

Preparation of the Plenary Assembly (PA) meeting

April 10-11, 2014, Madrid

GUIDING DOCUMENT

Purpose of the document

This document was developed to facilitate your preparation for and interactions at the upcoming PA meeting in Madrid, April 10-11, 2014. It follows the agenda of the meeting in describing specific areas or themes for discussion under each agenda item as well as describing the proposed format of interactions.

The aim of the meeting is to allow collecting as much input as possible from EUnetHTA's diverse constituency - specifically paying attention and ensuring that opportunities for input are provided for the representatives from

- a) Well-established and experienced HTA organisations as well as newly established HTA organisations
- b) HTA organisations from countries with regionalised healthcare systems
- c) "Big" and "small" HTA organisations (ie, "big"=with 30+ employees or embedded within a bigger organisation with a mandate and tasks wider than only producing/contributing to HTA reports to support decision-making for the national/regional health-care systems).

Meeting organisation – general

- **Day 1** of the meeting (before lunch) will be organised and managed in a plenary setting
- **Day 1** (after lunch) will include both discussions in plenary and group work (6 groups; each group discussing an identical set of issues focusing on the "EUnetHTA strategic development" in the mid-term (ie, a possible JA3 2016-20)).
- **Day 2** will start with presentations from the group work (thus, the group should identify a rapporteur from the start of the group work) and discussions in plenary (all around the table). The Plenary Assembly's position¹ on certain issues will then be clarified (when appropriate and needed).
- The groups will be formed on-site at the meeting.

¹ In case of need for voting for decision-making on certain issues, each PA member organisation has 1 vote. Decisions are taken by majority vote of PA members present at the meeting, in case of ties, the decision by the PA Chair prevails. PA Chair exercises his/her voting rights only in case of ties.

Agenda item “First half of EUnetHTA JA2 (18 months) – report from the Coordinator”

- The JA 2 Coordinator will report on the “state of the action” based (among other things) on the 1st Interim Technical Report to the European Commission (with contributions from all WPs), amendments made to the 3-year Work Plans, regular reports from the WP Lead Partners and Co-Lead partners and interactions in the Executive Committee as well as daily interactions of the Coordinator with the Partners and Associates. It will also cover external collaborations, e.g., EMA, FP7 projects, PARENT JA, etc; factors facilitating collaborations, main barriers; stakeholder involvement experience. The draft presentation slides are included among the background documentation for your review – it will also be presented (in an appropriate brevity) at the meeting.
- Interactions on the agenda point will be held in a plenary session. *The chairmanship of the meeting will specifically pay attention to solicit input that will represent views of the diverse EUnetHTA constituency (as described on p. 1 of this document).*
- **Currently, we kindly ask you – in preparation for the discussions at the meeting - to ponder the following issues reflecting on your (ie, your organisation’s) experiences during the first half of JA2**
 - a) Factors that facilitate collaboration and/or receiving greatest value by your organisation from EUnetHTA
 - b) Main barriers to collaboration and/or to receiving greater value for your organisation from EUnetHTA (including reflections on the formal/budget conditions of the Join Action as per the grant agreement as well as internal organisational barriers in your organisation)
 - c) Feasibility of incorporating/applying current EUnetHTA tools and processes into your own organisation’s processes and routines
 - d) Most useful of the current external collaborations of EUnetHTA
 - e) Stakeholder involvement in EUnetHTA and relevance/lessons learned for the national stakeholder involvement practices

Agenda item “EUnetHTA Elections 2014 - short presentation of candidates and procedure”

- The instructions on the election procedure as well as the nominations and letters of interest from the running candidates are shared in written form as part of the background documentation for the PA meeting. The candidates will have 3-5 minutes to verbally introduce their candidatures to the Plenary Assembly in Madrid. The election logistics on-site will be briefly explained by the EUnetHTA Secretariat at the meeting before the votes are to be cast.

