainable process to put in place, including collaboration with EMA*
- *Kick-off meeting (D1): October 21, 2013*
- *Preliminary work : procedures and templates for Briefing Books (medicines, MDs)*
- *All EDs in 2014, interim report after 5 EDs*

Scenarios to test

- *Independent advice and*
- *Parallel EMA-HTA advice*

- *Model for permanent ED activity to be proposed*

SEED consortium - Call for expression of interests:

- ***Selection of candidates - criteria:***
  - *Advice to be **prospective** in nature, requested before the start of pivotal clinical trial before the phase III for medicinal products;*
  - *Before or after exploratory/proof of concept/performance trial for medical devices;*
  - *Already available clinical data should be presented;*
  - *A health technology should be supposed to have an **added benefit***

- ***Will stay open until October 2014***
- ***If more than 10 requests fulfilling the criteria: vote by SEED partners***
  - *Reserve list of HTs to be used if one of the scheduled EDs cancelled*
  - ***Date of expression of interest will be taken into account***
- ***Published on several websites including EUnetHTA, EMA, HAS, etc.***

SEED consortium - Procedure:

- ***Topics to be covered :***
  - *Relative clinical effectiveness and cost effectiveness*
  - *Briefing book template for drug already published, for MD to be published soon*
- ***Procedure***
  - *Derived from the EUnetHTA procedure*
  - *Improvements to be proposed based on analysis of survey results: ongoing*
  - *To be discussed and adopted by SEED partners*
- ***Free of charge for companies***
- ***Dates of the meetings: April - December 2014/ beginning 2015***
  - *Timetable for briefing book submission in 2014 published*

Early dialogues/Scientific advice - Permanent model:

- ***EMA/HTA and multi-HTA EDs***
  - *Useful initiatives, may be optimised*
- ***Several scenarios within the EC call for tenders***
  - *Pros and cons for each scenario*
  - *Survey results after each ED to improve the following one*
- ***Towards a parallel EMA – EUnetHTA advice?***
  - *SEED results*
  - *Will depend on all actors views*
    - *HTA bodies – EUnetHTA*
    - *EMA (drugs)*
    - *Companies*
    - *Payers?*

Key comments and discussion / decision points:

- It was a question whether or not the outcome of SEED would be shared with the EUnetHTA Stakeholders and it was confirmed by HAS, that there will be a lot of interaction with the Stakeholders.

- There will be 3 Early Dialogues with medical device industry in SEED, and there is already contact with potential participants from the medical device industry, but further input from stakeholders is welcomed. As medical device industry is willing to provide input to improvement of Early Dialogues for the medical device industry; past and current initiatives will be pooled together and different models and opportunities will be discussed in coherence. In this way experiences from EUnetHTA and SEED will be linked together. Details, format and requirements between SEED and EUnetHTA should be taken into considerations before final format and proposal for an activity in the future can be put forward.

- There was a question if the process for the Early Dialogues in SEED would be the same as for the Early Dialogues in EUnetHTA in terms of responsibility for taking the minutes of the discussion and it was asked whether or not observers from Patients and providers could participate. SEED is exploring the round table option with observers and the participating company, but nothing has been decided yet. The minutes will for the time being be drafted by

the company. After each Early Dialogue there will be a small evaluating report focusing on areas of improvement.

3. EUnetHTA and HTA Network

- **Update on recent developments and interaction**

Julia Chamova (DHMA, EUnetHTA Secretariat) updated the Stakeholder Forum on the EUnetHTA's input to the efforts in developing the Europena cooperation on HTA.

SLIDES:
EUnetHTA's input to the EU cooperation on HTA (Oct-Dec 2013)

- *October 16, 2013 – 1st meeting of the HTAN, Brussels*
  - *EUnetHTA confirmed to ensure the scientific and technical cooperation on HTA in Europe (until the end of JA2, ie, end of 2015)*
  - *Input to the RoP, Work Plan*
- *WG "Long-term provisions for EU cooperation on HTA" (Dec 9, 2013 – 1st meeting)*
  - *EUnetHTA will provide input to the Position Paper*
- *Cooperation with the HTAN on the EUnetHTA Conference HTA 2.0 Europe (October 30-31, 2014, Rome)*
  - *HTAN will hold its 3rd meeting on October 29, 2013 in Rome*
- *Page on EUnetHTA and HTAN on the EUnetHTA website:*
  http://www.eunethta.eu/eunethta-and-htan

Flora Giorgio (DGSanco/HTA Network Secretariat) presented the Stakeholder Forum with the updates from the HTA Network.

