EUnetHTA Joint Action 2
Plenary Assembly

Copenhagen, Denmark
May 28, 2015, 09:00-17:30
May 29, 2015, 09:30-13:30

Address of the meeting venue:
Hotel Scandic Sydhavnen
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Summary Report

May 28, 2015

1. Opening remarks	**09:00 – 09:10**
2. Finalising JA2 - I • Report from the Coordinator • EUnetHTA CoI process update • EUnetHTA-SEED cooperation	**09:10 – 10:30**
Coffee break	*10:30 – 11:00*
3. EUnetHTA, HTA Network, and national HTA activities and processes • HTA Network Strategy and Reflection paper "Re-use of Joint work in national HTA activities" • National experiences with applying EUnetHTA tools, outcomes and processes	**11:00 – 12:30**
Lunch	*12:30 - 13:30*
4. Finalising JA2 - II • Remaining tasks and expected results of JA2; reporting of JA2 • Stakeholder perspectives on the experiences and learnings from EUnetHTA JA2	**13:30 – 14:30**
5. Possible JA3 – advice on priorities, objectives and activities (I) • Introduction by EUnetHTA and HTA Network • Group work (4 groups; including stakeholders in each)	**14:30 – 17:30**
Coffee break	*15:00 – 15:30*
Social event: Guided boat tour of Copenhagen and dinner at Restaurant Ravelinen, Torvegade 79, 1400 Copenhagen K	*18:00– Ca.23:00*

May 29, 2015

1. Possible JA3 - Reports from Group discussion (II)	**09:30 – 10:15**
Coffee break	*10:15 – 10:45*
2. Possible JA3 – advice on priorities, objectives and activities (III) • Plenary discussion	**10:45 – 12:00**
Lunch	*12:00 – 13:00*
3. Other issues and Conclusion	**13:00 – 13:30**

May 28, 2015

1. Opening remarks

Luciana Ballini (ASSR, PA Chair) and Finn Børlum Kristensen (DHMA, EUnetHTA Exec Comm Chair) welcomed the participants to the Plenary Assembly. Emphasis was placed on active contribution from all PA member organisations to the discussions at the meeting, especially in the context of EUnetHTA moving from the experimental phase of trying out new tools and process that required change in perspective, processes and demanded extra resources. EUnetHTA is moving to routine application of these tools and processes in everyday practice of the national work, where learning from each other will contribute to multi-faceted efforts of ensuring sustainability of the European cooperation on HTA in the long-run. The goal of post-2019 is ‘‘routinisation’’ where the use of the joint work and production of national HTAs that can be effectively used cross border will become a norm, not an exception, and becoming an integral part of the regular HTA production processes in the European HTA. A successful completion of the current phase of EUnetHTA development (i.e. JA2) is important to ensure an effective transfer and start of the next phase (possible JA3). The agenda was adopted as was.

2. Finalising JA2 – I

Report on Year 2 from the Coordinator

Julia Chamova (DHMA, EUnetHTA Secretariat) presented a report from the JA2 Coordinator on results, achievements and lessons learned from the activities in the second year of JA2 (*Appendix A, slides 8-17)*

EUnetHTA CoI processes and update

Lidia Becla (DHMA, EUnetHTA Secretariat) updated the participants on the development of the Conflict of Interest process in EUnetHTA (*Appendix A, slides 18-20*).

Key comments from the plenary discussion:

- As part of the update from the coordinator, the PA was informed that the adjustment of the JA2 budget took into account actual workload and distribution of tasks among partners and reflects the activity-based contribution by the participating organisations and their staff members involved in EUnetHTA activities. Up to 20 person days have now, following the budget reallocation, been allocated to the national uptake activities by the EUnetHTA partners.

