



MEDICAL TECHNOLOGY RECOMMENDATIONS ON STAKEHOLDERS' INVOLVEMENT IN THE EU HTA COOPERATION AT STRATEGIC AND OPERATION LEVELS

The goal of this document is to articulate constructive input from the Medical Technology Industries on stakeholder involvement in order to contribute to discussions at the 6th meeting of the HTA-Network on May 20 2016, and also sharing reflections on practical implementation aspects. In addition, it aims at articulating the Medical Technology Industries views on the proposal made by the European Commission¹, and complementing with additional recommendations.

While we recognize and fully respect the mandate of the HTA Network members and their decision on appropriate involvement of stakeholders, the Medical Technology Industries continue to be committed to support the HTA Network to reach its policy objectives defined in the in "Strategy for EU cooperation on HTA".

Hereafter is a summary of our recommendations towards HTA Network and EUnetHTA substantiated with detailed briefing.

1. AT THE HTA-NETWORK LEVEL

The Medical Technology Industries are keen to collaborate with the HTA Network.

On the topic of the Call for interest

We will appreciate to see clear and pragmatic eligibility criteria which will be put in place to allow participation of all interested stakeholders.

On the topic of Regular ad hoc consultations before / after HTA Network

We propose to move from a passive consultation mode to collaborative mode to increase efficiency and obtain appropriate stakeholder involvement.

We call for multi-stakeholders' dialogue platform with Member States within the current HTA Network structure. Such platform should have dedicated topics to medical technologies. It will be important to have the Member States representatives specifically responsible for medical technologies present. Such dialogue would be most effective if it takes place on a regular basis, (up front, during and after the reflection paper and other activities) to support the HTA Network outcomes. We recommend that such stakeholders' involvement be included as a priority reflection in the **Multi Annual Work Programme**.

On the topic of two representatives per category (full or parts of the HTA Network meeting)

We believe it is critical for our sectors to have a direct representation whenever (at general and Working Groups meetings) themes that impact the specific technology are going to be addressed; Given the specificities of our technologies in healthcare, we ask for three permanent seats at the HTA -Network meetings instead of two representatives for the whole industry including Pharmaceuticals.

2. AT THE EUNETHTA JA3 and LIAISON COMMITTEE Levels

EUnetHTA JA3 Governance

There is a need for clarification and transparency on governance and way of inclusion of stakeholders at a general and work package level. It will be appreciated that industry trade associations can be involved as facilitators (possible as subcontractors) when joint or collaborative assessments involving multiple technologies (class) are planned.

Liaison Committee

We will appreciate to see clear and transparent ways to set-up stakeholders' involvement, covering various aspects including composition, role, scope and governance. A dedicated liaison committee for medical technologies could ensure fit-for-purpose joint work and prioritization of relevant topics.

¹ EC Cover Note by secretariat dated 9 May 2016

DETAILED BRIEFING

1. AT THE HTA NETWORK LEVEL:

The Medical Technology Industries are keen to collaborate with the HTA Network.

1.1 On the topic of CALL FOR INTEREST

We will appreciate to see clear and pragmatic eligibility criteria which will be put in place to allow participation of all interested stakeholders.

1.2. On the topic of REGULAR AD HOC CONSULTATIONS BEFORE / AFTER HTA NETWORK

EU HTA activities have different consequences on patient access, sustainability of health systems, benefit and risks for the different medical technologies. In spite of this fact, we noticed that around 1/3 to 1/2 Member State's current participants at the HTA Network meetings have experience or responsibility on pharmaceutical technologies only (not on medical technologies). On topic specific to medical technologies we believe a direct representation of all parties will be most effective.

We call for **multi-stakeholders' dialogue platform** with Member States within the current HTA Network structure. Such platform should have dedicated topics to medical technologies. It will be important to have **the Member States representatives specifically responsible for medical technologies** present. Such dialogue would be most effective if it takes place on a regular basis, (up front, during and after the reflection paper and other activities) to support the HTA Network outcomes.

We propose to move from a passive consultation mode to collaborative mode to increase efficiency and obtain appropriate stakeholder involvement.

The HTAN MAWP plans a reflection on the best way to involve stakeholders during first half of 2017, but many reflections and activities will start way before the involvement of stakeholders and the governance of the network is clarified. In annex, Medical technology industry is referring to some valuable existing frameworks of good practices for stakeholder involvement that could be used while maturing the most efficient way to engage various stakeholders at the right time and for the right topic(s).

