EUnetHTA Joint Action 2
Stakeholder Forum meeting

Brussels, Belgium
February 26, 2015, 10:00 – 16:00 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

Summary Report - DRAFT

Agenda

Coffee, light snack upon arrival	*09:30 – 10:00*
1. Opening and presentation of participants	**10:00 – 10:15**
2. JA2: Current status and last year of implementation • Overview of remaining tasks and priorities • Stakeholder involvement activities in the last year of JA2 • Update on POP & EVIDENT access for SF/Public	**10:15 – 11:30**
3. Update on EUnetHTA Early Dialogue Survey	**11:30 – 12:15**
Lunch	*12:15 – 13:15*
4. HTA Network Update	**13:15 – 13:50**
5. JA3 – update on informal preparations	**13:50 – 14:15**
6. Stakeholder involvement in JA2 – lessons learned • **Open discussion**	**14:15 – 15:15**
Coffee break	*15:15 – 15:45*
7. Other issues and closing of the meeting	**15:45 – 16:00**

1. Opening and presentation of participants

Alric Rüther (IQWIG), Chair and Francois Houÿez (EURORDIS), Co-Chair of the Stakeholder Forum (SF) welcomed the participants and expressed their appreciation of having this opportunity to inform and discuss with stakeholders face-to-face about the activities and developments in EUnetHTA.

2. JA2: Current status and last year of implementation

Julia Chamova (DHMA, EUnetHTA Secretariat) gave the SF an overview of the accomplishments of EUnetHTA in Year 2 of JA2 (*Appendix 1, slides 3-16*)

Key comments and discussion points:

- The monitoring of the national uptake and adaptation in JA2 will focus on the activities performed by and work processes of the HTA bodies/organisations (both EUnetHTA Partners and Associates). Monitoring the impact of the EUnetHTA joint output on the national decision-making is not within the current remit and timeline of the work by the scientific and technical cooperation (EUnetHTA JA2), however, information on such impact is important. A webpage dedicated to national uptake is being developed and will open on the EUnetHTA website within the next 2 weeks (SF will be informed when the page is accessible).
- National implementation and adaptation, attention to process and project management will have special attention during the development of the JA3 proposal and its consequent implementation. EUnetHTA differentiated between national uptake (e.g. any output), national adaptation (e.g. joint assessments) and further impact on decision making). Link/impact on decision making was going to be address at next JA
- The criteria for assessing the conflict of interest and consequent process is being finalised by a special Task Force set up by the Executive Committee. The results of the work are to be approved by the Executive Committee in the next 2 weeks for pilot implementation in the remaining phase of JA2.
- Confidentiality handling procedures for stakeholders need to be improved; such procedures should not hamper timely access to and involvement of expertise from the stakeholder groups. It was suggested, as an example, to allow free circulation of confidential material between those SAG members that signed the confidentiality undertakings, in order to share learnings of the process and content among the SAG members.
- Interesting and positive results of cooperation between EUnetHTA and ROCHE Pharmaceuticals are available in a detailed report on the EUnetHTA website (http://www.eunethta.eu/news/roche-pharma-reviews-hta-core-model-pharmaceutical-perspective). The cooperation involved both the ROCHE Pharmaceuticals headquarters and the company's affiliates from 6 different countries (Europe and Canada). Presentations of the experience and outcome are scheduled for the international conferences (e.g., HTAi in Oslo in June 2015, ISPOR European Congress in Milan, November 2015). Adjustment of organisation's internal processes preparing to be active contributor and effective beneficiary of the European cooperation is expected not only from the HTA producers but also from the technology developing companies.
- One should consider the limited capacity of SME's to get engaged in general level exercises without direct connection to the "bottom line" improving their ability to deliver technologies and supporting evidence that is valuable to the healthcare systems. However, they should be equipped to learn from such exercises performed by the big companies.
- The point was also made to reduce complexity and the number of activities in the next Joint Action.

Action Points: EUnetHTA Secretariat to inform the SF when the national uptake webpage will be accessible).

Patrice Chalon (KCE, Belgium, WP6 LP) informed about the developments of the POP Database and Francois Meyer (HAS, France, WP7 LP) informed about the status of the EVIDENT Database concerning the public access to the databases (*Appendix 1, slides 17-19*).

Key comments and discussion points:

- A quicker access to the list of planned and ongoing projects respecting the confidentiality preferences indicated by the agencies would be appreciated.
- It was clarified that EUnetHTA has not asked for justification of the level of confidentiality chosen by the individual agencies when indicating possibility to make the POP Database contents publicly available.
- HAS will attempt to make appropriate contents of the EVIDENT database public before the end of JA2. It is important to understand that not all HTA agencies have a remit to request for additional evidence generation and therefore have no activities to report on in this area.

3. Update on EUnetHTA Early Dialogue Survey

Francois Meyer (HAS, France, WP7 LP) informed about the results of the EUnetHTA Early Dialogue survey and developments in the ED activities both in EUnetHTA and in SEED (*Appendix 2*).