- Regarding the use of CoI, it was clarified that when a new staff member joins the EUnetHTA teams in the EUnetHTA partner institutions, it is a responsibility of the partner institution to ensure that the new staff member has completed the relevant CoI forms. The LPs and Co-LPs of the WP in which the partner institution participates can give guidance when it is mandatory to fill in the EUnetHTA forms and help with the process (e.g. the WP5 LP and Co-LP check the completed CoI forms prior each of the new pilots to ensure that CoI issues are clarified before individuals start their work in the pilots.
    - The process of managing the CoI and confidentiality issues is being tested in the ongoing projects in order to introduce appropriate standardisation in the process across the WPs.

EUnetHTA SEED Cooperation

Francois Meyer (HAS) informed the PA about SEED and the process and topics to be addressed in the drafting of a permanent Early Dialogue (ED) model (*Appendix B*).

Key comments from the plenary discussion on SEED:

- Experience with EDs for medical devices companies shows that up to now small companies are more active in seeking an advice through EDs.
- SEED has placed information online about the possibility to participate in the ED pilots and informed about it via the HTA Network, EUnetHTA and SF channels. Market access consultancies were active in playing a role of intermediate in connecting some medical device companies to SEED.
- It was commented that ED activities in the future might benefit from connection to the HTA Core Model framework while taking into account the interest and choice of questions that the companies are coming with when seeking ED advice.
- The process of ED on procedures is not yet developed, but would be an area to look into more closely in the future.
- The Issue of "return on investment" for both a public institution and a technology producer in participating in the ED process needs further discussion. For the moment, the business model considered for implementation includes fee for service for those (commercial) organisations that seek such advice. Challenge of how to evaluate the results of the ED activity in order to establish ROI for the participating parties is an additional issue to discuss.

- ED advice are currently offered to the companies that have products going into Phase III studies for pharmaceuticals; for medical devices it varies when in the development this happens. Specifically for medical devices, further clarification on the process is needed as the questions in the ED should be prospective in order to inform appropriate evidence generation, whereas some of the medical device companies sought ED advice on products on which data have already been collected. Industry stakeholder representative pointed out the need for further explanation and taking inot account the differences and specificities medical devices and IVDs require in terms of data collection and evidence generation, such as the continuous innovation process which prospectively drives the data collection and evidence generation, so the timing of the ED becomes different for these technologies.
- Strict rules on confidentiality are applied in the SEED project. Signing specific confidentiality agreements directly with each participating company is not a preferred way of managing confidentiality issue; however, further discussion with industry on the matter is welcomed to find an effective way that would be acceptable to all participating parties (i.e. public institutions and commercial organisations). The industry stakeholder representative inidicated that due to a weaker patent protection system for medical technologies there is a need for suplemental confidentiality provisions.
- After each SEED ED a survey is sent to the participating parties to share feedback on the procedure in order to use this information in improving the procedure. The EMA early scientific advice procedure provided some ideas for ED procedure development. Consultation with the EUnetHTA PA in the autumn of 2015 will provide further feedback to the ED procedure improvement efforts.
- Written feedback received from various industry associations is useful and important, though at times indicating a more sceptical view on the activity than the feedback received from individual companies that actually participated in the ED reflects.
- Shortage of human resources, priorities in the HTA organisations, novelty of the ED process itself, unclarified ‘‘return on investment’’ for the public organisations participating in EDs, procedural matters (e.g. additional confidentiality provisions) associated with the companies’ choice of the HTA bodies that the companies want to be involved in the ED, legal aspects (eg, prohibition to discuss matters with industry prior to their submission of data for evaluation) are all among the aspects that hamper HTA bodies support or participation in the ED process.
- Exploration of appropriate alignment of the ED for medical devices with the developments in the medical device regulatory efforts at the European level could be beneficial.

Action points:

- SEED (Coordinator HAS) and the EUnetHTA Secretariat to clarify if there is an opportunity (and a date/place) to have an additional Face-to-Face meeting with PA members to discuss the SEED proposal for the ED process. Alternative ways of collecting the needed input are also to be clarified by the SEED. Time: as soon as possible.
- The legal issues associated with ability to participate in the EDs can be taken up by the HTA Network.