Here, concrete examples of potential for discussions that need to take place at policy and strategic levels: role and valuable model of EU HTA for medical technologies, scope, criteria for prioritization to select technologies for joint work and governance, timing in the lifecycle, implementation at national level, interactions with decision makers, ways of measuring value of the EU HTA cooperation on med tech, ways forward for a sustainable cooperation, highest value of EU HTA cooperation within the given access model, initiatives to limit HTA induced inequalities in Europe, impact of EU Legislative initiatives, role of HTA in a value based healthcare system, quality assurance and accreditation of HTA agencies assessing medical technologies, consistency in data requirements, among others.



1.3. On the topic of TWO REPRESENTATIVES PER CATEGORY (FULL OR PARTS OF THE HTA-NETWORK MEETINGS)

- Whenever the HTA Network addresses themes /policy issues that are expected to impact the different medical technology industries, a direct participation of the impacted industries is of the outmost importance. This possibility should be formally accepted / acted through the HTA Network Rules of Procedures.
- In general, we ask for three permanent seats at the HTA Network meetings instead of two representatives for the whole industry including Pharmaceuticals.
- As stated in the HTA Network Rules of Procedures², we understand that there is an opportunity for stakeholders, as the Medical Technology Industries, to propose agenda topics for the HTA Network meetings/activities. We look forward to contribute and provide support to the HTA Network and its Member States.

2. AT THE EUNETHTA JA-3 LEVEL and LIAISON COMMITTEE (LC) LEVEL

- Representatives from the Medical Technology Industries can play a critical/constructive role as partners in the LC ensuring the activities are fit-for-purpose responding to the needs of patients and decision makers.
- Medical Technology Industry supports the principle of a LC that could play a key role as a translator of the needs of decision makers at national level.
- The LC could support priority selection of technologies to assess jointly guided by a set of criteria (established by the HTA Network) able to identify technologies that could bring value across different Member States, in support of the member states health systems.
- When joint assessments or collaborative assessments involving multiple technologies are planned, industry trade associations could be involved as facilitators (possible as subcontractors) to enable involvement of multiple companies and address common points.
- It will be necessary to finalize at EU level, a framework to guide and facilitate collaboration between industry participants and HTA agencies before embarking in joint work on medical technologies.

² HTA – Network Rules of Procedures,
http://ec.europa.eu/health/technology_assessment/docs/hta_network_rules_procedures_en.pdf

ANNEX: Proposal for a framework on stakeholder involvement

- The European cooperation on HTA has been interacting with stakeholders since the beginning of its strategic and operational activities.
- Encouraging effective stakeholder engagement is key to promote good governance and accountability.
- The experience has shown that the interaction with stakeholders would benefit from a structured framework, implemented before the activities to set-up a permanent cooperation are initiated.
- The aim is to transform the current level of interaction (information & late stage consultation) into a broader concept of involvement as shown in the example in Figure 1.
- A set of core principles based on good practices that have successfully engaged stakeholders in other HTA and policy initiatives, would be the basis (Figure 2).
- A specific commitment from all HTA Network Members and HTA agencies participating in EUnetHTA, to apply the framework in all activities should be fostered by the European Commission.
- This can be achieved through guidelines, built in partnership with stakeholders, explaining the involvement process (who, how, when, where, for what purpose), following the best practice framework and considering previous input from stakeholder groups.³
- Adequate mechanisms to monitor the success of implementation should also be put in place.

