EUnetHTA JA 1 Stakeholder Forum Meeting
November 12, 2012, 1:00-3:30pm CET

E-meeting
Organised by EUnetHTA Secretariat
Danish Health and Medicines Authority, Denmark

EUnetHTA Participants:
Chair: Finn Børlum Kristensen, DHMA, Denmark, EUnetHTA Secretariat
Anne Raahauge, EUnetHTA Secretariat
Elisabeth George, NICE, United Kingdom
François Meyer, HAS, France
Gottfried Endel, HVB, Austria
Gro Jamtvedt, NOKC, Norway
Inge Merete Skov, EUnetHTA Secretariat
Ingvil Sæterdal, NOKC, Norway
Julia Chamova, EUnetHTA Secretariat
Julie Lange, EUnetHTA Secretariat
Kristian Lampe, THL, Finland
Lidia Becla, CVZ, Netherlands
Marina Cerbo, AGE.NA.S, Italy
Mirjana Huic, AAZ, Croatia
Nicola Vicari, AGENAS, Italy
Patrice Chalon, KCE, Belgium
Rosa Rico, OSTEBA, Spain
Wim Goettsch, CVZ, Netherlands

EUnetHTA Stakeholder Forum Members:
Andrea Rappagliosi, EFPIA
Christian Peters, ESIP
Constance Colin, CPME
Frank Bongers, Stryker
Joerg Lauterberg, APS
Liuska Sanna, EPF
Marie-Astrid Libert, COCIR
Ozgun Unver, EPF
Pascal Garel, HOPE
Pascale Brasseur, EUCOMED

European Commission
Anders Lamark-Tysse, DG Sanco

Meeting Agenda

A. General information and updates

1) SF meeting September 3, 2012, Venice
2) EUnetHTA Executive Committee meeting, Oct 3-4, Diemen
3) Joint Action 2
    a. JA2 SF open call for expression of interest – update
    b. Update on activities/planning
    c. EUnetHTA JA2 Plenary Assembly, March 21-22, 2013
    d. EUnetHTA JA2 pilots – participation of companies
    e. Cooperation with technology producers re HTA Core Model and its application in the internal (to companies) work processes
4) Article 15 (Directive 2011/24/EU) implementation update
5) New staff members at the EUnetHTA Secretariat

B. Information about JA1 WP activities (and SAG involvement):

- WP4, 5, 7

C. Other issues

- EUnetHTA Stakeholder Forum Update e-newsletter (mid-December 2012)

Finn Børlum Kristensen, (FBK), opened the meeting by welcoming everyone to the last e-meeting within JA1 followed by a presentation of the agenda.

A. General information and updates

1) SF meeting September 3, 2012, Venice

FBK presented the important conclusions from the Stakeholder Forum meeting in Venice in September

Key points:

- All in all it was a meeting with several good discussions and a general agreement among the stakeholders and the leads of work packages of EUnetHTA that the stakeholder involvement is working.
- There is a “learning curve” to climb, but the involvement is going in the right direction.
- The SF is enthusiastic about discussing the role of stakeholders in the permanent network.
- The call for declaration of interest to be member of SF should be specific on EUnetHTA’s expectations
- Four weeks should be (and were) given from call opening to deadline
- SF wishes to be involved in the choice of criteria for the selection of topics for pilots in JA2
- Each time a specific question is raised to SF, EUnetHTA should specify which stakeholders are the most relevant to respond
- The status and function of ”experts” in SAGs should be revisited
- EUnetHTA should collaborate more with EMA
- Remits of EMA and remits of EUnetHTA should be clearly defined

- The new pharmacovigilance directive and the nature of data to be provided for post marketing authorisation efficacy and safety assessment (EMA) and for HTA (EUnetHTA) is important
- See how EMA collaborates with different stakeholders - including involvement in committees
- EUnetHTA should develop towards working like EMA rather than like EFSA (European Food Safety Authority) – irrespective of legal status and formal roles.