3. EUnetHTA, HTA Network and national HTA activities and processes

The HTA Network Strategy and the reflection paper 'Re-use of Joint work in national activities'

Jerome Boehm (DGSante, HTA Network Secretariat) updated the Plenary Assembly on the reflection paper on Reuse of joint work in national activities and barriers associated (*Appendix C, slides 2-5*)

National experiences with applying EUnetHTA tools, outcomes and processes

Anne Raahauge (DHMA, EUnetHTA Secretariat) and Anna Nachtnebel (LBI-HTA) informed the participants about the development of definitions on National uptake and adaptation in EUnetHTA and the Survey on the topic (*Appendix A, slides 25-38)*.

Teresa Molina López, AETSA & Marisa López Garcia, AVALIA-t – Spanish Network presented to the PA how EUnetHTA approaches are used in the Spanish HTA Network (*Appendix, D*)

Raf Mertens (KCE) was due to delay not able to present the experiences in KCE, but joined the discussions. Presentation from KCE (*Appendix E)*.

Key comments from the plenary discussion on National uptake and adaptation:

- The relevance and timing of the topics to work on and alignment of priorities – both at the national level in the regionalised systems of HTA cooperation e.g. in Spain, and at the European level – is a crucial issue to address practically to build a foundation for useful joint work. Experiences of the Spanish HTA Network bring valuable insights into the process.
    - The Spanish HTA Network cooperation has a legal framework; it builds also on years of cooperation prior to the establishment of a legal framework (thus, trust and understanding of each other's processes have been achieved). The Spanish Ministry of Health is a decision-maker that identifies the relevant topics for HTAs that then are being coordinated for production between the participating regional HTA agencies. Any other player in the healthcare systems of Spain (e.g. national medical societies) need to approach the Ministry to put a topic on the agenda in order for it to become a topic for actual assessment.
    - There is an agreement – also supported by a legal provision (Royal Decree) – between the Spanish HTA Network agencies that if one agency produced a report on a specific topic no other agency duplicates the work on the same topic.
    - The topic for a EUnetHTA joint assessment on renal denervation was timely for the national priorities of the Spanish HTA Network – thus they took an initiative to be a co-author in this joint assessment which then allowed them to effectively use the results of this joint assessment for their national purposes and decision-making (after adaptation). The decision on procurement of the technology waited for the results of the assessment.
    - National HTA guidelines in Spain make use of the EUnetHTA guidelines when updated.
    - The Spanish HTA Network produced a detailed summary of the EUnetHTA joint assessments in Spanish, accompanied by links to the original joint assessments (in English) when adaptation was made and then sent to the relevant decision-makers in Spain.