Figure 1.
Example of Stakeholder Engagement Spectrum –levels of involvement⁴

| | Current state | | | Desired state | |
|------------------------------|---|---|---|--|---|
| | Inform | Consult | Involve | Collaborate | Empower |
| Stakeholder engagement goals | To provide balanced, objective, accurate and consistent information to assist stakeholders to understand the problem, alternatives, opportunities and/or solutions. | To obtain feedback from stakeholders on analysis, alternatives and/or outcomes. | To work directly with stakeholders throughout the process to ensure that their concerns and needs are consistently understood and considered. | To partner with the stakeholder including the development of alternatives, making decisions and the identification of preferred solutions. | To place final decision-making in the hands of the stakeholder. Stakeholders are enabled/equipped to actively contribute to the achievement of outcomes. |
| Promise to stakeholders | We will keep you informed. | We will keep you informed, listen to and acknowledge concerns and aspirations, and provide feedback on how stakeholder input influenced the outcome. | We will work with you to ensure that your concerns and aspirations are directly reflected in the alternatives developed and provide feedback on how stakeholder input influenced the outcome. | We will look to you for advice and innovation in formulating solutions and incorporate your advice and recommendations into the outcomes to the maximum extent possible. | We will implement what you decide. We will support and complement your actions. |
| Methods of engagement | <ul style="list-style-type: none"> • Fact sheets • Open houses • Newsletters, bulletins, circulars • Websites, external and edugate | <ul style="list-style-type: none"> • Public comment • Focus groups • Surveys • Public meetings • Ultranet • Web 2.0 tools | <ul style="list-style-type: none"> • Workshops • Deliberative polling • Web 2.0 tools • Forums | <ul style="list-style-type: none"> • Web 2.0 tools • Reference groups • Facilitated consensus building forums for deliberation and decision-making • Experimental projects | <ul style="list-style-type: none"> • Dialogue with Government • Local governance • Joint planning • Provision of data • Shared projects • Capacity building |

Source: adapted from the International Association for Public Participation (IAP2) spectrum www.iap2.org (2007)

Figure 2.
Proposed 9 core principles of stakeholder involvement to guide the joint work at the HTA Network and EUnetHTA levels^{1 5 6 7 8 9}

³ [Position paper of value of industry involvement, value of European organizations of patients, consumers, health care providers and payers and the common view by all stakeholder's on "Appropriate Stakeholder Consultation in the EU Health Technology Assessment \(HTA\)](#)

⁴ Adapted by the State of Victoria. Department of Education. Stakeholder engagement framework, 2011 from the International Association of Public Participation core values.

1.INCLUSIVENESS 'All stakeholders who have an interest in, or who will be affected by, a specific decision should be involved'. 'The level of involvement should be determined by the degree of influence/impact the policy will have on stakeholders and their level of interest in participating';

2.EQUITY 'All stakeholder groups involvement should be regarded as equally important;'

3.TRANSPARENCY & TRUST 'Information should be shared equally and directly with all stakeholders' 'It should be clear to stakeholders what they can and cannot influence through their involvement' 'There should be transparency about how stakeholders were identified, selected and invited to participate';

4.EARLY AND CONTINUOUS ENGAGEMENT 'Stakeholders should be engaged as early as possible in the process' 'The engagement should continue throughout the whole assessment and policy making process';

5.COMMITMENT 'Respect should be shown for all stakeholders by giving the appropriate priority and resources to the engagement process, and demonstrating that it is a genuine attempt to understand and incorporate other opinions even when they conflict with pre-conceived ideas of the coordinating team';

6.ACCESSIBILITY 'Different ways should be provided for people to be engaged and to ensure that people are not excluded through barriers of language, culture or opportunity'. 'Stakeholders should not be forced to provide instant responses – they should be afforded the opportunity to give consideration and to consult with members of the organisation they represent, as appropriate.';

7.RESPONSIVENESS 'The assessors and policy makers should be open to the idea that their pre-existing ideas can be improved, and that they will, if necessary, amend them' 'Stakeholders should perceive that their voice will be taken seriously, and that changes can be made.' 'A platform to exchange views and promote dialogue with stakeholders on topics that are relevant and will impact them should be provided' 'The communication should be provided in a direct, efficient, and timely way to stakeholders, in a proactive manner';

8.WILLINGNESS TO LEARN 'All participants should learn from each other; this means giving sufficient time to communicate and dialogue in face-to-face or other forms of meetings';

9.ACCOUNTABILITY 'As soon as possible after the end of the engagement process, participants should be provided with a clear account of how stakeholder contributions have – or have not – influenced the advice, joint work or policy';'

⁵ Adapted from [Health Information and Quality Authority Ireland. Guidelines for Stakeholder Engagement in Health Technology Assessment in Ireland. 2014](#)

⁶ [National Institute for Health and Care Excellence Charter, April 2013.](#)

⁷ [European Medicines Agency. Framework for interaction between the European Medicines Agency and industry stakeholders, 2014.](#)

⁸ [International Association of Public Participation \(IAPP\). Core Values for the Practice of Public Participation](#)

⁹ [European Commission's Staff Working Document on 'Better Regulation Guidelines. General principles for stakeholder consultation, adopted May 2015.](#)