Action Point

- The different types of stakeholder involvement must be clear. Some stakeholders will mainly be interested in discussions at the policy level while others will also be interested in the more detailed discussions on methodologies and ways of handling scientific information.
    - **EUnetHTA** has to make sure that stakeholders' needs are met in JA2 and not expect the same type of involvement from all stakeholders.

2) EUnetHTA Executive Committee meeting, Oct 3-4, Diemen

FBK presented the outcome of the face-to-face meeting of the Executive Committee in October

Key points:

- All deliverables (1-2 exceptions) will be in place by January 2013
- JA 1 Final report to be submitted to the EAHC in March 2013
    - Evaluation report will take into account requests from the SF on lessons learned and survey results
- Review of and policy to manage external initiatives where EUnetHTA is involved
    - E.g. Tapestry networks, Green Park Collaborative, HTAsiaLink/RedETSA, INAHTA, EU (DG Sanco JAs on rare disease and patient registries, FP7 projects, IMI Call for projects in relative effectiveness research, cooperation with EMA and Committee on Investigation and Evaluation (CIE), CAVOMP)
- HTA Core Model:
    - Further development based on field application in JA2
    - The final product of application of the HTA Core Model is a collection of data, not a report
    - A license for use of HTA Core Model will be developed by May 2013
    - HTA Core Model Policy will be developed for the Executive Committee approval by end of 2012 (to be endorsed by the Plenary Assembly in March 2013)
    - **FBK elaborated on the Core Model Policy**:
        - The development of this Policy has been ongoing in WP4 since the summer of 2011.
        - It has been circulated in the WP and among the partners and brought up for discussion in the Executive Committee.
        - It is now undergoing a revision in order for deadlines to be met for the process.
        - The Policy is defining who, how, and when the HTA Core Model can be used.
- **Input from Kristian Lampe (KL) on the Core Model Policy, JA1 WP4**:
    - Firstly, the matter was discussed within the Executive Committee and a draft was made to be submitted to the Stakeholder Advisory Group for comments before the end of 2012.
    - Originally, it was the idea to involve the Stakeholder Advisory Group earlier, but there were too many open issues
    - Therefore, it was thought best to consult the Executive Committee first to create a common view on the major issues, e.g. possible fees for using the Core Model etc.
    - *Action Point*: The Policy will be finalised at the end of November and sent to the Stakeholder Advisory Group early December for comments.

- Cooperation with industry and specific companies (issue later on the agenda) on improving the HTA Core Model and development of the submission template for technology producers
- JA 2 conflict of interest policy to be developed:
    - Declarations will be connected to the concrete project and activity associated with specific output
    - Reference to the conflict of interest policies and declarations in the participating organisations
    - General guidance on conflict of interest will be developed
- Cooperation with EMA will continue in a structured way to support activities in JA2
- Stakeholder modalities in JA2 will include closer collaboration with specific companies (for pilots); stakeholder training sessions in HTA methodology and specifically in EUnetHTA tools will be provided; national decision-makers will be an important group to consult (e.g. during the development of a submission template)

Andrea Rappagliosi (via text chat) asked why training was not offered during the JA1 (specifically with relation to the HTA Core model)

FBK commented that Within the JA1, there were never any specific plans to provide training to stakeholders in the use of the HTA Core Model, as it was unclear from the beginning who would be the primary user. Julia Chamova (via text chat) commented that the secretariat will follow-up if the training had been included in the plans/grant agreement for JA1.