Agenda item “Approval of amended SOP and EUnetHTA JA2 Conflict of Interest Policy”

- The amended SOP and Conflict of Interest (CoI) policy (with the amendments visibly highlighted in the text of the documents) are shared in written form as part of the background documentation for

the PA meeting. The amendments in the SOP have been introduced on the basis of the collected further experience of implementation of the EUnetHTA JA2 3-year Work Plan and developed in cooperation with the Lead and Co-Lead Partner project managers.

- The background document introducing the proposals for standardisations in the handling of the Col and confidentiality issues in the EUnetHTA JA2 includes a description of the development process. The proposed amendments will be briefly introduced by the Secretariat at the PA meeting, followed by clarifying questions with the aim of adoption of the proposed changes. **The participants at the meeting are expected to be acquainted with the details of the proposal in advance and to have a mandate to adopt.**

Agenda item “Short- (2014-2015), mid- (2016-2020, possible JA3) and long-term (post-2020) strategic development of EUnetHTA”

- Both EUnetHTA (*as the scientific and technical mechanism of the European cooperation on HTA*) and the HTA Network (*as the strategic level of the same European cooperation on HTA*) perspectives will be introduced at the start of the discussions of the strategic development of EUnetHTA.

The short-term (2014-2015) developments:

- Discussions will be led in a plenary setting. *The chairmanship of the meeting will specifically pay attention to solicit input that will represent views of the diverse EUnetHTA constituency (as described on p. 1 of this document).*
- Participants in the meeting are encouraged to refresh their memories of the Technical Annex of the EUnetHTA JA 2 Grant Agreement
- **Currently, we kindly ask you – in preparation for the discussions at the meeting - to ponder the following issues reflecting your (ie, your organisation’s) expectations and/or views regarding the remainder of the JA2 (April 2014-September 2015) –you are welcome to bring up other issues as well:**

a) National uptake and implementation of the EUnetHTA outputs

- Does national legislation directly or indirectly hinder uptake of international (e.g., EUnetHTA) reports / collections of information in the national assessments? What can we do about this?
- As per the EUnetHTA JA2 Grant Agreement, “at least 40 national HTA reports are to be produced with use of tools and information from JA2” (p. 44 of the GA). Would the following minimum requirements for identifying the “national reports produced with the use of the EUnetHTA tools and outputs” be acceptable?

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| ○ Local (national/regional) HTA report is produced <u>with usage of one</u> of the full Core HTAs produced in JA1 or JA2 |
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| <ul style="list-style-type: none">○ The whole Core HTA is used○ Parts of the Core HTA is used |
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- Local (national/regional) HTA report is produced with usage of the rapid HTAs produced in JA1 or JA2

- The **whole rapid HTA** is used
- **Parts of the rapid HTA** is used

- Local (national/regional) HTA report is produced with **application of the EUnetHTA Adaptation Toolkit** in adapting of one of the *national/regional reports* from a different country to local settings
- An local (national/regional) HTA report is the outcome of collaboration facilitated by the **POP database** service
- Local (national/regional) HTA report is produced with application and has reference to one or more of the **EUnetHTA guidelines**
- Local (national/regional) HTA report clearly describes the development process that includes usage of or reference to any of the EUnetHTA tools (i.e., POP Database, Evident Database, HTA Core Model (including Online Service and Database))

- Your organisation's specific suggestions of feasible ways to overcome barriers for collaboration and ensure national uptake of the EUnetHTA outputs in the remainder of the JA2.

- b) Recent discussions in the HTA Core Model Challenges meeting and the WP5 meeting in Vienna (end of November 2014) followed by the discussions and agreement in the EUnetHTA Executive Committee confirmed that the final product in the form of a report is seen as an acceptable and desirable output in the production of the rapid Core HTAs of pharmaceuticals to fit with the Transparency Directive requirements. It was agreed at the same time that the final product's format should not compromise the goal of transferability/re-usability, transparency and possibility to assess the quality of the final product as well as respect the Member States' competences and responsibilities for the organisation and delivery of health services and medical care. "Joint assessment report" is one of the currently used **formats**.

Any comments on the above?

