EU Regulation on HTA
Striking the right balance for medical technology assessment

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MedTech Europe welcomes advances in the assessment of medical technology innovations, and the appropriate rewarding of the value these innovations bring in the EU.

In particular we support initiatives that:

- **Promote timely access** to, and **funding** of, innovation
- **Enable accelerated and equal accessibility** of innovative technologies
- **Enhance** the **use** of **innovative technologies in** the delivery of health care itself, to contribute to more sustainable and resilient national health systems.

MedTech Europe welcomes the fact that the EU Regulation on HTA recognizes the **specificities of medical technologies**, (medical devices, in-vitro diagnostics and other technologies) and how it aims to produce high-quality and timely assessments of selected innovations, avoiding duplication and **improving decision making** in Europe.

Despite the past years of HTA cooperation, **many open questions remain unresolved**, and further work is needed if HTA cooperation in Europe is to truly deliver better-informed investment decisions and accelerated patient access to innovation.

For those **medical technology** innovations eligible to undergo **Joint Clinical Assessments (JCA) and Joint Scientific Consultations (JSC)** under the new Regulation, we call on the Member State Coordination Group to ensure that, the work soon to be done genuinely **adds measurable value** for patients, medical communities and society at large.

As **MedTech Europe**, we seek to **take an active role throughout the Regulation's implementation phase and beyond,** as a partner to the Coordination Group's medical technology configuration, as well as to the subgroups, the EU Commission, and the relevant stakeholders.

The Regulation foresees that after 12 January 2025, the Commission, after seeking a recommendation from the Coordination Group, shall adopt a decision, by means of an implementing act selecting the medical devices and in vitro diagnostic medical device for a JCA.

In preparation for this, we see the coming implementation phase as a **5-year journey to which we are pleased to contribute, working towards a regulation that is fit for purpose and meets its stated goals**.

A **critical measure** of the Regulation's success, from a medical technology perspective, will be the extent to which **high-quality expertise in medical technology is secured**, early on, for JCA and JSC purposes. This expertise should cover different impacts the assessed medical technology has, while appreciating the specific roles the innovation plays in national/ regional healthcare delivery pathways.

Further we see as main factors of future success:

1. ***Dedicated methodologies***

It is critical to always consider the specificities and intended purposes of medical technologies, and especially how the evidence underpinning them continuously evolves over time. JCAs on selected medical technology innovation, likely to have a high value, are those with:

(1) A well-established process for timely, predictable selection of the technologies to undergo JCA, managing confidentiality of data and with opportunities for timely, insightful joint scientific consultation.

(2) The involvement of decision makers and key stakeholders (such as patients, clinicians) unique expertise and experience with the technology as part of the process to streamline scoping and inform quality assessments and not lose key information input. Appropriate consideration on the conflict of interest is required.

(3) The use of clear and proportionate available evidence, which uniquely evolves over time and the use of a jointly defined appropriate time of the JCA involving decision makers, stakeholders, and innovators.

(4) In cases where accelerated access is intended, the application of new methodologies such as "adaptive" approaches is needed. These should be further developed and applied while avoiding any duplication. In general, adaptations will be needed to reflect the nature of technology, nature of disease and evidence expectations.

(5) A special focus should be given to recognize the unique value of diagnostics and digital health technologies. Value frameworks should appreciate the interplay of diagnostics with pharmaceuticals and other interventions.

2. ***Involvement of Health Technology Developers (HTD)***

"*Active involvement of health technology developers' unique expertise and clinical experience is essential, to ensure that:*

(1) assessments are transparent, and that

(2) the information that JCAs deliver to decision-makers is of high quality

This active involvement is especially critical during the early phases of medical technology's adoption, when familiarity with that technology 'in the field' is limited.

In addition to involving individual health technology developers in individual JCAs, we also call on the Coordination Group and EU Commission to develop new methodologies and guidelines via an active, collaborative dialogue with all members of the stakeholder network, including the European organisations representing industry."

3. ***No interference with other legislation, avoiding the risk of ambiguity and duplication***

As clearly foreseen in the Regulation and its recitals, there must be no interference between the JCA and JSC processes and the assessments carried out on medical technologies in other legislation, as this would considerably delay to the timely availability of medical technology innovation to patients.

This principle applies both to the EU CE marking legislations (i.e., the Medical Devices Regulation 745/2017 and the in vitro Diagnostic Medical Devices Regulation 746/2017), and to any national regulations and processes that might potentially need to be adapted in the course of the 3-year transition period.

Any interaction that takes place must be guided by the principles of obtaining maximum process efficiency, predictability, and avoiding duplication of work already done.

At all times, any assessment on health technologies that is to have true value, will need to have a clear purpose and inform decisions of adoption and investment/funding.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices, and digital health. Our members are national, European, and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services, and solutions.

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