3) Joint Action 2

Julia Chamova, JUCH, EUnetHTA secretariat, briefed the meeting on this agenda point:

a) JA2 Stakeholder Forum open call for expression of interest:

- 21 applicants (all 4 stakeholder groups represented)
- *Key discussion points*
    - There was a discussion on how many of the applications would be selected.
    - The immediate impression is that the majority is eligible and will most likely be selected.
    - However, there can only be 6 participants per stakeholder group per meeting.
    - A few issues with certain composite organisations. A couple of applicants can be placed within more than one of the 4 stakeholder groups. However, it is necessary that an organisation clearly represents interest of one specific stakeholder group.
- Executive Committee to review and make recommendation on Nov 28 (Executive Committee e-meeting)
- Final decision on membership to be taken by the Plenary Assembly by December 10 2012.
- Applicants to be informed immediately after.

b) Update on activities/planning

- Development of the 3-year work plan: presentation of the work plans of the WPs will be given at the 1st face-to-face meeting of a new Stakeholder Forum on February 5, 2013 in Brussels. Draft work plan will be shared for comments in February (short deadline!)
- Clarifying stakeholder involvement modalities in each WP
- Development of a new EUnetHTA public website and intranet: dashboard structure supporting project-based activities; dedicated area for the Stakeholder Forum. Launch – January 2013.

c) EUnetHTA Plenary Assembly, March 21-22, 2013, Zagreb, Croatia, Hotel Westin Zagreb

- Day 1: 9:00-17:00 - Day 2: 9:00-13:00
- JA 2 SF to provide input in agenda development
- Main focus on JA2 3-year work plan, election of the Executive Committee members; EUnetHTA SOP; permanent network development as per Article 15 of the Directive 2011/24/EU

d) EUnetHTA JA2 pilots – participation of companies

- There will be 14 pilots or "field tests" on 14 different technologies of which 10 will be pharmaceuticals
- Facilitation of the SF members:
  - EUnetHTA produced a letter to EFPIA to ask EFPIA to facilitate the recruiting of volunteer sponsors of technologies
  - Involvement of medical device producers are equally important
- *Key discussion points*:
  - The stakeholder recruitment process and the selection of which companies and therapeutic areas which should be chosen for the pilots in JA2 were discussed at the meeting
    - Some companies have already expressed interest, details are being clarified by the WP5 LP (CVZ, Netherlands) and it is foreseen that the process can start in the first quarter of next year.
    - The process should be transparent
    - WP5 prefers participation from as many companies and pharmaceuticals as possible to get a broad range of different aspects and not only focus on acute chronic diseases etc., but also to take e.g. orphan drugs into account.
    - WP4 is working on providing a methodology to collect proposals for assessments from all stakeholders and also the Commission, which will include the technical annexes e.g., describing that the Commission should be heard in relation to pilots with European interests

e) Cooperation with technology producers re: HTA Core Model and its application in the internal (to companies) work processes

- Cooperation invitation from Roche
- An opportunity for cooperation and input from individual companies
- Terms of Reference for cooperation (WP8)
- Access to the development of concept/applications of the Model (not to the Online Tool and Service); opportunity for early insight into the Model structure and potential adaptation of the internal processes to meet the needs of tomorrow's requirements of the HTA organisations (e.g., submission template development)
- *Action point:*
  - The deadline for expressing interest in potentially participating in such cooperation is **14 December 2012**. A company that is interested to get involved should send a letter of interest to the EUnetHTA Secretariat.

4) Article 15 (Directive 2011/24/EU) implementation update

- Anders Tysse (AT) presented the input form the Commission (DG SANCO)
  - Most of the stakeholders in the Stakeholder Forum provided input to the public consultation
  - The report of the findings from the consultation should have been published on the Commission's website; however, it has not yet taken place due to technical reasons.

- The input from the stakeholders gave valuable insights that needs to be taken into account when the future network is established regarding stakeholder consultation
- In the October meeting, the Cross-Border Healthcare Committee (implementation Committee set up by the Commission with 1 representative per MS) had a first introduction to the article 15 and the need for the Commission to formally establish a network in line with the provisions of the article
- The MS shall appoint experts for an expert group within the Commission to DG SANCO with the details of setting up the network
    - There will be a meeting in January, February and if necessary in March
- The foreseen timeline of the process:
    - Following the conclusions from the expert meetings, there will be a first full round of discussions in the Cross-Border Healthcare Committee in March 2013.
    - If everyone is happy in March-April 2013, a draft text can be provided for approval by the Committee in June for the Commission to adopt the final measures next autumn.
- The MS have appointed as their experts representatives of the current EUnetHTA, which suggests that the countries are confident in the role EUnetHTA can play in providing advice to the Commission on these issues.