The mid-term (2016-2020) development:

- The discussions will be held both in group-work and plenary settings
- The discussions will be opened to initiate the exchange by laying out some specific issues and views within the already existing outline of discussions on the mid-term presented in this document. Introduction will be followed first by the exchange in the plenary (*The chairmanship of the meeting will specifically pay attention to solicit input that will represent views of the diverse EUnetHTA constituency (as described on p. 1 of this document)*) and continued further in the group work.
- Participants in the meeting are encouraged to refresh their memories of
 - the "EUnetHTA Strategy 2012 and beyond"
 - the "EUnetHTA Business Model Report – Version 1.2" of May 2012
 - Article 15 of the Directive 2011/24/EU

- Commission Implementing Decision of June 26 2013 providing the rules for establishment, management and transparent functioning of the HTA network
- Multiannual Work programme 2014-2015 of the HTA Network

All documents are shared among the set of Background documentation for the PA meeting in Madrid (<https://intranet.eunetha.eu/assembly/node/3375>)

- o A few background considerations to facilitate preparation for the discussions about the main prerequisites for having optimal conditions for further development of the scientific and technical cooperation (including supporting structures and processes) in a possible JA3:

The drive and the aim for the development of EUnetHTA since its inception in 2005 has been “ to involve and ensure HTA interests across Europe to secure an efficient and sustainable network”² . After several years of development the more operational EUnetHTA purpose can be expressed as “to support the production of **HTA information tailored to the needs of the national/regional HTA organisations participating in EUnetHTA. A wide range of formats and solutions are offered to facilitate various steps in the HTA production process accommodating various types of healthcare technologies as well as different phases in their life-cycle.**”

While EUnetHTA has been rather concrete in developing and testing specific solutions to address HTA of various types of technologies in the various stages of their life-cycle³, potentially more (and more systematic) work needs to be done - and focus of activities to be transferred - to define and work on incorporating the developed EUnetHTA approaches into the “real life” HTA production processes in the European HTA organisations, both at the national and regional level (e.g., the topic selection and prioritisation procedure for joint work is one of the processes where further improvement is needed).

This has to be done while

- taking into account and fitting into the various health-care systems’ dynamics of managing healthcare technologies (*Member State (MS) level*)
- taking into account various “appetites for engagement” of different Member States and their specific HTA organisations – this has to be done via developing concrete feasible and sustainable types of engagement at various levels (*MS level*)
- ensuring that the work of EUnetHTA fits and functions in synergy with the vision of the HTA Network (*European level*)
- ensuring that EUnetHTA developments and developments in its member organisations are in sync and remain relevant to changes in the interaction between MS, e.g. with the changes happening in the regulatory sphere (both pharmaceuticals and medical devices) and changes in international cooperation in HTA, and relevant to developments in science and applied research (*MS, European and global levels*)

² Excerpt from the invitation letter of February 2005 to participate in the consortium of organisations that led to the implementation of the EUnetHTA Project (2006-2008).

³ E.g., starting from early dialogues, to POP Database and collaborations based on it, to producing full and rapid Core HTAs, to facilitating additional evidence generation (EVIDENT Database), to developing methodological guidance, to providing training and facilitating capacity building in HTA

- exploring, creating and exploiting the opportunities of cooperation with leading research and academic institutions in research and development, i.e., the Horizon 2020 programme (*European level*)
- continuing to interact with the stakeholders in ways that ensure maximum value and appropriate engagement for the scientific and technical mechanism of the European cooperation on HTA.

To “close the gap” between the piloting done and the “real life” implementation in daily HTA production operations of the HTA organisations, all the wealth of experience, results and achievements in JA1 and JA2 need to be presented from the points of view of

- feasibility for implementation
- already established effectiveness and
- what remains to be done

All three points above need to be assessed both by EUnetHTA as a whole and by the member organisations that voluntarily decide to be involved into the cooperation and once they join the cooperation are expected to be ready to adhere and deliver as per the agreed conditions , requirements and shared - as well as individual - responsibilities of the network members.

