EUnetHTA Joint Action 2
Stakeholder Forum meeting

September 17, 2013, 13:00 – 15:00 CET
E-meeting
Organised by EUnetHTA Secretariat
Danish Health and Medicines Authority, Denmark

Participants:
Meeting Chair: Julia Chamova, DHMA, Denmark, EUnetHTA Secretariat

Stakeholder Forum Representatives:

Andrea Rappagliosi, EFPIA
Christian Peters, ESIP
Christine Dawson, ESIP
Constance Colin, CPME
Edith Frénoy, EFPIA
Frank Bongers, EGA
Francois Houÿez, EURORDIS
George Yiangou, AESGP
Ilaria Passarani, BEUC
Isabel Klinnert, EGA
Karsten Berndt, EDMA
Liuska Sanna, EPF
Panagiotis Petrou, HIO
Paolo Morgese, EuropaBio
HTA team-SAG members, EUCOMED
Rosa Giuliani, ESMO

EUnetHTA Executive Committee Representatives:
Alric Rüther, IQWIG
Anna Nachtnebel, LBI
Anne Raahauge, DHMA, EUnetHTA Secretariat
Claudia Wild, LBI
Elisabeth George, NICE
Ingvil Saeterdal, NOKC
Irena Guzina, HAS, France
Kristian Lampe, THL
Marianne Klemp, NOKC
Marina Cerbo, Agenas
Mathias Christiansen, DHMA EUnetHTA Secretariat
Mira Pavlovic, HAS, France
Mirjana Huic, AAZ
Nicola Vicari, Agenas
Sarah Kleijnen, CVZ
Sonja Scheffel, HVB

European Commission
Flora Giorgio, DG SANCO

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)

3. EUnetHTA Expert meetings
- a. Proposed meeting with the medical device industry

4. Discussion of the implementation of Co-Chair function in the Stakeholder Forum

5. Permanent EU cooperation on HTA
- a. EUnetHTA
  - i. Update and RoP
- b. HTA Network (DG SANCO)
  - i. Stakeholder representative for HTA Network meeting

6. EUnetHTA training – can we expand beyond patients and providers?
- *a.* EUnetHTA trainings to SMEs

7. EUnetHTA Conference Rome 2014 (October) – update

8. Reporting of EUnetHTA JA2 Year 1 – SF input

9. Procedural issues
- a. Availability of presentations during e-meetings and circulated to the SF
- b. Status of SAGs of remaining WPs
- c. SAG consultation – harmonization of consultation methods across WPs
- d. Relation between public consultations and SAG consultation

B. Other issues

1. Update on status of JA1 report
2. Registration of time spend on EUnetHTA – clarification
3. Next EUnetHTA Stakeholder Forum Face-to-Face meeting – January 2014, Brussels (Tentatively 15 January, in connection with WP2 Stakeholder trainings).
4. Next EUnetHTA Newsletter issues – October 1, 2013 (deadline for input – Sept 20, 2013)

Julia Chamova, DHMA, Denmark, EUnetHTA Secretariat welcomed everybody to the meeting and informed the meeting that the Chair Mr Bert Boer (CVZ) was not able to attend the meeting due to sickness.

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 (DHMA, EUnetHTA Secretariat) presented a short overview of actions points from the last meeting and their status. For future meetings, the draft action point report will be shared along with the draft agenda. WP's and Stakeholders are requested to review the report and inform the secretariat on the status of the relevant action points - the final version will be distributed together with the final agenda.

#	Action Points	Responsible	Deadline
1	*All Stakeholders are to create an account on EUnetHTA public website and indicate to the secretariat that they wish to be part of the Stakeholder Forum area on the EUnetHTA website*	*Stakeholders*	*On-going – only 14 accounts created out of 24 main contact persons*
2	*Secretariat to follow up with WP2 on the lack of response to EPF*	*Secretariat*	*Clarification on-going*
3	*Stakeholders to reply to the WP3 Survey*	*Stakeholders*	*June 30, 2013* *Done - 47% response rate*
4	*WP8 LP to send a draft HTA Core Model Policy for commenting by the WP8 SAG*	*WP8 LP*	*Done. Send out 4 June*
5	*Edith Frenoy (EFPIA) will send a note on the stakeholder groups ideas and comments on the Co-Chair function to the secretariat for further work.*	*EFPIA*	*Done – issue is on the agenda of the e-meeting 17 September*

2. JA2 WP updates (including JA2 SAG activities update)

WP7

Mira Pavlovic (HAS) gave an update on the activities of WP7 SG1. SG1: activities of the early dialogues (EDs) are close to completion. SG2: A survey (to capture experience with the performed EDs and lessons learned to guide improvements in the ED process in the future) has been sent to all participating HTA organisations and all participating companies.