Key discussion points:

- Anders Tysse will look into the possibilities of a stakeholder information meeting on the implementation, but cannot promise anything as this does not normally take place on this kind of act due to the comitology setting.
- Background report (draft text) from Ecorys produced for the Commission to help in the considerations before providing advice to the Member States for the discussion is received and being reviewed by the Commission. The results will be made publicly available (when and how is still to be clarified).
- Écorys was delayed in producing the report, which means that a clarifying meeting on the draft content is still to be held.

5) New staff members at the EUnetHTA Secretariat

FBK presented two new staff members at the EUnetHTA secretariat:

- Ms. Anne Raahauge, M.A., Project Manager of EUnetHTA (JA2), and
- Ms. Julie Lange, M.A., Communication Officer of EUnetHTA

B. Information about JA1 WP activities (and SAG involvement):

KL informed about the activities of W4, Strand A

- Updates – JA1
    - **18 September:** Validation started
        - EUnetHTA Partners, INAHTA
    - **25 September:** SAG validation started
    - **16 October**: Public consultation started
    - **23 October (Extended to 30 October):** Validation ends
    - **12 November:** Public consultation ends
    - **End of December:** Final version of deliverables

        - (HTA Core Model Online, Screening Model)

- Validation responses – JA1

	OTS	**Screening Model**
EUnetHTA Partners	**15** responses	**8** responses
SAG	**3** responses	**N/A**

- Next steps (strand A)
    - Refinement of HTA Core Model Online and possibly Screening Model
    - Further Policy set discussions within WP4 and the Executive Committee
- Joint Action 2 – WP8
    - Maintenance of HTA Core Model infrastructure to support shared production and sharing of HTA information
    - Milestones
        - Update of already existing HTA Core Model applications M10
        - Drug core HTA model (based on REA model) M12
        - First version of Online service and database ready M14
        - Final version of Online service and database ready M36
    - Stakeholders Involvement
        - Primarily through SAG:
            - Model updates
            - Online tool update

Marina Cerbo (MC) presented the activities of WP 4, Strand B

- Updates – JA1

    - **18 September:** Validation started
        - EUnetHTA Partners, INAHTA
    - **25 September:** SAG validation started
    - **16 October**: Public consultation started
    - **23 October (Extended to 30 October):** Validation ends
    - **12 November:** Public consultation ends
    - **End of November:** Deadline for changes in Core HTAs (by each Domain Team)
    - **End of December:** Final version of deliverable
        - (2 Core HTAs)

- Validation responses – JA1

	PTBCR	**AAA Screening**
EUnetHTA Partners	**8** responses	**10** responses
SAG	**2** responses	**No** response

- Objectives, JA2

Test the capacity of national HTA bodies to produce structured core HTA information (full core/rapid HTAs) together and apply it in national context (including collection of data on costs and overall efficiency of the production in the network).	Implement, pilot and further develop models and tools as well as production processes to support collaborative production of core HTA information with reinforced secretariat and coordination function.	Develop and test a methodological basis for European cooperation on HTA including guidelines for distinct methodological issues and quality improvement of evidence generation for HTA

- Milestones, JA2
  - M08: First draft of methodological guidance for partners' collaboration
  - M14: 1st core HTA
  - M15: Final guidance for partners' collaboration
  - M23: 2nd core HTA
  - M34: 3th core HTA
  - M35: 20 national reports based on core HTAs, core structured information, local information
  - M36: Final reporting