- Mutual recognition of reports from different agencies needs to be based on a transparent process of quality assurance that builds on the shared understanding, procedures and methodologies of the coordinated HTA report production. In the Spanish HTA Network a special quality control tool has been developed for application in checking the quality of the reports.
- Not only the EUnetHTA joint assessments but also their national adaptations are then used again by the EUnetHTA partner organisations in producing their HTA reports that suit their local settings (e.g. HVB, Austria).
- For the assessment of hospital/expensive drugs the length of the joint assessment production needs to be shortened – it should actually start before the EMA/ European Commission makes the official licensing decision.
- EUnetHTA joint assessments can feed into the national clinical guidelines development (e.g. ZIN experience).
- Change of the originally agreed timings (e.g. extension of timelines) in the EUnetHTA joint assessment process negatively affects national adaptation possibilities – as the national timelines are strict and in most cases cannot wait for the extended production times at the European level. There is an urgent need to ensure stricter adherence to the production timelines (attention to project by all parties including the company, management and respect of deadlines need to be improved).
- Topic notification and selection at a centralised level would be important to set up in JA3 in order to improve the relevance of the selected topics to a larger number of EUnetHTA partners (probably more relevant for medical devices?)
- Application of the HTA Core Model in producing original local HTA reports gives a high promise to allow production of the HTA reports in a transparent and standard way that would contribute to utilisation of the national reports across borders, thus contributing to increasing cost-effectiveness of the HTA production processes.
- It was suggested that besides working on the barriers to national implementation of the European output at the national level, there should be a joint effort at the central European level on scientific and technical cooperation on HTA, regarding priority setting and alignment through a concerted joint effort of the different Member States.
    - There are 4 ways of maximising value from the joint efforts:
        - Through joint assessments.
        - Through adapting results of joint assessments at the national/regional level.
        - Through cross-border utilisation of national adaptation of the joint assessments.
        - Utilising cross-border original national HTAs that from the start are developed in a transparent, standardised way (using EUnetHTA tools and frameworks) allowing their swift utilisation by partner HTA agencies in Europe.
- Formalisation of the different ways of re-using the European cooperation output could be helpful in the next phase (JA3) of the development of cooperation.
- Joint assessments make conclusions on the quality of the available evidence on a specific topic and whether for certain end-points there is a significant difference between options and if it is relevant. The next steps in how to use this information in the national settings are up to the Member States that then use the results of the joint assessment for their assessment and decision-making nationally.

- The Community of Practice set up in the EUnetHTA JA2 can contribute to sharing experiences in national uptake of the participating agencies and also linking to the efforts of the Secretariat and WP5 Co-LP in monitoring the national uptake.
- Utilisation of the POP Database resource to identify potential partners for collaboration on shared topics is one of the ways of sharing workload and using resources wisely through cooperation.
- Several agencies (e.g. KCE, LBI) started to produce their own original HTA reports in the framework and format of the HTA Core Model e.g. producing cards with answers to the questions from the model on a specific subject. This is a way of standardising scientific information which can then be shared and utilised across borders, i.e. producing reusable material. Commitment from the agencies to go this way in developing collaboration further would allow building up a sustainable model for collaboration.

4. Finalising JA2 – II

Remaining tasks and expected results of JA2, reporting on JA2

Anne Raahauge updated the PA on the key remaining task of JA2 and initial information on final reporting (DHMA, EUnetHTA Secretariat) (*Appendix A, slides 43-49)*.

Stakeholder perspectives on the experiences and learnings from JA2

Francois Houÿez (EURORDIS, Co-Chair EUnetHTA Stakeholder Forum), Victoria Wurcel (EDMA), Valentina Strammiello (EPF), Menno Aarnout (AIM) and Jacques De Haller (CPME)[1] presented the participants with the collected experiences gained in JA2 from the four Stakeholder Forum member groups (*Appendix F*).

Key comments from the plenary discussion:

- Broad scope of HTA, going beyond economic considerations, should be preserved and strengthened – also with a more structured inclusion of views and experiences of patients and providers on the technologies being assessed.
- The most inclusive process with mandatory stakeholder consultations makes the assessment process take a lot of time – considerations must be given to the value of these consultations and trade-offs that can be made in making the process more efficient while preserving high quality and ensuring appropriate accountability for input and results.
- The European cooperation on HTA is to contribute with reliable and transparent information to the decision-making on health technologies but not "to make market access quicker", but "to contribute to seamless introduction and faster patient access to effective health technologies in Europe".
- Prioritisation and selection of topics can benefit from the involvement of stakeholders (attention should be given to the observation that up to now attempts to involve the stakeholders into the topic notification process for joint assessments were not successful – the stakeholders did not

[1] Please see Participants List for indication of representation of stakeholder group interests by the attending representatives.

respond to the invitations to contribute). There is a need for higher transparency in topic proposal and selection to improve understanding and participation of stakeholders in the process

- From the patient stakeholder group perspective, cooperation and alignment of views on methods and what can be done for different types of products on the national level beyond the joint REA on the European level, can contribute to speeding up the assessment processes of making effective technologies available to the patients in the European countries. More cooperation on post-marketing data collection is welcome.
- Stakeholder involvement practice should be adjusted to improve meaningful and helpful involvement of stakeholders that contributes value to the assessment process – mapping areas where that can be done in JA3 could be helpful. It was proposed that , eg, one or several HTA bodies should take the lead to create a dedicated unit for stakeholder involvement. In all relevant EUnetHTA JA3 activities where patients can take part patients' organisations would be willing to advice on how to best achieve this.