SLIDES:

WP7 SG1 ED Update

Activity	Due date / Milestone	Status
4 new ED pilots (different disease areas)	*Jun'13 – Sept 13*	*Finished*
2 ED pilots	*Nov 13*	*Procedure started*
Survey on the pilots targeted to HTA organisations and companies which participated the ED pilots	*Sept-Oct 13*	*Questionnaire (45 questions) sent to organizations mid Sept.*

***In addition to EUnetHTA ED**, to facilitate the continuation of the ED process*

- *At least 10 EDs (7 drugs and 3 MD) with at least 10 HTA organisations*
- *Consortium formed by HAS+ 14 HTA partners selected*
- *Timetable (?):*
- *Preliminary work: Sept. – Dec. 2013*
- *ED meetings: 2014*

WP7 SG1 DSG Update

Activity	***Due date / Milestone***	***Status***
4 new ED pilots (different disease areas)	*June '13 – Sept 13*	*Finished*
2 ED pilots	*Nov 13*	*Procedure started*
Survey on the pilots targeted to HTA organisations and companies which participated the ED pilots	*Sept-Oct 13*	*Questionnaire (45 questions) sent to organizations mid Sept.*

Upcoming WP7 SAG involvement

Activity	***Timing***	***Type of input***	***Info from SAG to be used for…***
SG1 *Early dialogue (ED) process* *Results of survey to be presented* *Review of draft consolidated procedure for ED for drugs and non drugs* *Disease specific guideline on osteoarthritis* *Review of the draft of guideline*	*Begin. 2014** *Mar. 14 – Jun. 14 ** **depending on timetable of the EU call for tenders for ED* *May 14- Jun. 14*	*Expert meeting (or e-meeting)* *Comments* *Comments*	*Improvement of procedure* *Improvement of procedure* *Improvement of document*

Irena Guzina (HAS) gave an overview on the activities of WP7 SG2.

SLIDES:

WP7 SG2 Update

Activity	***Due date / Milestone***	***Status***
First survey on the possibilities and conditions for performing harmonised ADC	*M10 - July '13*	*survey circulated in July to all EUnetHTA partners, some responses still awaited* *- analysis of received responses ongoing*
Development of the first draft of guidelines/position paper on How to best formulate a research question and How to decide on the appropriate trial design	*M17 – Feb '14*	*Initially scheduled for September, the activity will begin as soon as the analysis of the results of the survey is finished (in October at the latest)*
Maintaining EVIDENT database	*-*	*Updated version released in September 2013*

Activity	***Timing***	***Type of input***	***Info from SAG to be used for…***

SG2 Choice of a common technology of interest for the pilot core protocol for Additional evidence generation *(One of the objectives of WP7 SG 2 is to* *study and set-up possibilities for* *collaboration on additional evidence* *generation (further to initial HTA) through* *a pilot of a common core protocol.)*	*- Response forms will be sent in November '13 (by HAS)* *- Approximately 2 weeks response time* *(HAS will inform the SAG on the exact dates mid-October)*	*SAG will be asked to suggest 3 technologies of interest for the pilot protocol*	*the creation of a consolidated list of technologies to be selected for the pilot*

Alric Ruether (IQWIG) gave an overview on the activities of WP7 SG3.

From slides:

WP7 SG3 Update

Activity	***Due date / Milestone***	***Status***
Elaboration of new general methodological guidelines	*M15 – Dec´13*	*Since May 2013 three guideline teams are at work in the first of two consecutive elaboration cycles:* *Internal validity of non-randomised studies (NRS) on interventions* *Meta-analysis of diagnostic test accuracy studies* *Economic evaluations* *Initial concept phase finished, drafting of 1st guideline versions is work in progress, minor delay for guideline on economic evaluations* *Missing first author for guideline on personalised medicine (2nd batch 2014-15) identified (OSTEBA)* *Collaboration achieved in June with FP7 Research Project MedtecHTA concerning Medical Device guideline (2nd batch 2014-15)*
Review of existing JA1 methodological guidelines	*-*	*Ongoing phase of practical experience in using the JA1 guidelines for the REA work in WP4 / 5*
Process description for the future methodological guideline elaboration and maintenance in EUnetHTA	*M36-Sep 14*	*Continuous work on a SG3 working manual (internal consultation October 2013); working manual will be the basis for the final process description at the end of JA2*

Elisabeth George (NICE) gave an overview of the activities of WP7 SG4 and the Expert meeting held with EFPIA:

From slides:

- *Aim of WP7 SG4: to develop a submission template that includes the evidence requirements from European HTA organisations and reflects the HTA Core Model, to support production of core HTA information and rapid assessments.*
- *Could be used to support national HTA processes in European countries, and where appropriate, joint assessments.*
- *Starting point: <u>all</u> current national evidence requirements across Europe*
    - *Establish all national evidence requirements: 33 countries contacted, 27 provided enough information in English*
    - *Analysis how the evidence requirements are reflected in the CORE model*
- *EUnetHTA has no authority to stipulate the use of a submission template by any national agency, or that any national agency must adapt their existing practice in any way.*
- *Feedback on the REA model and the pilots*

Current national evidence requirements

- *Requirements vary*
    - *Specific vs general*
    - *Size/ quantity*
    - *Content*
- *How much guidance given*
- *How safety and clinical effectiveness are considered*
- *Interpretation/conclusion*
- *Domain 1+2: similar to CORE model*
- *Domain 3+4: different from the CORE model*

Proposals for submission template

- *EUnetHTA Proposal: taking into account the evidence requirements of national agencies and the structure of the CORE model domains introducing modules and questions, with a modification of the structure for domain 3 + 4 to reflect what countries are actually asking for.*
- *EFPIA Proposal: much shorter template, making use of the overlap between regulatory and HTA submissions and focussing on REA issues only*

Breakout group discussions

1. *'Guidance' provided by national agencies for filling out submission templates varies (guidance in the actual template, separate documents, additional in handbooks manuals).*
2. *'Interpretation': Agencies tend to request an interpretation of the available evidence that takes into account benefits and harms and issues of internal validity and representativeness.*
3. *'Focus on safety': CORE model has a strong focus on safety but only very few national agencies ask detailed safety questions. The CORE REA model has fewer safety assessment elements than the full CORE model, but even REA includes assessment elements that are not included in the national requirements.*

Next steps

- *For the piloting: focus on all evidence requirements from national agencies related to REA only, and exploring in how much information prepared for regulatory submissions can be re-used*
- *For final submission template (to be consulted in 2014): to include all information requested by national agencies*

Key comments and discussion / decision points:

- The guidelines developed in WP7 SG3 are the methodological guidelines, which should be the background for the activities in the Core Model. The aim of the guidelines is to give advice on the quality of the content.