- Stakeholders Involvement (draft), JA2

Timing (preliminary)	Type of involvement	Topic	Notes
Fall 2012-2013	SAG	Topic selection and prioritization procedures draft	Feedback will be used to improve methodology
2013	SAG	1st draft of 1st core HTA protocol	Feedback will be used to improve document. Experts from stakeholder groups can be invited during activities according to the needs
2014	Public	1st core HTA	
2014	SAG	1st draft of 2nd core HTA protocol	Feedback will be used to improve document. Experts from stakeholder groups can be invited during activities according to the needs
2014-2015	Public	2nd core HTA	
2015	SAG	1st draft of 3rd core HTA protocol	Feedback will be used to improve document. Experts from stakeholder groups can be invited during activities according to the needs
2015	Public	3rd core HTA	
2013-2015	SF	Updates on ongoing activities	

Wim Goettsch (WG) presented the WP5 update with a specific focus on relative effectiveness assessment (REA) of pharmaceuticals

- Overview of deliverables

Deliverable	Planned delivery	Actual delivery
• Background review	May 2011	June 2011
• Including publication in Value en health (Value in Health, Volume 15, Issue 6, Pages 954-960)		Sept 2012
• Model for Rapid REA of Pharmaceuticals	Oct 2012	Dec 2012
• Publication on model in scientific journal		2013
• Guidelines on methodology to be incorporated in Model for Rapid REA	Oct 2012	Jan 2013
• Final report	Dec 2012	Dec 2012

- Lessons learned (i)
    - WP5 members have proven that there is high willingness to collaborate in the field of relative effectiveness assessment of pharmaceuticals
        - A tremendous amount of work has been done within 3 years
    - The traditional HTA Core Model has undergone significant adaptations in order to be suitable for rapid assessments on pharmaceuticals
        - Focus on 4 domains
        - Focus on limited number of assessment elements
        - One general methods section instead of domain specific methods section
        - Relevant methodological issues get detailed attention in focused guidelines

- Lessons learned (ii)
    - The traditional mode of collaboration for the HTA Core Model in which multiple agencies are functioning as authors is not suitable for doing rapid assessments
        - For rapid assessments WP5 proposes one authoring agency and one co-authoring agency (and a dedicated pool of reviewing agencies)
    - Generating guidelines is extremely useful for discussions among HTA Agencies and between HTA agencies and stakeholders
        - However it is a very resource and time consuming process that requires more focused attention in Joint Action 2

- Update WP5 activities – pilot & REA model
    - First pilot: rapid assessment of pazopanib
        - Public consultation finalised: 6 June – 6 July >> 5 responses
        - Report to be finalised in December 2012
    - Model for Rapid REA
        - SAG consultation: 18 June -31 July 2012 >> 4 responses
        - Public consultation: 1 October – 14 November 2012

- Update WP5 activities – barriers for implementation of REA model/joint assessments
    - WP5 is investigating the potential barriers and success factors for implementing the rapid REA model/ doing joint assessments

- Replacement of implementation plan (WP5 work plan)
- Methods
  - Literature review
  - WP5 survey (July 2012)
  - Interviews with 6-8 countries (CVZ is using a subcontractor)
- Deliverable: report and publication

- Update WP5 activities – Guidelines on methodological issues
  - WP5 and SAG consultation:
    - 1st batch (4 guidelines): 7 March – 13 April 2012
    - 2nd batch (5 guidelines): 18 April – 21 May 2012
  - Huge number of valuable comments which contributed to improved methodology draft guidelines before public consultation
  - Some comments from SAG to be addressed at the same time as EMA and public consultation comments

- Update WP5 activities – Guidelines on methodological issues
  - EMA and Public consultation (including alerts to MEDEV, AHRQ, PBAC, Vancouver group):
    - 1st batch: Choice of comparator, composite EP, surrogate EP and applicability: 29 June – 10 Sept.
    - 2nd batch: Direct and indirect comparisons, clinical EP, HRQoL, safety and internal validity: 3 Sept. – 31 Oct.
  - The draft guidelines have drawn a high level of interest!
  - Impressive number of thorough and relevant comments from a variety of sources: industry, public bodies, HTA agencies and the EMA
  - Final discussion with WP5 members at f-t-f meeting in Budapest (22&23 November 2012)
  - Meeting on endpoints with EFPIA and stakeholders to discuss common issues-related issues before finalisation of GLs: 21 January 2012 in Brussels
  - Final guidelines: end of 2012/beginning 2013