SLIDES:
EU Cooperation in HTA – today:

- *HTA Network (art 15 Directive 2011/24)– strategic level (1st meeting 16 October 2013) →MS representatives (mainly MoH); stakeholders associated*
- *EUnetHTA (Joint Action HP)– scientific level – on-going until October 2015 → HTA doers (mainly HTA Agencies) + SAF*
- *Two levels in synergy and complementary*
- *Involvement of stakeholders - both @ strategic level and @ scientific level*

HTA Network 1st meeting 16 October 2013:

- *Adoption of MWP (2014-2015)*
- *Agreement on stakeholders as "observers"// directive 2011/24*
- *EUnetHTA as the scientific/technical cooperation mechanism to complement the HTAN*

1st Meeting WG on "long term provision" – 9 December:
13 MS : Austria, Belgium, Croatia, Finland, France, Germany, Italy, Netherlands, Lithuania, Luxemburg, Portugal, Spain, United Kingdom + EUnetHTA

- *Scope and overall content of the documents discussed*
- *Objective: to have a clear common vision, while respecting diverging appetites for cooperation*

HTAN - MWP 2014-2015 – Content

- *Adoption of a long term vision on HTA cooperation and priorities for next phase of scientific cooperation (JA 3)- planned Oct 2014:*
  - *Scope of technologies (pharma, MD, interventions)*
  - *Scope of HTA: clinical versus other domains*
  - *Scope of interventions (from single technologies to micro/ intermediate/ macro issues)*
  - *Sustainable and cost/ effective cooperation mechanism*
  - *Reflection paper on conditions to facilitate take up and re-use at national level of joint HTA production including information and joint assessments →adoption in 1st half 2015*
    - *Lessons from EUnetHTA pilots*
    - *Lessons from WP3 on cost/ effectiveness of the process*

        - *More "pilots" in the next phase of scientific cooperation*

    - *Reflection paper on synergies between HTA and regulatory process → 2nd half 2015*
      "Life-cycle approach"; Defragmentation; cost-effectiveness. To be reflected in the vision paper
        - *EUnetHTA pilots on early dialogues*
        - *EMA early dialogues with HTA bodies*
        - *EC funded tender "SEEDS" 10 pilots on early dialogues (pharma + MD)*
        - *EMA-EUnetHTA Joint workplan*

EC/MS policy developments and actions relevant to HTA:

- *Pharmacovigilance: cooperation with regulators/* ***upstream***
    - *Delegated Act on PAES*
    - *Future Joint Action on Pharmacovigilance*
- *Network of Competent authorities for Pricing and Reimbursement: cooperation* ***downstream***
    - *Pilots on MOCA for OD*
- *Clinical Trials Directive – political agreement – improved access to summary CT reports*
- *Medical devices regulation – negotiations ongoing*

Conclusions:

- *New phase of EU cooperation on HTA → doing versus agreeing on …*
- *Share common vision between MS → reach out to stakeholders*
- *"Life cycle approach": increase synergies/ defragmentation → greater integration between different actors*
- *Build on achievements → prepare the future*

Key comments and discussion / decision points:

- Stakeholders are involved in both EUnetHTA and the HTA Network. - What stakeholder involvement in EUnetHTA and the HTA Network will look like in the post-2015 phase needs to be developed, and stakeholders were encouraged to provide input to this development.

- The joint work is entering an acceleration phase as a result of the work for the last 10 years driven by EUnetHTA, and the focus is now on concrete, practical cooperation between Member States. Remaining assumptions on practical cooperation will now be validated through developments of pilots and the national uptake of the pilots' results.