- EFPIA thanked EUnetHTA and NICE for a well-planned and organised meeting and a thorough reporting. The meeting demonstrated that sharing the work and working on a common understanding across various constituencies will improve the Core Model and submission template tools and avoid duplication in work. WP7 has with this meeting paved the way for ensuring a collaborative success of EUnetHTA.

- On the timing of three methodological guidelines for SAG consultation, Julia Chamova stated that SAG's should be operational by October, and will be involved according to the JA2 3-yar work plan.

ADDITIONAL QUESTIONS (and ANSWERS) TO WP7 SUBMITTED THROUGH THE TEXT CHAT:

1) **Q:** What is the role of guidelines in comparison to the EUnetHTA Core Model?
   A: The methodological guidance within HTA Core Model can link/point to WP7 guidelines whenever relevant
2) **Q:** About early dialogue WP7: is it envisaged that clinicians and patients' representatives will participate as provided for in the CAVOMP-information flow (Clinical Added Value Orphan Medicines Products - Information Flow)?
   A: In the framework of early dialogues supported by the European Commission, there will be a possibility for patient representatives to be involved as observers according to the disease area.
   Clinicians are already involved as experts on the as needed basis to support HTA bodies representatives in the up to date knowledge of a disease and its treatment.

WP5

Sarah Kleijnen (CVZ) presented an overview of the WP5 activities

SLIDES:

Overview of activities:

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: Finalised with 1 month delay due to the possibility of EMA involvement and consultation (finalised in May 2013)* • *Strand B: Finalised in April 2013*

Discussion and evaluation of on-going pilots at f-t-f meeting in Vienna	*M9: Jun '13*	*This Milestone should be changed from M9 to M14 as the f-t-f meeting in Vienna will be held in November 2013.*
Discussion and evaluation of on-going pilots at f-t-f meeting in Helsinki	*M21: Jun '14*	*Expected delivery on time*

Update of pilots Strand A

Pilot nr.	***Compound***	***Status/Clarification***
1.	*Herpes zoster vaccine (Zostavax®)*	*o Finalisation of report (published by mid-September).* *o First evaluation: Timelines were overall manageable but a very resource intense process due to technical issues with the shared use of word documents and the multiple layer structure of the REA Model*
2.	*Canagliflozin (Invokana®), for the treatment of diabetes mellitus*	*o Scoping phase completed* *o Further progress and start of assessment phase postponed due to delayed pending CHMP decision*
3.	*Next pilots:*	*- topic for end of 2013: author/co-author established, submission file requested from MAH.* *- 2 topics that could start beginning of 2014: authors recruited, MAH to be contacted*

Claudia Wild (LBI) updated the SF on the pilots of strand B.

Update of pilots Strand B

Pilot	***Topic***	***Status/Clarification***
1.	*Duodenal-jejunal bypass sleeve (EndoBarrier®) for the treatment of obesity with or without Type 2 diabetes mellitus*	• *Final report available **online** since 9 August 2013 on EUnetHTA Website* *Main challenge: resource intense process due to technical issues with the shared use of word documents and the multiple layer structure of the (results cards, domains, summary)*
2.	*Renal denervation systems for treatment-resistant hypertension*	• *On-going* • *Scoping Phase completed, Project Plan finalised* • *1st draft Rapid Assessment currently compiled by authors and co-authors (to be finalised 4 October)* *Main challenge: Consultation procedures (SAG, public, manufacturers), topic selection*
3.	*Next pilots*	*3rd Pilot Rapid Assessment scheduled autumn 2013 - not confirmed yet*

Stakeholder involvement Strand A

Previous:

- *Stakeholder consultation (SAG) of procedure manual and evaluation forms in March 2013*
- *Marketing authorisation holder: for first two pilots provision of submission file, scoping meeting and consultation of draft assessment for first pilot*

Upcoming Stakeholder involvement:

- *expert meeting in 2014*
- *It is to be explored whether other stakeholders can be included in the scoping and/or consultation phase of the pilots.*

Stakeholder involvement Strand B

Previous:

Stakeholder advisory group (SAG):

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

Manufacturer(s):

- *consultation on draft project plans of first 2 pilots and on first pilot assessment, provision of evidence*

Others:

- *medical experts, patient/consumer representative consultation on first/second pilot assessments*

Upcoming:

- *notification/consultation on further draft project plans*
- *expert meeting in 2014/2015*

Key comments and discussion / Decision points:

- The selection process for the next pilot in WP5 Strand A is done by the Partners through a process of prioritisation; EUnetHTA does not currently have any Marketing Authorisation Holder volunteering for a pilot. It is at the moment a challenge for WP5 Strand A to get MAHs volunteering for the pilots.

- The topic selection process is focused on the identification and prioritisation of the topics by the WP5 Strand B participating organisations that identify the topic of interest based on their national/regional HTA priorities of research topics that are to support reimbursement decision-making.