- Update WP5 activities – Early dialogue
  - 2 preparatory pilots (May and July 2012)
  - Coordinated and hosted by HAS
  - 2 oncology drugs
  - Successful
  - First experience gained on:
    - Feasibility, including draft procedure
    - HTA bodies collaboration/governance issues,
    - HTA prospective thinking on evidence requirements based on 2 examples
    - Consolidated view/agreement/transparency on the choice of comparators and endpoints for REA
  - Help define how we want to work in the future (JA2 WP7)
  - Feed-back on the procedure from participating HTA bodies and 2 companies – draft procedure currently amended
  - More formal feed-back planned after 5-6 pilots (end 2013)
  - In 2013:
    - For pharmaceuticals: early dialogues planned in February, April, June and November

        - At least one early dialogue for other technologies (MD, diagnostic in vitro).
        - There is a waiting list with products for pharmaceuticals and other technologies
        - Successful
        - First experience gained on:
            - Feasibility, including draft procedure
            - HTA bodies collaboration/governance issues,
            - HTA prospective thinking on evidence requirements based on 2 examples
            - Consolidated view/agreement/transparency on the choice of comparators and endpoints for REA
        - Help define how we want to work in the future (JA2 WP7)
        - Feed-back on the procedure from participating HTA bodies and 2 companies – draft procedure currently amended
        - More formal feed-back planned after 5-6 pilots (end 2013)

- Update WP5 activities – Collaboration with EMA
    - Next f-t-f meeting: 20 November, 2012 in Copenhagen
    - Draft agenda:

EUnetHTA Methodological guidelines for REA (HAS)
EPAR improvement project – reporting of first experiences, additional proposals from EUnetHTA in light of the reviews of recent EPARS (HAS, EMA)
Databases for post-licensing studies (HAS) **Update on the new EU PhV Legislation and opportunities for bridging to HTA (EMA)**
Rapid model for REA, pilot and future developments; i.e. possibilities to streamline the timelines of rapid pilots with EMA assessments **(CVZ)**
Early scientific advice; EMA-HTA scientific advice, and multi-HTA scientific advice (HAS, EMA) **Significant benefit for orphan medicinal products: concept and experience (EMA)**

- Update WP5 activities – Final f-t-f meeting
    - November 22-23 2012 in Budapest
    - Agenda items:
        - Update of WP5 activities
        - Workshop on guidelines: outstanding issues
        - Presentation of online tool
        - Pilots in WP5 JA2
        - Early dialogue in WP7 JA2

Mira Pavlovic (MP) and François Meyer (FM) presented the information about WP7 activities and SAG involvement

- Brief recall on WP 7 Objectives
  - Strand A (HAS, France)
    - Facilitating evidence generation on new H - 3 deliverables:
      - minimum dataset to share information on policy relevant clinical studies in development (developed by NETSCC)
      - criteria to select new technologies in need of further evidence
      - database (EVIDENT) to share information & facilitate collaboration on additional evidence generation
  - Strand B (LBI-HTA, At) (*separate slides*)
    - Facilitating exchanges on current assessment projects

- Brief recall on stakeholder involvement in WP7
  - Only for Strand A
  - Stakeholders involved in two different ways:
    1. through Stakeholder advisory group (SAG): reviews of the first drafts of the 3 WP7A deliverables
    2. through Public consultation on final versions of deliverables on EUnetHTA's website