- The HTA Network has been established to complement the work done at the scientific and technical level with the efforts to be undertaken at the strategic and policy level; it was reported by the HTA Network that at its first meeting there had been a very positive attitude of the Member States about the cooperation. By October 2014 there should be a clear picture of what the Member States wish to work on. It was agreed that the HTA Network would share the timeline for the development of the "Long-term provisions for EU cooperation on HTA" document.

  Action Points: HTA Network Secretariat to share with the SF the timeline for developing a document on long term provisions for EU Cooperation on HTA.

- **Open discussion: EUnetHTA contribution to the HTAN 'Position Paper'**

SLIDES:
Open discussion: EUnetHTA contribution to the HTAN 'Position Paper':

- *SF's comments and views to contribute to the EUnetHTA input to the position paper*
    - *With a view of EUnetHTA's role as* ***the scientific and technical*** *cooperation on HTA in Europe*
    - *SF is a part of the current EUnetHTA structure*

Possible questions:

- *Needs of the scientific and technical cooperation expressed towards the political level?*
- *How to ensure the long-term (2016-2020) synergistic functioning of the political cooperation and scientific & technical cooperation to meet the objectives of the Directive 2011/24/EU Article 15?*

SF involvement in developing the EUnetHTA input – practicalities:

EUnetHTA will follow the timeline for the position paper development as per the HTAN Secretariat

- SF members are welcome to share their considerations (both collective views and individual SF members input) with EUnetHTA (via the EUnetHTA Executive Committee) specifically focusing on the long-term (2016-2020) functioning of the scientific and technical cooperation

***Timeline**:*

- *from now until **February 4, 2014, 10:00am CET** (send to eunethta@sst.dk)*
- *The EUnetHTA input will also be further discussed at the PA meeting on April 10-11, 2014 where SF Co-Chair+team are invited to attend*

Key comments and discussion / decision points:

- The EUnetHTA Secretariat highlighted the fact, that in the process of commenting on the position paper it would be important for the Stakeholder Forum members to keep the focus on the needs of EUnetHTA and the stakeholder participation at the scientific and technical level. The Directive 2011/24/EU is formally implemented with a dyad of policy and science/technical levels; stakeholders constructive input to the implementation process should consider this dichotomy in order to move it forward synergistically.

- The Stakeholder Forum members expressed their concerns about their possibility to communicate and interact with the HTA Network. In the first meeting the Stakeholders were invited to a debriefing but with time they would like to be part of the discussions.

- The EUnetHTA Secretariat informed the Stakeholder Forum, that the EUnetHTA SF meetings should focus on EUnetHTA issues and as such cannot be used for long discussions on HTA Network issues. However, the Secretariat will look into changing the meeting format so more time can be allotted for discussions of strategic issues like the HTA Network. Further, EUnetHTA Secretariat extended the possibility of using the SABA e-meeting facility to the Stakeholder Forum for organising meetings between the stakeholders for their purposes of contributing to the HTA Network developments.

- It was further decided that the Stakeholder Forum could share their collective but also individual member views on the draft position paper both to EUnetHTA and the HTA Network - following the timeline given by the HTA Network Secretariat.

- It was agreed that the HTA Network would share the timeline for the development of the Long term provision document.

  ***Action Point*:** HTA Network Secretariat to share the Long term provision for EU Cooperation on HTA timeline with the SF

  ***Action Point*:** Stakeholder Forum members to share input to the draft position paper before 4 February with the EUnetHTA Secretariat and the HTA Network Secretariat.

***Action Point*:** EUnetHTA Secretariat to explore provision of practical solutions to support strategic discussions among SF members (eg, e-meetings) and make more room in the SF meetings for discussions of strategic issues such as general European cooperation on HTA issues in the EUnetHTA meetings.

4. EUnetHTA Conference HTA 2.0 Europe – Stakeholders input

Julia Chamova (DHMA, EUnetHTA Secretariat) presented an update on the early preparations for the EUnetHTA conference to be held in Rome 29-30 October 2014.