- The challenges and lessons learned during Year 1 of JA2 will be on the agenda of the EUnetHTA Executive Committee meeting on Sept 25-26 in Dublin. A meeting dedicated to the HTA Core Model application challenges is scheduled for Nov 2013 for the LPs and Co-LPs of WP4,5 and 8 (Secretariat to organise and lead).

- *Action point:* Within a framework fior cooperation between EUnetHTA and EFPIA, it was suggested to organise a workshop to discuss lessons learned from and investigate effective approaches to recruiting MAHs to volunteer for the next pilots in WP5 Strand A.

- The next WP5 Face-to-Face meeting in November will be devoted to motivating partners to making local adaptations as they are part of the contract.

WP2

Ingvil Sæterdal (NOKC) updated the SF on the activities of WP2.

From slides:

Activity	***Due date***	***Status***
3-year work plan		*Published on EUnetHTA website*
Reporting	*M12-Sep'13*	*Ongoing*
Production of learning material on the EUnetHTA tools and methods	*M16-Jan'14*	*LP have received some learning material from WP5 and WP7* *Learning material for the first training courses (EUnetHTA members and Stakeholders) need to be produced and shared with WP LP.*
Communication strategy	*M9-Jun'13*	*Published on the EunetHTA intranet*

Activity	***Due date***	***Status***
Promotion of national HTA reports based on Core HTA	*M36-Oct'15*	*«Output» on website.* *Work on how to provide a workflow to catch the relevant information from the EUnetHTA members is ongoing.*
E-learning about EUnetHTA tools and methods	*M20-May 14'*	*Discussions within WP2 on which tools to select for e-learning.* *E-learning platform: Use the Intranet and the Saba meeting*
Face-to-face training course	*M13-Oct'13*	*Training course in January 14 (EUnetHTA members) and January 16 (Stakeholders) 2014 in Brussels* *Content **members**: HTA Core Model, POP, EVIDENT, methodological guidelines* *Content **Stakeholders**:* *Brief introduction to EUnetHTA and its Tools* *EUnetHTA HTA Core Model* *How to use HTA for decision making* *EUnetHTA methodological guideline on clinical outcomes* *How can patients' best contribute to the HTA process?*

Activity	***Due date***	***Status***
Support HTA Capacity Building *Identify steps in the learning path on HTA capacity building and education*	*M17-Feb'14*	*Ongoing*
Community of Practice	*M13-Oct'13*	*Planning of a webinar with potential CoP participants is ongoing* *Identification of network members is ongoing*

WP2 Stakeholder Advisory Group (WP2 SAG)

EUnetHTA Stakeholder Organisation	***Name of SAG candidate***	***Position of candidate***
European Patient Forum (EPF)	*Liuska Sanna*	*Programme Manager*
The Standing Committee of European Doctors (CPME)	*Constance Colin*	*EU Policy Advisor*
	Jacques de Haller	*Vice President of CPME, Rapporteur for HTA*
European Society of Cardiology (ESC)	*Giuseppe Boriani*	*Professor of Cardiology, University of Bologna*
European Federation of Pharmaceutical Industries and Associations (EFPIA)	*Would like to be copied in on correspondences.*	
The European Association of Bioindustries (EuropaBio)	*Would like to have a representative included from small and medium sized enterprises (SME).*	
Eucomed – Medical Technology (EUCOMED)	*Pascale Brasseur*	*Director Reimbursement & Health Economics, Medtronic*
	Sophie Cros	*Director Reimbursement & Health Economics, Medtronic, Abbott*
The Association of the European Self-medication Industry (AESGP)	*Prof. Dr. Oec.troph. Eva Münster, MPH*	*Early Benefit Assessment/HTA BAH*
	Dr. George Yiangou	*Economic Affairs, AESGP*

SAG tasks

Stakeholder training in EUnetHTA Tools and methods:

- *January 16, 2014 in Brussels (venue to be confirmed later)*
  - *To comment on the program for the first training course.* ***October****, 2013*
  - *To provide feedback on the learning material that will be used for the first training course.* ***November, 2013.***

Key comments and discussion / Decision points:

- The focus of the training will not be on the design of the studies that are used by HTA, it is a more broad focus on the HTA process as such.

- The number of trainees will be limited to 20 people in total, 10 from the providers group, 10 from the patients group. The focus on the training will be on the broader HTA process. However, if seats becomes available other stakeholder groups especially SMEs will be invited to participate.

  Action Point: WP2 to follow up and inform other Stakeholder Groups about potential vacant seat in the Stakeholder trainings.

COMMENTS FROM THE TEXT CHAT:

- Programme and practical information on the training courses should be sent as soon as possible for the SF and their individual members to be able to organise themselves in time.

WP3

Sonja Scheffel (HVB) gave an update on the activities of WP3

From slides:

Activity: Calculation of efficiency gains

Activity: Routine data	***Due date***	***Status***
Collection of available information on pilots from WP4 and WP5, interviews about cases of local pilot-transformation	*M11 Aug. 13 –* *M12 Sept. 13*	*Done* • *Together with NETSCC by structured interviews*
Calculation and preparing report of results out of the information collection from WPs 4&5, according to the prepared formula	*M12 Sept. 13 –* *M12 Sept. 13*	*Ongoing* • *by evaluation of routine data*

Activity: Auditing of the progress in implementation of JA2 as per the JA agreement and verifying if it is on course to achieve its objectives