5. Possible JA3 – advice on priorities, objectives and activities

Introduction by EUnetHTA and HTA Network

Julia Chamova (DHMA, EUnetHTA Secretariat) and Jerome Boehm (DG Sante, HTA Network Secretariat) informed the participant on preparations for the possible JA3 as a basis for the discussion in the group work (*Appendix A, slides 55-63*) & (*Appendix C, slides 7-13*).

May 29, 2015

1. Possible JA3 –Group reports and plenary discussion

Wim Goettsch (ZIN) presented the discussion in Group 1 (*Appendix G*); Simone Warren (ZIN) presented the discussion in Group 2 (*Appendix H*); Andrew Cook (NETCC) presented the discussion in Group 3 (*Appendix I*); Alric Rüther (IQWIG) presented the discussion in Group 4 (*Appendix J*)

Key comments from the plenary discussion:

- Much better insight into the national HTA processes and decision-making processes on reimbursement needs to be in place rather soon in JA3 to inform and shape the joint assessment process in order to maximise attractiveness, utility, relevance and impact of the joint assessments and their outcomes. Mapping the decision-making landscape in the network participating countries (e.g. who are the decision-makers that the HTA agencies are serving with their information?) will be helpful.
- Link between HTA and decision-making, i.e. the need to better understand how and how much HTA informs decision-making in different European countries in order to possibly identify commonalities and divergences to positively contribute to the process. This link in its turn affects the level of commitment to the joint efforts on the European level. The patients' representatives indicated that

patients' organisation would very much welcome HTA reports to include a general opinion on the added value for the assessed health technologies.

- Better use of horizon-scanning would be helpful.
- The topic selection process needs improvement; needs of decision-makers and their appropriate involvement in identifying relevant topics for HTA must to be thoroughly considered. Potentially requesting Member States to identify and nominate representatives who would participate in and be responsible for the topic selection for the European joint assessments should be considered with the HTA Network.
- Priorities and focus for joint work need to be discussed from a practical perspective to identify those areas of joint effort that would bring most value.
- Methodologies of stakeholder involvement to secure more efficient stakeholder involvement and qualified input need to be in place.
- The HTA community should not take direct responsibility for evidence generation in terms of data collection efforts, but should take responsibility for agreeing on the set of requirements for which data is needed and should be collected.
- Working together and committing to the notion of producing the national HTA reports in a format that allows re-use across borders (via e.g. standardisation efforts, quality assurance and possibly accreditation of HTA production processes etc.) might contribute to reducing duplication and increasing effectiveness. Additionally, patients' organisations suggested that several formats are developed for HTA reports to be understood by different audiences.
- Different levels of commitment and partnership constellations in the technical and scientific cooperation should be developed via e.g. a charter with 3 levels, which all partners will have to sign: Level 1 (minimum): an agency commits to put all planned and ongoing HTAs in the POP Database and consults the POP Database when considering or starting a new project; an agency actively commits to re-use the material produced in the network. Level 2: an agency actively commits to work towards the standards of quality and methodology of the network in its own setting and production routines; an agency commits to producing their own products in the standard format allowing its re-use by the other partners in the network. Level 3: an agency commits to actively search for opportunities to do joint work in own programmes according to the quality standard and methods of the network. Such a charter can formalise a commitment concept.
- Training on the job and mentoring should not be the exclusive ways of capacity building in the participating agencies; other more formalised approaches to training should be considered – via cooperation with already established training programmes offered by e.g. societies, to use limited resources efficiently.
- Financial support to translation of local reports produced in a re-usable format (and following the agreed standards and methodologies of the network) might be considered as an incentive mechanism.
- Distinction between the notion of a decision-maker and a consumer of the HTA information should be upheld, because HTA information might feed into the development of e.g. clinical practice guidelines, healthcare pathways and health systems reviews.
- Involving the network partner's staff members who are in charge of and perform national assessments into the joint assessment work will help with overcoming the barriers inside the organisation to accepting the results of the joint work. Involving the same people only who have