SLIDES:
Objective:

- *To present a draft programme structure and content*
- *To provide an opportunity for the SF to give initial comments on the structure/format and content of the conference*

***Conference Keywords** (sense of "what, why and how" in HTA 2.0 Europe):*

Data, Standards, Sharing, Inclusion, Networking, Interaction, Collaboration, Action/implementation,

EUnetHTA achievements, HTA developments, Science, Policy, Decision-making,

Change, Sustainability, Value, Future

Collaborative leadership

Conference Objectives:

- *To present and discuss EUnetHTA's work in progress and achievements in a larger and more complex/multi-layer/multi-faceted (geographically, content-wise, etc.) context of the current developments in HTA, regulation, health policy/decision-making with the view to the future =* ***HTA 2.0***
- *To outline and further explore ways of collaborating with external (to EUnetHTA) parties, eg, FP7/Horizon 2020 programmes and research projects, EMA, relevant European Joint Actions, etc bringing insight from the contributing to HTA fields =* ***HTA 2.0 Europe***
- *To bring forward a positive pragmatic approach of "working concertedly together" going beyond the immediate EUnetHTA network partners/associates =* ***Teaming Up***
- *To facilitate action-oriented focus on value for all involved – and ultimately for the patients* ***= For Value***

Conference Target Groups and Speakers:

Target Groups:

1. *Health technology assessors (Europe and globally) and those consulting on HTA*
2. *Technology producers*
3. *Health policy makers (national/regional)*
4. *Wider stakeholder community (patient organisations, healthcare payer and provider organisations)*

Speakers (tbc):

EUnetHTA WPs, Stakeholder Forum; DG SANCO; EMA; DG RTD; National/Regional policy makers (2nd half 2014 – Italian EU Presidency); Committee on Medical Devices; Network of Competent Authorities for Pricing and Reimbursement; relevant FP7 projects and EU JAs;

Conference Organisation:

Organising Committee:

- *EUnetHTA Secretariat, AGENAS dedicated staff members, Conference Bureau Project Leader (and a team)*
- *Daily management of preparation for the conference*

Programme Committee:

- *Pragmatic approach/ advisory function: to suggest themes, ensure coherence of the whole programme and its meeting the objectives of the conference, assisting with identifying appropriate speakers, debate moderators, etc*
- *PA Chair, EUnetHTA Secretariat, 3 Executive Committee members (HAS, CVZ, NOKC), Commission representative*

- *The Executive Committee to be informed on the work of both committees. Has the final word on the content of the conference.*

Programme draft structure, format and content:

Pre-conference events – October 29, 2014 (Wednesday):

Time	***Event***	***Comments***
XX-XX	*EUnetHTA Training for Stakeholders*	*Organised by WP2*
XX-XX	*3rd HTAN Meeting*	*Organised by the European Commission*
XX-XX	*EUnetHTA Community of Practice meeting*	*Organised by WP2*

Open to the invited participants only

Programme draft structure, format and content

Day 1 – October 30, 2014, 8:00-17:00 (17:00 – social event):

Time	***Event***	***Comments***
8-9am	*Registration*	• *Limited on-site registartion* • *Conference fee (differentiated; early fee)*
9-1.30pm	• *2-3 sessions with individual presentations, presentations and panel discussion; moderated Q&A with the audience* • *Networking coffee break – EUnetHTA Activity Stations (eg, Rapid assessments, Full HTAs, Early Dialogues, Methodological Guidelines, etc)*	• *Introduction to 2.0 and HTA 2.0 concepts* • *Example of topic: Current developments in the interface between HTA, research, regulation, health policy making and technology development to deliver value to the patient: individual perspectives* • *Stakeholder Forum speaker on at least one occasion*
1.30-3 pm	*Networking Lunch*	• *Interaction at the EUnetHTA Activity Stations and possible specially organised access to speakers*

3-5 pm	• *Moderated debate* • *Getting an effective technology from the lab to the patient in Europe: Controversies, opportunities and concrete action steps: regulation, HTA, national priorities and technology developers' challenges – how can we effectively collaborate* • *Summation of Day 1 and laying out highlights of Day 2*	• *HTA, regulation (pharma and medical devices), national priorities/processes, technology developer/producer (industry) perspective* • *Audience involved at some stage of the debate*
5- 7 pm	*Networking Event*	• *Focus on providing an opportunity for informal interaction*

Day 2 – October 31, 2014, 9:00-14:00 (15:00?)