Activity: Surveys	***Due date***	***Status***
Conception and coordination of first WP3 yearly survey for EUnetHTA Partners and Associates & for Stakeholders	*M7 Apr. 13 –* *M8 May 13*	*Done* *Together with NETSCC,* *Together with WP1, WP4, & WP6 for Partners' survey*
Preparing and announcing first WP3 yearly survey for EUnetHTA Partners and Associates & for Stakeholders	*M8 May 13 –* *M8 May 13*	*Done* *Together with WP1 and in a newsletter for Partners' survey*
Start first WP3 yearly survey for EUnetHTA Partners and Associates & for Stakeholders and reminder after 2 weeks	*M9 Jun.13 –* *M9 Jun.13*	*Done*
Analysis of results of the first WP3 yearly survey for EUnetHTA Partners and Associates & for Stakeholders and preparation of reporting	*M10 Jul. 13 –* *M12 Sept. 13*	*Done* *by WP3 following the structure in JA1 (from NETSCC)* *reviewed by NETSCC*
Interim report (status for Commission, feedback for all WPs), relevant information will be prepared for the Stakeholder meeting	*M12 Sept.13 –* *M13 Oct.13*	*On-going*

Activity: Capturing cross-boarder collaboration activities of the «spin-offs/add-ons» in the network as the outcome of the EUnetHTA activities

Activity: Tool usage	***Due date***	***Status***

Capture the utilization of EUnetHTA tools and included in the report at yearly level *POP database – regularly report* *EVIDENT – regularly report* *Core HTA information database* *Adaption toolkit*	*M12 Sept.13 –* *M12 Sept. 13*	*On-going*
Collection of available information on collaboration in the context of EUnetHTA, interviews about cases of collaboration	*M11 Aug. 13 –* *M12 Sept. 13*	*On-going*
Preparation of reporting the results	*M12 Sept. 13 –* *M12 Sept. 13*	*On-going*

Activity: Quality assessment process

Activity: Deliverables	***Due date***	***Status***
Evaluating the project progress and its timely attainment of the milestones, deliverables, etc. Findings will be included in the interim report (method: structured interview with LPs and Co-LPs)	*M12 Sept. 13 – M12 Sept. 13*	*Done* *Together with NETSCC by structured interviews*
The interim/final reports will be used (additional interviews if needed) for: *Qualitative assessment of the review process utilized in each pilot project* *Assessment of the transfer of the core HTA information into the national/regional report* *Conflict of interest process review, ie, how the conflict of interest was handled in the pilots*	*M12 Sept. 13 – M12 Sept. 13*	*Done* *by structured interviews*

Key comments and discussion / Decision points:

- The response rate from the Stakeholder Forum for the EUnetHTA yearly survey was rather low – only 47%; the Stakeholder forum was encouraged to increase their participation in the survey for Year 2 of JA2.

WP 4

Marina Cerbo (Agenas) gave an update on the activities of WP4

From slides:

Activity	***Due date / Milestone***	***Status***

1st Core HTA	*M14 (Nov '13)*	*On time* *1st draft ready by the end of Sept '13*
Methodological Standards & Procedures – Final	*M15 (Dec '13)*	*First revision on-going* *Waiting for Core Model Updates for implementing new features*
2nd f-t-f meeting	*Zagreb* *Oct 7-8 '13*	*MS&P discussion* *2nd core HTA starting production* *organizational and technical issues*

Activity	***Due date / Milestone***	***Status***
National Pilots		*On-going* *"Volunteers" identified* *Production phase to be defined (update after 2nd f-t-f meeting in Zagreb Oct. 7th-8th)*
2nd Core HTA	*M12* *Sep '13*	*Topic selection procedure on-going*

Activity	***Due date / Milestone***	***Status***
1st draft of Core HTA 1	*Oct 13*	*Draft finalization on-going* *SAG and Public Consultation in Oct-Nov '13*

WP6

No representatives of the WP6 LP or Co-LP could be present at the meeting but slides had been shared.

SLIDES:

Activity	***Due date / Milestone***	***Status***
Implementation of a new Public site	*M4*	*Maintenance*
Implementation of a new intranet (including "work rooms")	*M5-36*	*Problem link Newsletter fixed* *Trainings for group managers happened during summer* *User documentation currently updated* *Webcasts planned*

Activity	*Due date / Milestone*	*Status*
Planned and On-going Projects database operation	*M4-M36*	*1254 Projects described* *Release 2 functionalities revised (planned 09-10/13)*
Centralized authentication system (EUnetHTA ID)	*M4-M36*	*Deployment release 2 in progress*
EUnetHTA Toolbar	*M4-M36*	*Updated according to websites changes*

Activity	*Due date / Milestone*	*Status*
"e-learning " platform	*M7-M9*	*Proposal of strategy : delayed to M13 to include results of 1st survey*
Reporting	*M9*	*News provided to Secretariat*

WP8

Kristian Lampe (THL) gave an update on the activities of WP8.