participated in the international cooperation on HTA is not particularly helpful in spreading the culture of cooperation internally in organisations.

- HTA on complex interventions should not be left out of the scope of the JA3 joint work.
- The issue of too wide/too narrow indication, definition of population (too general) and then results of the scoping exercise for joint assessment might lead to inability to align with the national HTA process needs.
- Economic evaluation is a responsibility of the national level in HTA; however, certain alignment of the aspects to be covered by the economic evaluation which will then be performed nationally can be suggested (and is being looked into in the work of JA2 WP4). Patient stakeholder group also insisted on the importance to develop Guidelines on cost and economic aspects, as different methods are used in the EU and the public may have difficulties understanding diverging conclusions based on different methods.
- The role of the HTA Network in the identification of topics for joint assessments should be explored; developing a standard procedure for topic identification and selection must be brought in place.
- Increase in awareness of the decision-makers about EUnetHTA on the national level would be helpful; some central support from the EUnetHTA coordination facility is welcome in this effort. Besides, knowledge of the target groups at the national level should be more aware of the EUnetHTA efforts which would be helpful in devising communication activities to increase awareness.
- Finding ways of involving clinicians in topic selection could be useful ways of influencing the primary customers of the HTA reports (e.g. policy makers or reimbursement agencies) to bring the topic on the to do-lists of the HTA agencies.
- Brokering of topics for a joint assessment done by a smaller cluster of agencies (2-3 agencies) could be a possible way forward.
- Benchmarking and accreditation of HTA agencies might be helpful; training to support this exercise would also be helpful.
- The JA3 should be structured in a way that during the first two years the business model for a permanent structure is developed and in the last two years it is field-tested for viability
- Concentration on fewer activities in JA3 should be adhered to.
- The Network coordination function is not a task of the Coordinator only it is a responsibility of the WP Lead partners – a responsibility that is not limited to focusing on coordination and delivering results exclusively inside their own WP, but making sure that there is consistency, coherence and effectiveness in coordination across WPs. More buy-in, planning of the activities inside the WP must reflect this shared sense of responsibility and accountability for coordination.
- Engagement of financial, organisational, legal competences at the national level in developing post-2019 scenarios for a permanent mechanism of support of a sustainable cooperation needs to be initiated from day 1 of JA3 in order to have timely solutions – bringing these solutions to life takes time (especially with regards to having a legal basis for their implementation).
- Choices need to be made with meeting acute needs and long-term needs and plan accordingly in JA3 activities. Added value at EU level and what can be pursued after 2019 should be the focus for making choices; working with other initiatives (Horizon2020, IMI, scientific societies resource should be engaged in finding effective solutions that can contribute to effectiveness JA3).

2. Other issues and Conclusion

- On behalf of WP3 the chair encouraged the PA meeting participants to complete the yearly WP3 survey and ask their colleagues back home to do the same.
- The EUnetHTA Secretariat was thanked for having done a great work in preparing and holding the PA and Luciana Ballini and Mairin Ryan was thanked for their contribution as PA Chair and Co-Chair and for leading the meeting.

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Apologies:

Ministry of Health, Cyprus	Cyprus
Ministry of Health of the Czech Republic	Czech Republic
NSPH, National School of Public Health	Greece
UETS, HTA Unit, Agencia Lain Entralgo	Spain
TÜBITAK-TÜSSIDE, Scientific and Technological Research Council of Turkey	Turkey