Paolo Morgese (EuropaBio) briefly informed on the outcomes of the workshop held by EuropaBio in November 2014 on regulatory and HTA scientific advice for small and medium enterprises (SMEs) highlighting the importance and usefulness of early dialogue activities for biotechnology industry SMEs[1]

Key comments and discussion points:

- There is an observed positive outcome in terms of quickly learning from each other (HTA and industry), gaining experience and improving the process and content of such exercise. Increased trust and confidence is observed among and towards both participating parties (HTA agencies and industry).
- EUnetHTA and SEED EDs on medical devices will have a survey attached to each of the performed EDs to gather feedback on experience. There will not be a general survey after all EDs on medical devices have been performed
- It was indicated that it might prove beneficial to inform payers about the process of EDs (although their direct involvement in the process of EDs is not seen as appropriate; consensus on the mode of involving payers in the ED process has not yet been achieved)
- Issue of sustainability of the activity is on the agenda of both the HTA agencies and participating industries with exploration of feasible ways to finance such an activity in the long-term
- Preparation of the patient group participants in the EDs in advance to the ED meetings would be helpful to improve patient representatives' input and commitment to the activity

4. HTA Network Update and
5. JA3 – update on informal preparations

Flora Giorgio (DG SANTE) informed about the activities in the HTA Network (*Appendix 3*). Jerome Boehm (DG SANTE) informed on the developments in patient registries initiatives. Julia Chamova (DHMA, EUnetHTA Secretariat) updated on the JA2 Executive Committee's discussions and input to the JA3 proposal development (*Appendix 1, slides 23-28*).

Key comments and discussion points:

- Guidelines produced by the PARENT JA might be taken up by EMA in their adaptive pathways initiatives; there might be a Task Force set up by EMA on registries (in the pharma area); with regards to medical devices much less is done; some considerations to charge JA3 to coordinate development of standardised post-marketing requirements in different MS. It was commented that setting up registries and actually collecting data would not be an appropriate task of JA3, but

[1] EuropaBio has made the report from the workshop public http://www.europabio.org/HTA-SMEs

someone would need to actually start collecting data, i.e., practical steps of going beyond methodological and academic exercise of standards alignment towards starting collecting data must be taken some time soon in the future.

- Involvement of stakeholders in the JA3 proposal development process needs to be clarified. One option is to be nominated by a MS to be an official partner in the JA3 consortium. Industry representatives commented that stakeholder involvement in JA3, which according to the perspective of the industry, should be revised and changed towards a "true partnership" mode.
- General support was expressed by the SF, Executive Committee and DG SANTE representatives to have a mechanism of stakeholder involvement at the political/strategic level in connection to the HTA Network, and have a purpose-specific involvement of stakeholder representatives at the scientific and technical level in JA3 (for the scientific and technical activities it would be useful to explore practical possibilities to engage with the stakeholder representatives on the national/regional level to have access to expertise and opinions in e.g., specific cases of joint assessment production).
- The activities and output of JA3 must have a direct utility to the national HTA processes, and not be an academic exercise. Strategic alliances must be built with other initiatives to ensure continuous scientific support and development to the general HTA processes (e.g., with H2020, scientific societies, etc.)
- JA3 is to develop a final workable business model for the permanent European cooperation for HTA that can be tested for viability and consequent adjustments preferably in the final year or two of the JA3. At the same time, all need to keep in mind the practical implementation challenge connected to the fact that the framework and financing that might be made available through the JA is organised on a project basis, not on a basis of permanent operations basis.

6. Stakeholder involvement in JA2 – lessons learned (open discussion)

Paolo Morgese (EuropaBio) presented joint input from the industry stakeholder group (*Appendix 4*). Jacques De Haller (CPME) and Irina Odnoletkova (AIM) shared providers and payers input respectively.

Key comments and discussion points:

- General positive attitude to continuation of the European cooperation on HTA activities, both at the strategic and scientific/technical levels. Lessons learned indicate the necessity of adjustment of the current system and practice of the stakeholder involvement in the activities.
- It was recognised that the stakeholder groups need to work with their constituencies to make them prepared, to learn the language and process, to contribute and harvest benefits of the involvement in the European cooperation on HTA
- Stakeholder involvement process and practice needs to be "fit-for-purpose" and in accordance to Article 15 of the Directive on cross-border healthcare. Continuation of appropriate stakeholder involvement should take place both at the strategic as well as scientific and technical levels of the European cooperation on HTA.
- It was agreed that the stakeholder groups will share with the EUnetHTA Secretariat their "lessons learned" and concrete suggestions for improvement of the stakeholder involvement in writing. This contribution will also be a part of the final reporting from JA2 and can be helpful in developing a possible JA3 proposal. If such an input can be provided within the next 2 months it will be useful for both processes (JA2 reporting and JA3 preparation).
- Payers expressed the most reserved recognition of the current practical value of the European cooperation on HTA indicating that the European cooperation process must be further improved to provide visible value added to the national processes; the participation of industry has been perceived as limited, involvement of decision-makers must be better organised (e.g., early in scoping phase cooperation between MS is very important). Payers further expressed that all

technologies receiving public financing must be subject to HTA; the process of Early Dialogue must clearly support differentiation between the remits of regulators and HTAs, payers might possibly be included in the scoping phase, ED procedure must be further defined and clarified. Payers further indicated that they can be more proactive in the submission template uptake, but requested to establish first the efficiency of such cooperation. Furthermore, they were rather sceptical on the SAG mechanism of payers representatives' involvement. The most useful for payers is to be kept informed on the activities and output through newsletters, participation in the general meetings (Plenary Assembly), conferences.