SLIDES:

Activity	*Due date / Milestone*	*Status*
Review and update of the Policy for the HTA Core Model and core HTA information	*M8 – May 2013*	*Delivered in June 2013* *Available at http://www.corehta.info/documents/PolicyForHTACoreModelAndCoreHTAInformation_Version1.1.pdf*
Commercial license for the HTA Core Model	*M8 – May 2013*	*Delivered in June 2013* *Available at http://www.corehta.info/documents/HTACoreModel_TermsOfUse_1.1.pdf*
Piloting of HTA Core Model for internal processes of technology manufacturers (Roche + Medtronic)	*M15 – Dec 2013*	*Terms of Reference document being prepared together with the Secretariat. LP (THL) approved Terms of Reference document.*

Activity	*Due date / Milestone*	*Status*
Update of the HTA Core Model, including expansion of rapid REA model into a core HTA model	*M12 – Sep 2013*	*Update content under review by EUnetHTA agencies and WP8 SAG. Deadline 9 Sep. Final adjustments during September.* *Minor delays possible. PDF version of the update will be ready by the end of September or – the latest – mid October. Online version by end of Oct.* *Legal domain not yet updated at all, due to lack of primary investigator. A solution is sought to include legal domain update during 2013.* *According to the Policy: possible to register users beyond EUnetHTA members*
Upgrade HTA core Model Online to support production of rapid HTAs and local reports	*M14 – Nov 2013*	*First version of rapid REA model implemented during the summer, still requires discussions with WP5.* *Local report functions will be developed during the fall.*

WP8 SAG Activities / Stakeholder involvement

- *WP8 SAG participated in the Review of HTA Core Model Update (same timeline as for EUnetHTA partners). Suggested changes currently being considered by developers.*
- *Once ToR with Roche and Medtronics finalized, collaboration to pilot the HTA Core Model can commence (Sep/Oct?)*

3. EUnetHTA Expert meetings

a. Proposed meeting with the medical device industry

Julia Chamova (DHMA, EUnetHTA Secretariat) updated the Stakeholder Forum on the proposed meeting with the medical device industry.

SLIDES:

Meeting with the medical device industry

- *Background: discussions at the EUnetHTA PA in Zagreb, specific suggestion from EUCOMED*
- *Tentatively planned for the beginning/spring of 2014*
- *Will invite participation of EUCOMED, EDMA, COCIR (EUnetHTA SF members)*
- *to address **the contextual issues for medical devices** in the working processes of the EUnetHTA JA2 work packages (WP4, 5 and relevant work streams of WP7)*
    - *Aiming at bringing EUnetHTA and medical device industry experts on the meeting discussion topics.*

Key comments and discussion / Decision points:

- EUCOMED thanked for the opportunity to have such a meeting and EUCOMED has reached out to EDMA and COCIR so they will all be present in the meeting.

  Action Point: EUnetHTA Secretariat to follow-up on planning the meeting with the medical device industry

4. Discussion of the implementation of Co-Chair function in the Stakeholder Forum

Julia Chamova (DHMA, EUnetHTA Secretariat) updated the Stakeholder Forum on the status of the implementation of the Co-Chair and the clarifications of details of the Co-chair function.

The EUnetHTA proposal-document on the position of EUnetHTA on the Co-chair function, shared before the meeting was presented:

Proposal from EUnetHTA Executive Committee:

***Mandate duration**: 2 year (i.e. until the end of EUnetHTA JA2);*

Tasks:
- *at least co-prepare agendas and co-chair meetings of the EUnetHTA JA2 SF*
- *attend meetings of the HTA network on behalf of the EUnetHTA SF*

***No proposed objections from EUnetHTA** to tasks suggested by SH Forum:*
- *be a key point of contact for common areas of SF's input*
- *put forward stakeholder issues in consultation with the SF constituency (appropriate transparent mechanism for soliciting SF member input to be put in place)*
- *attend EUnetHTA JA2 PA meetings*
- *have a clear overview of stakeholders' role in the EUnetHTA WPs*
- *take an active role in the functioning of the HTA Network according to the provisions of the formal means establishing and governing activities of the HTA Network*

***No proposed objections from EUnetHTA** to SF internal arrangements as suggested by SH Forum (if found necessary and possible by the SF) for supporting the Co-Chair tasks:*
- *a support team consisting of one representative from each stakeholder group (one person from each)*
- *regular meetings with SF members*

Workload:
- *attendance at 1 face-to-face SF meeting*
  - *1 person day attendance and 1 person day of preparations*
- *Attendance at the PA meeting*
  - *2 person days for attendance and 1 person day of preparations*
- *attendance at 4 yearly e-meetings (duration of 2 hours each)*
  - *2 person days per year for preparation of 4 e-meetings*
- *Attendance at the HTA Network meetings (1-2 yearly)*

Total: 8-10 person days annually

If additional tasks are agreed by the SF to be an integral part of the SF Co-Chair role, the workload will increase – estimation of 15 person days/year (?) for additional tasks (?)

Resources:
- ***Available at EUnetHTA**: travel and subsistence coverage for a Co-Chair to the EUnetHTA SF face-to-face meeting (1/year) and EUnetHTA PA face-to-face meeting (1/year)*

Needed:
- *depend on the scope of role/tasks of the Co-Chair*
- *Secretarial support might be needed to facilitate the function of the co-chair*

- *A EUnetHTA Stakeholder Liaison function might need to be put in place at the EUnetHTA Secretariat to provide coherent stakeholder involvement service across EUnetHTA*

- *Clarification needed on the practical implementation of Article 15 point 3(e), which states "aid can be granted by the Union in order to facilitate the consultation of stakeholders on the work of the HTA network".*

Profile:
The person to hold a position of the Co-Chair should have a good understanding of the HTA concept and an insight into the HTA processes – including some experience with the activities of stakeholder involvement in HTA. The person should be interested in representing all four stakeholder groups (Patients, Providers, Industry and Payers). Track record of the stakeholder interest alignment is preferable.

Key comments and discussion / Decision points:

- EFPIA informed that Stakeholder Forum has identified a person for the Co-Chair position. The Co-chair is Francois Houÿez from EURORDIS. The Stakeholder Forum supported the presented proposal of the Co-Chair function as described by EUnetHTA (see background documents for the meeting) including the idea of a co-chair team consisting of representatives from each stakeholder-group. The full list of representatives should be finalised within a few days. As for secretariat support the Industry group is willing to support.