Time	***Event***	***Comments***
9-11 am ***12- 2 (3) pm***	• *2 -3 sessions with individual presentations and panel discussions* • *Networking coffee break* • *Round table discussion* *"Yesterday's lessons for today's action: paving a better road to get an effective technology to the patient- what needs to change to work in an integrated way?"*	• *Focus on tangible outcomes, presentation of case studies: for example, national and regional experiences of appliying eg, EUnetHTA tools and information; EU cooperation/scientific inquiry put into practice and decision-making;* • *Technology producer, regulator, HT assessor, Commission, national payer and/or policy maker perspective, patient perspective*

Key comments and discussion / decision points:

- Having collaborative input in the conference from Stakeholders on how companies experienced participating in pilots was suggested and thought to be a benefitthe.

- The possibility of having Stakeholder Forum members represented on the Conference Programme Committee was raised. The suggestion will be brought forward to the Executive Committee for decision and reported back to the Stakeholder Forum

  Action Points: EUnetHTA Secretariat to present to Executive Committee and look into the modalities of having SF representative in EUnetHTA Conference Programme Committee and participating in the Conference.

5. Other issues and closing of the meeting

- How EUnetHTA reaches groups/experts for input to EUnetHTA activities on EDs, disease guidelines etc?

  SLIDE:
  General approach:
  - *Organised through the identification of the external experts for the involvement in the specific WPs based on the subject matter (input from the LPs)*
  - *Through SAGs and expert meetings*
    JA2 Expert meetings:

*August 29, 2013 – EUnetHTA/EFPI expert meeting "**Development of a manufacturer submission template for pharmaceuticals"***

May 8, 2014 –** EUnetHTA/COCIR, EDMA, EUCOMED expert meeting **on HTA on Medical Devices (agenda in development)

INPUT FROM LPs/Co-LPS….

- JA1 technical report – lessons learned from JA1 and how are challenges tackled by JA2?

Key comments and discussion / decision points:

- In WP5 strand A the way experts are reached is through securing access to national experts organised through the reviewers team comprised of EUnetHTA Partners and Associates – there is no streamlined way in strand A at the moment. It may be difficult to find experts that do not have conflict of interest. In strand B in the first pilots medical experts were involved. For the second pilot the SAG was contacted and one medical reviewer was found this way.

- WP8 does not deal with detailed data on specific technologies but in general and the Stakeholder Forum members are approached to provide expert advice (expectation is that SF can be a contact point to find the expertise if none is immediately available at the SF member organisation) . In public consultations the information is distributed through the website and intranet and this way organisations/experts which could be interested are invited to provide input.

- The Stakeholder Forum members emphasised the difficulty to get the right experts in time and encouraged to have information on upcoming publications on the website so the Stakeholder Forum members can prepare in time and consult and look for the right expertise to be made available.

- The EUnetHTA Secretariat informed the Stakeholder Forum that notes from stakeholder meetings and letters received from Stakeholders will all be used as input to the HTA Network position paper, so there is no need to share what has already been shared in the past and in the JA1.

Action Points: EUnetHTA Secretariat to update the list of public consultations and place it on the Stakeholder Forum area.

#	Action Point	Responsible	Status
1	Timeline for the 'Long term provisions for EU cooperation on HTA' shared with SF	HTA Network Secretariat	Done
2	SF comments on HTAN Position Paper compiled and shared with HTAN Secretariat	EUnetHTA Secretariat	Done. Shared by SF 4 Feb and shared with HTAN before 12 Feb
3	Make more room as appropriate for discussion of strategic (e.g. HTAN) issues in EUnetHTA SF meetings	EUnetHTA Secretariat	Done. New e-meeting structure and preparations piloted in

			e-meeting on 4 March.
4	Explore practical opportunities for strategic discussion among SF members.	EUnetHTA Secretariat	Done. SF offered to use SABA Centra e-meeting system
5	Opening of POP and EVIDENT to SF	EUnetHTA Secretariat	On-going. Update on the agenda for e-meeting 4 March
6	Result of WP7 Survey shared with SF and SAGs	WP7	Postponed
7	SF representative in EUnetHTA Conference Programme Committee	SF	On-going
8	Look into details of SF participation in EUnetHTA conference	EUnetHTA Secretariat	On-going
9	EUnetHTA Secretariat to update the list of public consultations and place it on the Stakeholder Forum area.	EUnetHTA Secretariat	On-going