- Update on WP7A deliverables
  - All deliverables finalized:
    - Minimum dataset delivered to HAS in June 2011 and integrated into EVIDENT database
    - Selection criteria published on EUnetHTA's website in August 2012
    - EVIDENT database launched in November 2012
      - **https://evident.has-sante.fr/has/login.xhtml**

- Overview of Stakeholders' involvement in WP7A
  - 3 SAG consultations (first drafts of the 3 deliverables)
  - 2 public consultations (final proposal of criteria and EVIDENT database):
    - All tasks were performed according to the Workplan and the Standard procedure for Stakeholder involvement
    - Responses were heterogeneous: from short-ones to really elaborated-ones
    - Feedback helped improve the deliverables
    - Great interest expressed for the deliverables, especially by industry representatives

WP 7B: New Technologies - Pre-market/ pre-reimbursement assessment of new (non-pharmaceutical) health technologies

LBI-HTA, Austria

- POP/ planned and ongoing projects database
  - From excel-sheets to Fully searchable Database to Collaborations („offsprings")
  - POP Statistics: quarterly updates
    - Currently the POP database contains: 1260 planned, ongoing and recently published projects

- from 43 EUnetHTA JA partners
- from 24 countries

9th (May/June 2012) **POP Request**

Out of 59 EUnteHTA JA partners:

- **37 responded** and **entered projects** into the database
- **5 responded** but **DID NOT feed** the database
- **17 did not respond at all** (29%)
- **Total number of projects: 1266**
- **Alert (SAME) topics: 150 (12%)**
- **Similar projects** (within alert topics): **390**
- **Access-rights: 42** partners

10th (Sept/Oct 2012) **POP Request**

Out of 55 EUnteHTA JA partners:

- **31 responded** and **entered projects** into the database
- **12 responded** but **DID NOT feed** the database
- **12 did not respond at all** (29%)
- **Total number of projects: 1259**
- **Alert (SAME) topics: 143 (11%)**
- **Similar projects** (within alert topics): **394**
- **Access-rights: 43** partners

- „Offspring“: Collabs on cancer drugs (among 5 agencies)

1. **LBI-HTA + AHTAPol:** Dasatinib (Sprycel®) for the 1st-line treatment of Philadelphia-chromosome positive chronic myeloid leukaemia in the chronic phase; April 2011
2. **LBI-HTA + HTA Centre Bremen:** Second-line chemotherapy with Cabazitaxel (Jevtana®) for the treatment of castration-resistant metastatic prostate cancer; May 2011
3. **LBI-HTA + AHTAPol + UVEF (Reg. Veneto):** Eribulin (Halaven®) as third- or late-line monotherapy for advanced/metastatic breast cancer, July 2011
4. **LBI-HTA + HTA Centre Bremen:** Abiraterone acetate (Zytiga™) as 2nd-line therapy for the treatment of metastatic castration-resistant prostate cancer after docetaxel therapy; December 2011
5. **LBI-HTA + ULSS20:** Vemurafenib for patients with BRAF V600E mutation positive advanced/metastatic melanoma; January 2012
6. **LBI-HTA + ULSS20:** Axitinib (AG 013736, Inlyta ®) for the 2nd-line treatment of metastatic renal cell carcinoma; February 2012
7. **LBI-HTA + UVEF (Reg. Veneto) + AHTAPol:** Lenalidomide (Revlimid®) for the treatment of low /intermediate-1 risk myelodysplastic syndrome with chromosome 5q deletion; May 2012
8. **LBI-HTA + ULSS20:** Ipilimumab for the first line therapy of advanced/metastatic melanoma (ongoing)

C. Other issues

As the concluding topic JUCH briefed the meeting on this final agenda point:

1) EUnetHTA Stakeholder Forum Update e-newsletter (mid-December 2012)

- EUnetHTA Members Update: a quarterly newsletter contains news and WP updates
- Suggestion: to include SF updates on their organisations' activities in HTA area
- *Action point:*
  - Next issue: **14 December 2012** (input to be provided 1 week in advance)