- Francois Houÿez thanked the Stakeholder Forum for the nomination for Co-chair and informed the meeting that he looked forward to being part of pioneering the involvement of Stakeholders in the HTA agencies activities.

Action Point:
- EFPIA to share the full list of Co-Chair team representatives with EUnetHTA Secretariat.

- EUnetHTA Secretariat to liaise with the new Co-Chair and Co-Chair team on clarifying the practical and technical details in order to ensure a good collaboration between the Stakeholder Forum and the Exec Comm.

5. Permanent EU cooperation on HTA

a. **EUnetHTA**

i. Update and RoP

Julia Chamova (EUnetHTA Secretariat) briefly updated the meeting on the activities on the EUnetHTA's side.

From slides:

- *Comments on the preliminary draft of the Rules of Procedure of the HTA Network (August 22, 2013)*
- *Facilitated collection of the SF comments on the preliminary RoP draft*
    - *The stakeholder involvement in the HTA Network activities is proposed to be coordinated via the technical scientific cooperation*
- *EUnetHTA performs the function of the scientific and technical cooperation for the HTA Network until the end of JA2 (to be clearly recognised in the RoP)*
- *Draft RoP and multiannual Work Programme was distributed for commenting by the EUnetHTA Partners and Associates as well as the SF (deadline to send comments to the EUnetHTA Secretariat – September 19)*

b. **HTA Network (DG SANCO**)

i. Stakeholder representative for HTA Network meeting

Flora Giorgio, HTAN Secretariat/DG SANCO gave an update on Stakeholders in the permanent HTA network.

From slides:

Stakeholders in HTA Network
- *Proposed* as "Observers":*
    - *Invited to all meetings (part of the meeting may be Members ONLY)*
    - *Access to and comment on the same docs as Members (unless specifically requested by the HTA Network)*
    - *Possibility to propose topics for the Agenda*
    - *No voting rights*

- *Phase 1 - up to 2015:*
  - *Stakeholders consultation to the HTA Network will rely on the EUnetHTA Stakeholders Forum*
  - *at strategic level → SF will propose 5 representatives (HTA Network to vote/confirm)*
  - *at scientific :Level → according to the EUnetHTA Process (SAG in different WPs)*
  - *Different profiles of representatives in the two levels.*

- *Phase 2 – post 2015 →proposals are welcome:*
  - *New Stakeholder Forum ?*
  - *New call for Interest?*
  - *Financing?*
  - *Specific topics?*

SH Comments preliminary draft RoP

1. General comments

- *Flexibility in representation Continuity of representation (same as HTAN Members)*
- *Full participation partially (Art 4.3; 5.1,2;8.2)*

Specific comments

- *Deadlines (Art 3,5,10)→ kept short but with flexibility*
- *Adoption procedure (Art 6)→ 2/3 is kept + Quorum issue to be addressed*
- *Attendance to Mtgs (Art 8) → awaiting position of HTAN*
- *Minutes (Art 10)→ eH Network experience*
- *Confidentiality (Ex Art 14) → OK new 6.3*

HTA Network Draft Work Programme:

1. Overall objective

- *Long term cooperation on HTA at European level, agree on:*
  - *Scope*
  - *Financial sustainability*
  - *Future trends*

2. Specific objectives

- *Guidance to Work Prpgramme of post EUnetHTA scientific cooperation mechanism.*
- *Conditions/guidance to facilitate national take up and re-use of HTYA joint work*
- *Interaction between Regulatory and HTA issues*

3. "Permanent" tasks ("other tasks")

- *Involvement of all interested parties in HTA process (longer term)*
- *Proposes strategic directions on how to allocate EU funding for HTA (R&D, deployment etc) (medium term)*
- *Provide input/being informed on EU semester Agenda and HTA issues (yearly)*

Next steps/timelines:

- *SF to propose their representatives for HTA Network* ***by 20 September***
- *HTA Network Members to send comments on both WP + RoP by 25 September*
- *EC to send revised draft →****October 2***
- *1st meeting HTA Network →* ***October 16***

Key comments and discussion / Decision Points:

- The list with the institution being members of the HTAN will be made public right after the first meeting of the HTA Network on 16 October, 2013. However, the actual names of the special representative cannot be disclosed right away and the process of working on this might take a little longer.

- The Co-Chair and Co-chair team of EUnetHTA Stakeholder Forum will also act as the HTAN Stakeholder representatives for the first meeting.

6. EUnetHTA training – can we expand beyond patients and providers?

a. EUnetHTA trainings to SMEs

Julia Chamova (DHMA; EUnetHTA Secretariat) briefly informed the Stakeholder Forum on the request from EuropaBio for SMEs to participate in the EUnetHTA Stakeholder Forum trainings.

From slides:

EUnetHTA training – beyond patients and providers?

Background: EuropaBio request to extend the EUnetHTA trainings to SMEs

- *Discussed with WP2 LP and in Executive Committee*
- *EUnetHTA will maintain its focus and scope of training on patients and providers (as initially described in the Grant Agreement)*
- *Pragmatically: if additional seats are available, people from SMEs are welcome to participate (having understanding of the given focus and scope of the trainings)*

7. EUnetHTA Conference Rome 2014 (October) – update

Julia Chamova (EUnetHTA Secretariat) updated the Stakeholder Forum on the latest developments in the planning of the EUnetHTA Conference.