The formal, realistically possible conditions for continuing our work with the support from the European Commission has a decisive impact on the success of the continuing endeavour. Based on the experience of the first two joint actions certain adjustments need to be implemented into the structure and conditions of the formal joint action mechanism in order allow further development of a sustainable European cooperation on HTA in 2016-2020 (JA3).

The organisational and governance structure of EUnetHTA need to be adjusted to take into account a new reality of relationship with the HTA Network and support efficient and sustainable operations of the scientific and technical cooperation on HTA. Role and concrete engagement with stakeholders need to be adjusted to reflect the new reality.

Further refinement and clarification of what the remit of each of the levels in the European cooperation on HTA as per Article 15 entails (i.e., strategic level and scientific and technical mechanism) is needed.

Concluding remarks – with a view to the long-term perspective (years 2020+):

Discussing, describing and developing

- the formal conditions at the EU level,
- certain adjustments in the structure and processes of the participating organisations that will make them more receptive and effective/efficient in the cross-border cooperation in Europe ,
- appropriate and relevant (both in a national and European context) approaches to changing contexts of interaction and cooperation in HTA,
- prioritising areas for developing new specific activities,
- appropriately adjusting the organisational structures for cooperation

to be implemented during the years 2016-2020 will be the main input to developing the EUnetHTA “Recommendations on implementation of a sustainable European network on HTA” (Deliverable 1 of JA2, please see pp. 34-36 of the EUnetHTA JA 2 Grant Agreement). They will also lay down a foundation for what can be further developed and concretely taken forward in years 2020+.

No concrete details or solutions are currently in place with regards to the financing options and opportunities in years 2020+ so not much detail can be discussed at this stage in this regard. Nevertheless, the Directive as a legislative act secures that the European cooperation on HTA “may receive Union aid”

which definitely could not be the only source of funding for sustainability (at least co-funding from the Member States must be in place in addition to the Union aid).

- **Currently, we kindly ask you – in preparation for the discussions at the meeting - to ponder the following issues reflecting your (ie, your organisation's) views regarding the mid-term EUnetHTA strategic development, i.e., a possible JA 3 (2016-2020):**
 - a) What will be the objective of EUnetHTA in the next phase (2016-2020) of its development (what will EUnetHTA want to achieve in these years?)
 - b) What will define priorities that will guide identification of the specific activities to pursue in years 2016-2020?
 - c) What are the limitations of the current conditions of cooperation (both formal on the EU level and organisational (EUnetHTA-wise and within your own organisation's internal structure and processes) that need to be adjusted?
 - d) What modes of operation will your organisation see as preferable in JA3?
 - e) What should the relation be between the HTA Network and the scientific and technical cooperation to make it attractive to EUnetHTA after JA2?
 - f) Which specific processes already employed in JA2 should be further improved and how? *Some of the processes:* stakeholder involvement; topic identification, selection and prioritisation for joint work; capacity building and continuous education for EUnetHTA members and stakeholders; national adaptation of joint collaborative results.

The questions above will be the main areas to address during the group work at the PA meeting in Madrid – certainly, other issues that your organisation find important to be addressed should be brought forward during the group discussions.

The long-term (2020+) development:

- The discussions will be held in a plenary setting. *The chairmanship of the meeting will specifically pay attention to solicit input that will represent views of the diverse EUnetHTA constituency (as described on p. 1 of this document).*
- **Currently, we kindly ask you – in preparation for the discussions at the meeting - to ponder the following issues reflecting your (ie, your organisation's) views/concerns regarding the long-term EUnetHTA strategic development (2020+):**
 - a) What concerns does your organisation have with regards to the period post 2020?
 - b) What will be important to clarify and achieve in the mid-term in order to lay-down a foundation for a sustainable development post 2020?
 - c) What constitutes your organisation's considerations of ensured sustainability – besides access to the finances to fund the activities?

- d) What would in your view ensure that EUnetHTA will have higher chances to have access to sufficient financial resources to continue its work?
- e) Given the expectations that the HTA Network will facilitate “quick access of patients to new technologies”, how could relationships between HTA agencies, regulators and manufacturers be further developed and qualified (in format, content and objectives) in order to speed the process from proof of concept to reimbursability ?