Views from the medical technology industries* on the specificities required for a valuable HTA cooperation on medical technologies at European Level

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European HTA joint work on medical technologies has not been widely taken up by Member States, and its value to inform local decision-making processes has been minimal. We believe this can be addressed if European HTA cooperation acknowledges the uniqueness of the European access model for medical technologies in bringing innovation to patients, and takes into account their specificities when joint assessments are produced.

The question of what European HTA joint work will inform needs to be addressed before discussing how it will do it. To achieve this, we call for a dedicated European Commission supported **multi-stakeholder dialogue platform with seats for the medical technologies* at the HTA Network level, to be set-up and implemented through specific meetings and reflections on value and the assessment of medical technologies**. This will contribute to establish common grounds and build trust, key steps towards a valuable cooperation for all partners. These meetings should involve representatives from Ministries of Health, with responsibility on areas such as access and adoption of medical technology innovation, patients, medical technology industries, decision makers, providers and HTA bodies experienced in assessing medical technologies.

Concerns of medical technology industries

- European HTA joint work performed on medical technologies has not been widely taken up by Member States and it has not had a clear impact in local decision-making processes.
- European HTA joint work has not increased predictability and/or consistency on topic selection, timing of assessment, evidence requirements, joint production processes, stakeholder/industry involvement or use of assessment results to inform decisions on funding, reimbursement and adoption.

Previous HTA JA have therefore had limited value, as the European HTA cooperation has been unable to address relevant European and/or common national policy questions for the different medical technologies. Furthermore, it has given little consideration to the specific contextual issues related to the adoption of medical technologies, and has not been able to fully address methodological challenges for value demonstration.
If European HTA cooperation continues to follow this approach, the joint assessments will create an additional burden for industry and Member States without directly informing or influencing the take up of innovative medical technologies that contribute to effective, efficient and resilient health systems.

Fit-for-purpose HTA: taking into account 3 main specificities of medical technologies

1. Joint EU HTA initiatives should be conducted based on a defined policy and access-related demand of Member States.

European HTA joint work needs to clarify how it will help to inform existing decision-making processes by answering relevant policy questions across Member States. Topic prioritisation, selection and timing of assessment should be predictable and determined in partnership with all relevant stakeholders including decision makers and medical technology industries.

2. Medical technologies need the use of appropriate methodologies that comprehensively demonstrate their value.

Medical technologies comprise a wide variety of products, all of which have a specific nature and well defined mode of action (physical, mechanical, chemical, and electrical) that differentiates them from other health technologies, such as pharmaceuticals.

*medical technology industries = medical devices, in vitro diagnostics, medical imaging, radiotherapy and health ICT industries

Medical Devices are used for human beings for the purpose of diagnosis, prevention, monitoring, treatment, disease alleviation, handicap or injury compensation, investigation, replacement or modification of the anatomy or of a physiological process. Their effectiveness is impacted by contextual factors such as the skills and experience of the healthcare professionals and patients, as well as the organizational set-up. Medical devices can provide a therapeutic effect, enable interventions and directly improve outcomes.

Medical imaging, radiotherapy and health ICT are technologies covering the complete continuum of care including prevention, screening, treatment and after care/rehabilitation play a vital role in the detection and treatment of serious illnesses or injuries, helping doctors to make accurate diagnoses/treatment and enable conditions such as cancer to be caught early and therefore treated more successfully. eHealth solutions are increasingly used by healthcare professionals to store or exchange information and to remotely monitor patients or deliver healthcare services. They reduce health inequalities by giving access to healthcare to people located in remote places, cut the risk of medical errors and allow safer and faster transfer of important patient data.

In Vitro Diagnostics provide vital information allowing patients and health care professionals to select the most appropriate management pathway to improve health outcomes. This value of knowing, delivered without touching the human body, helps to sustain health systems by diminishing subsequent health problems and improving the use of available resources (i.e. avoid unnecessary hospitalizations, treatments, etc.). HTA should include the value of diagnostic information within the context it is delivered, in any assessment.

HTA joint work should further account for specific data collection systems and fit-for-purpose methodologies that address the value of medical technologies. Overall, the value assessment for these technologies should also adopt a broader perspective: medical technologies have a positive impact on health outcomes for individual patients, but can also improve financial sustainability of health systems, helping to achieve wider economic benefits for society. Although many of these attributes are context specific (access decisions are made at national or local levels), they could benefit from shared information.

3. HTA should have an impact on national decision making. Specific patient access pathways and access model for medical technologies need to be taken into account.

Decision-making processes and access pathways for medical technologies are unique from other health technologies such as pharmaceuticals. For medical technologies it will be important to assess their effectiveness or utility. These vary between countries and regions, hospital and the ambulatory setting, as well as the type of product. HTAs are conducted on a small subset of medical technologies to inform decisions on reimbursement or clinical use. As local procurement practice varies greatly for medical technologies, and reimbursement of hospital activity is more often performed through the use of case-payment systems, HTA is rarely linked to reimbursement decisions for medical technologies.

Patient access to medical technology innovation can be considered as gradual 3-phase process:

1. Research, development and CE marking phase: The CE-marking approval process, covered by the MDD and IVD regulations, guarantees safety and performance of the products. They go through predefined testing, conform to international standards, demonstrate performance per intended use and go through quality assurance before market access. There is a continuous monitoring and re-evaluation of the products during their lifecycle.
2. Initial market access: Once CE-marked, a small set of early adopters start using the new medical technology, which, if value is perceived, is gradually adopted. When moving from this initial market access phase to wider uptake, most products go through procurement with multiple competitors and technologies. It is only for some technologies with new or updated reimbursement, funding, or other agreements, HTA might be a source of information.

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3. Market usage and adoption: The medical technologies with valued outcomes are widely adopted in clinical practice and possibly supported by clinical guideline recommendations. HTA may play a role for some products at this stage (e.g. to define population that will benefit most, cost-effectiveness, etc.)

Providing solutions for a fit-for-purpose European HTA cooperation

If European HTA joint work is performed on medical technologies, it has to bring value. A valuable European HTA cooperation needs to acknowledge the uniqueness of the European access model for medical technologies in bringing innovation to patients. It must also recognise that CE-marking demonstrates safety and performance throughout the life of a medical technology and is a separate process from HTA. If joint HTA work is performed, it should not jeopardise innovation, European small and medium sized enterprises (SMEs), or delay access to medical technologies. Instead, it should shift the focus from cost to value by addressing unmet needs for patients, decision makers and health systems, and using data collected in daily clinical practice (i.e. in the post-market space).

We therefore ask Member State representatives in HTA Network, the European Commission and EUnetHTA:

1. That joint European HTA initiatives are conducted based on a defined policy and access-related demand of Member States, e.g. in terms of which technologies should be evaluated and what should be the guiding questions for evaluation. This would be a prerequisite to ensure national-relevance and that HTA results will be taken up for national decision making.
2. The use of appropriate methodologies that comprehensively demonstrate the value of medical technologies should be established; these should clearly acknowledge the role of CE-marking in demonstrating safety and performance throughout the life of a medical technology; and
3. That HTA has an impact on national decision making. This would necessitate a commitment from Member States to link positive HTA to national access decisions. This can only happen if point 1 is truly applied.

To achieve this, we call on Member State representatives in HTA Network, the European Commission and EUnetHTA to ensure the set up a dedicated European Commission supported **multi-stakeholder dialogue platform with seats for the medical technologies at the HTA Network level, implemented through specific meetings and reflections on value and medical technologies assessment**.

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