

Stakeholder involvement in HTA cooperation

Position from medical technologies industries¹

This document suggests principles of “appropriate stakeholder consultations”² that we believe should be established in HTA cooperation. Our goal is to contribute to constructive dialogue and we are more than happy to further elaborate on these points.

We call for a collaborative governance approach in HTA cooperation in Europe:

1. We kindly ask for re-assessment of EUnetHTA JA3 governance regarding the consistent inclusion of stakeholders at a general level and work package level. Clear and pragmatic eligibility criteria need to be in place to allow participation of all interested stakeholder’s organisations.
2. We call for a framework on stakeholder involvement to guide a collaborative mode of working. Please refer to 9 core principles on stakeholders’ involvement to guide the joint work at the HTA Network and EUnetHTA levels, provided in the Annex I.
3. Any reflection on efficient cooperation on Medical Technologies should be initiated after there is a clarity on the rules of stakeholders’ involvement.
4. We propose that industry trade associations are involved as facilitators when technologies are planned to be assessed and that relevant companies are involved consistently in joint and collaborative assessments throughout the full process.
5. The medical technology industries should be seen as a partner in meetings and preparatory work as there is an increase activity focusing on medical technologies. The healthcare industry believes it can be a valuable partner in the overall HTA process as 1. industry is concerned with the assurance of efficiency and quality of HTA; 2. over time, industry has developed substantial in-house HTA-capacity; and 3. sharing the ‘rules of the game’ leads to better HTA outcomes.

We call to reflect on the previous input towards stakeholder involvement, as expressed in:

- [Joint Healthcare Industry Paper, The value of industry involvement in HTA](#), 24 November 2011³
- [Stakeholder involvement in the Second EU Joint Action on health technology assessment \(HTA\)](#), 26 April 2012⁴
- [Call for a Multi-Stakeholder Forum in the implementation for “Appropriate Stakeholder Consultation” in the EU HTA Network](#), 19 June 2013⁵
- [Stakeholder involvement with the European HTA cooperation at strategic and operational levels - A proposal from the Medical Technology Industries](#), 11 May 2016⁶.

¹ Medical Technology Industries = medical devices, in vitro diagnostics, medical imaging, radiotherapy and health ICT industries

² Directive 2011/24/EU of 9 March 2011 on the application of patients’ rights in cross-border healthcare under article 15 “Cooperation on health technology assessment ”

³ Signed by AESGP, COCIR, EDMA, EFPIA, EGA, Eucomed, EuropaBio, GIRP

⁴ Signed by AESGP, AIM, BEUC, COCIR, CPME, ECPC, EDMA, EFPIA, EGA, EPF, ESIP, Eucomed, EuropaBio, EURORDIS, GIRP, HOPE

⁵ Signed by AESGP, BEUC, COCIR, CPME, EDMA, EFPIA, EGA, EPF, ESIP, ESMO, EUKOMED, EuropaBio, HIO, Weight Watchers International

⁶ Signed by EDMA, EUKOMED, COCIR

Annex I

9 Core Principles of “Appropriate Stakeholder Involvement” in HTA cooperation in Europe ^{7 8 9 10 11}

1. Inclusiveness

- a. All stakeholders who have an interest in, or who will be affected by, a specific decision should be involved.
- b. The level of involvement should be determined by the degree of influence/impact the policy or the assessment 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

- a. Information should be shared equally and directly with all stakeholders to improve the quality and balance of feedback.
- b. It should be clear to stakeholders what they can and cannot influence through their involvement.
- c. There should be transparency about how stakeholders were identified, selected and invited to participate.
- d. It should be clear what is expected from stakeholders, especially when it comes to evidence.

4. Early and continuous engagement

- a. Stakeholders should be engaged as early as possible in the process.
- b. 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

- a. 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.
- b. 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

- a. The assessors and policy makers should be open to ideas.
- b. Stakeholders should perceive that their voice will be taken seriously, and that changes can be made.
- c. A platform to exchange views and promote dialogue with stakeholders on topics that are relevant and will impact them should be provided.
- d. 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.

⁷ Adapted from [Health Information and Quality Authority Ireland. Guidelines for Stakeholder Engagement in Health Technology Assessment in Ireland. 2014](#)

⁸ [National Institute for Health and Care Excellence Charter. April 2013.](#)

⁹ [European Medicines Agency. Framework for interaction between the European Medicines Agency and industry stakeholders. 2014.](#)

¹⁰ [International Association of Public Participation \(IAPP\). Core Values for the Practice of Public Participation](#)

¹¹ [European Commission's Staff Working Document on 'Better Regulation Guidelines. General principles for stakeholder consultation, adopted May 2015.](#)