From slides:

HTA 2.0 Europe – Rome Oct 2014 Update

Date: ***October 30-31, 2014***

Delay in identifying a professional conference bureau (September instead of June 2013)

Programme to be in place by January 2014 (will work with the 4 stakeholder groups of the SF)

8. Reporting of EUnetHTA JA2 Year 1 – SF input

Anne Raahauge (EUnetHTA secretariat) gave a short update on the reporting of the EUnetHTA JA2 Year 1.

From slides:

Timeline for finalisation and commenting on JA2 Technical interim Report

When	***What***
15 Oct	*LPs send Drafts of the WP Technical Interim Reports to Secretariat*
16 Oct	***Secretariat shares the Drafts with SF members for comments*** ***"high-level" comments*** ***Confidential drafts, not for distribution***
30 Oct	***Deadline for SF to send comments to Secretariat***
4 Nov	*Secretariat sends its own and SF comments to LPs*
11 Nov	*LPs submit final drafts of the WP Technical Interim reports to Secretariat*
1 Dec	*Secretariat submits the final EUnetHTA JA2 Technical Interim Report to EAHC*

Key comments and discussion / decision points:

- It has been agreed by the Exec Comm that the Stakeholder forum should be invited to give input to the draft Technical interim report for year 1 of JA2. The draft reports will be shared with the Stakeholder Forum through the SH Forum Area on the Website on 16 October 2013.

- The Stakeholder Forum Area on the website will more and more be utilised as the place to share information with the Stakeholder Forum, so members should sign up.

Action Points: EUnetHTA Secretariat to share the JA2 draft Technical Interim Reports with the Stakeholder Forum through the SH Forum Area on the Website on 16 October 2013.

9. Procedural issues

Edith Frenoy (EFPIA) presented the general comments and suggestions on procedural issues from the stakeholder forum members.

From slides:

a. Availability of presentations during e-meetings and circulated to the SF
b. Status of SAGs of remaining WPs
c. SAG consultation – harmonization of consultation methods across WPs
d. Relation between public consultations and SAG consultation

Key comments and discussion / decision points:

- The Stakeholder Forum has had a meeting where it was discussed to bring the issue on the slides forward to the Executive Committee on procedural issues.
  a) The Stakeholder Forum would very much appreciate if there were slides at all e-meetings for each agenda topic as it can be difficult for the Stakeholders to follow the discussions and provide input.
  b) The Stakeholder Forum would appreciate an update on the developments of the SAGs for all WPs. In the meantime the SAG for WP7 has been formed so this issue is already taken care of.
  c) Regarding SAG consultations the Stakeholder Forum would very much appreciate if there could be standard procedures for the SAG consultations. At the moment it is done in different ways depending on the Lead Partners.
  d) The Stakeholder Forum questioned the value of the SAG input if the SAG is at the same time as the Public consultation.

- The Secretariat is already working on some of the points raised and is happy to receive any further input from the Stakeholder Forum on ways to improve the work and meetings of the Stakeholder Forum. Regarding the issue of aligning the work on the SAG consultations the Secretariat invited the Stakeholder Forum to share specific suggestions for adjustments.

Action Points: Stakeholder Forum to provide input to how the SAG consultation process could be adjusted and aligned across WPs.

B. Other issues

1. Update on status of JA1 report
   - Julia Chamova (EUnetHTA Secretariat) informed the meeting that the Secretariat will upload the JA1 technical report on the public website in agreement with the EAHC.

2. Registration of time spend on EUnetHTA – clarification
   - Anne Raahauge (EUnetHTA secretariat) clarified that the secretariat will not be collecting registrations on time spend on EUnetHTA activities from the Stakeholder Forum members.

3. Next EUnetHTA Stakeholder Forum invitations to the Face-to-Face meeting – January 2014, Brussels (Tentatively15 January, in connection with WP2 Stakeholder trainings).

- The next EUnetHTA stakeholder Forum Face-to-Face meeting will be held 15 of January 2013 in Brussels. (Not a tentative date anymore) will be distributed as soon as possible.

4. Next EUnetHTA Newsletter issues – October 1, 2013 (deadline for input – Sept 20, 2013)
   - The deadline for input has been extended to Sept 20. In the future the secretariat will remind stakeholder forum in the meetings before the deadline, or send out an email.

#	Action Point	Responsible	Deadline
1	WP2 to follow up and inform other Stakeholder Groups about potential vacant seats in the Stakeholder trainings.	WP2 LP	After final deadline for registering to the trainings in December. Instructions on registration process to be provided in October.
2	EUnetHTA Secretariat to follow-up on planning the meeting with the medical device industry	EUnetHTA Secretariat	December-January
3	EFPIA to share the full list of Co-Chair representatives with EUnetHTA Secretariat	EFPIA	Done
4	EUnetHTA Secretariat to liaise with the new Co-Chair and Co-Chair team on clarifying the practical and technical details in order to ensure a good collaboration between the Stakeholder Forum and the Exec Comm.	EUnetHTA Secretariat	In advance to the next SF meeting (allowing sufficient time for preparation)
5	EUnetHTA Secretariat to share the JA2 draft Technical Interim Reports with the Stakeholder Forum through the SH Forum Area on the Website on 16 October 2013.	EUnetHTA Secretariat	16 October
6	Stakeholder Forum to provide specific suggestions to how the SAG consultation process could be adjusted and aligned	Stakeholder Forum members	Ongoing (possibly as part of their comments on the Interim report)