- Improved communication on the nature and remit of the HTA Network and EUnetHTA/ scientific and technical level to various external parties would be helpful, e.g., some patients groups perceive EUnetHTA as a possible "appeal body".
- With regards to possible JA3, it was mentioned that:
    - this joint action was the main mechanism of implementing the HTA Network Strategy,
    - Simplification of administration and management of JA3 is needed
    - Improving joint production, capacity building and uptake at national level are among the planned top priorities of JA3

Action Points: SF members to provide written input on lessons learned and concrete suggestions for improvement of the stakeholder involvement processes in the European cooperation on HTA. Deadline: end of April.

7. Other issues and conclusion

Julia Chamova (DHMA, EUnetHTA Secretariat) updated on the dates of the SF meetings. The SF is to inform the EUnetHTA Secretariat by April 20, 2015 on the names of individuals who will attend the PA meeting in Copenhagen (May 2015).

Chair and Co-Chair thanked all the participants for active contribution to the discussions and adjourned the meeting.

Action Points: The SF is to inform the EUnetHTA Secretariat by April 20, 2015 on the names of individuals who will attend the PA meeting in Copenhagen (May 2015).

Participants List

As of January 26, 2015

EUnetHTA Stakeholder Forum

Attendee	Organisation
George Sarelakos	***AESGP (Association of the European Self-Medication Group)***
Irina Odnoletkova	***AIM (Association Internationale de la Mutualité)***
Menno Aarnout	***AIM (Association Internationale de la Mutualité)***
Ilaria Passarani	***BEUC (The European Consumers Organisation)***
Marie-Astrid Libert	***COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry)***
Jacques de Haller	***CPME (Standing Committee of European Doctors)***
Constance Colin	***CPME (Standing Committee of European Doctors)***
Victoria Wurcel	***EDMA (European Diagnostic Manufacturers Association)***
Yves Verboven	***EDMA (European Diagnostic Manufacturers Association)***
Milena Richter	***EFPIA (European Federation of Pharmaceutical Industries and Associations)***
Pieter Dylst	***EGA (European Generic Medicines Association)***
Erick Tyssier	***EGA (European Generic Medicines Association)***
Valentina Strammiello	***EPF (European Patients' Forum)***
Christina Dawson	***ESIP (European Social Insurance Platform)***

Rosa Giuliani	***ESMO (European Society for Medical Oncology)***
Pascale Brasseur	***EUCOMED (Medical Technology)***
Paolo Morgese	***EuropaBio (European Association of Bioindustries)***
François Houÿez	***EURORDIS (European Rare Diseases Organisation)***
Pascal Garel	***HOPE (European Hospital and Healthcare Federation)***

EUnetHTA Executive Committee

Claudia Wild	***LBI-HTA (Ludwig Boltzmann Institut für Health Technology Assessment), WP5 Co-LP***
Sonja Scheffel	***HVB (Hauptverband der Österreichishen Sozialversicherungsträger), WP3 LP***
Patrice Chalon	***KCE (Belgian Health Care Knowledge Centre), WP6 LP, WP2 Co-LP***
Julia Chamova	***EUnetHTA Secretariat (Danish Health and Medicines Authority), WP1 LP***
Julie Lange	***EUnetHTA Secretariat (Danish Health and Medicines Authority), WP1 LP***
Kristian Lampe	***THL (National Institute for Health and Welfare), WP8 LP***
Francois Meyer	***HAS (Haute Authorité de Santé), WP7 LP***
Alric Rüther	***IQWIG (Institute for Quality and Efficiency in Health Care), WP7 co-LP; SF Chair***
Marina Cerbo	***Agenas, Agenzia Nazionale per i Servizi Sanitari Regionali***
Luciana Ballini	***ASSR (Regione Emilia Romagna, Regional Agency for Health and Social Care), PA Chair***

Ingvil Sæterdal	***NOKC (Norwegian Knowledge Centre for the Health Services), WP2 LP***
Simone Warren	***ZIN (National Health Care Institute), WP5 LP***
Christoph Künzli	***SNHTA (Swiss Network for HTA)*** ***Ex Comm***
Nick Crabb	***NICE (National Institute for Health and Care Excellence),*** ***Ex Comm***

European Commission – DG SANCO

Attendee	Organisation
Flora Giorgio	***DG SANTE, European Commission***
Jerome Boehm	***DG SANTE, Commission***