Participants List

As of January 14, 2014

EUnetHTA Stakeholder Forum

Attendee	E-mail	Organisation
George Yiangou	g.yiangou@aesgp.eu	**AESGP (Association of the European Self-Medication Group)**
Irina Odnoletkova	irina.odnoletkova@mloz.be	**AIM (Association Internationale de la Mutualité)**
Ilaria Passarani	ipa@beuc.eu	**BEUC (The European Consumers Organisation)**
Nicole Denjoy	denjoy@cocir.org	**COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry)**
Jacques de Haller	jdehaller@bluewin.ch	**CPME (Standing Committee of European Doctors)**
Karsten Berndt	karsten.berndt@roche.com	**EDMA (European Diagnostic Manufacturers Association)**
Andrea Rappagliosi	arappagliosi@spmsd.com	**EFPIA (European Federation of Pharmaceutical Industries and Associations)**
Isabel Klinnert	iklinnert@egagenerics.com	**EGA (European Generic Medicines Association)**
Liuska Sanna	liuska.sanna@eu-patient.eu	**EPF (European Patients' Forum)**
Christina Dawson	christine.dawson@esip.eu	**ESIP (European Social Insurance Platform)**
Rosa Giuliani	RGiuliani@scamilloforlanini.rm.it	**ESMO (European Society for Medical Oncology)**

Pascale Brasseur	pascale.brasseur@medtronic.com	**EUCOMED (Medical Technology)**
Paolo Morgese	pmorgese@deerfieldpartners.com	**EuropaBio (European Association of Bioindustries)**
François Houÿez	francois.houyez@eurordis.org	**EURORDIS (European Rare Diseases Organisation)**
Isabella Notangelo	eco@hope.be	**HOPE (European Hospital and Healthcare Federation)**

EUnetHTA Executive Committee

Attendee	E-mail	Organisation	Country
Marina Cerbo	cerbo@agenas.it	**Agenas (Agenzia Nazionale per i Servizi Sanitari Regionali), *WP4 LP***	Italy
Wim Goettsch	wgoettsch@cvz.nl	**CVZ (College voor zorgverzekeringen), *WP5 LP***	The Netherlands
Finn Børlum Kristensen **Julia Chamova** **Anne Raahauge** **Julie Lange**	fbk@sst.dk juch@sst.dk araa@sst.dk jula@sst.dk	**EUnetHTA Secretariat (Danish Health and Medicines Authority), *WP1 LP***	Denmark
Francois Meyer	f.meyer@has-sante.fr	**HAS (Haute Autorité de Santé), *WP7 LP***	France
Sonja Scheffel	Sonja.scheffel@hvb.sozvers.at	**HVB (Hauptverband der Österreichishen Sozialversicherungsträger), *WP3 LP***	Austria
Alric Rüther	Alric.ruether@iqwig.de	**IQWIG (Institute for Quality and Efficiency in Health Care), *WP7, co-LP***	Germany
Patrice Chalon	patrice.chalon@kce.fgov.be	**KCE (Belgian Health Care Knowledge Centre), *WP6 LP, WP2 Co-LP***	Belgium

Anna Nachtnebel	Anna.Nachtnebel@hta.lbg.ac.at	**LBI-HTA (Ludwig Boltzmann Institut für Health Technology Assessment), WP5 Co-LP**	Austria
Marianne Klemp	marianne.klemp@kunnskapssenteret.no	**NOKC (Norwegian Knowledge Centre for the Health Services), *WP2 LP***	Norway
Kristian Lampe	kristian.lampe@thl.fi	**THL (National Institute for Health and Welfare), *WP8, LP***	Finland

European Commission – DG SANCO

Attendee	E-mail	Organisation
Flora Giorgio	Flora.giorgio@ec.europa.eu	**DG SANCO, European Commission**

APOLOGIES received

- AAZ, Croatia
- AHTAPol, Poland
- NICE, United Kingdom
- EMSP (European MS Platform)