EU Regulation on Health Technology Assessment (HTA)*

MedTech Europe's Recommendations for the Trilogue Negotiations
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POSITION PAPER

MedTech Europe
from diagnosis to cure

EU Regulation on Health Technology Assessment (HTA)[1] MedTech Europe's Recommendations for the Trilogue Negotiations

MedTech Europe, the trade association representing the 'medical technology[2]' industry in Europe, acknowledges the Council's agreement to start trilogue negotiations on the proposed EU Regulation on Health Technology Assessment (HTA).

We hereby make the below recommendations to the EU Institutions, to ensure that the trilogue negotiations on this proposed Regulation lead to **equal and timely access to innovation** across Europe, without leading to a redundant exercise that restricts access.

Three Key Recommendations for Striking the Right Balance in Joint Clinical Assessments conducted on Medical Technologies

1. **Have predictable joint clinical assessments on selected[3] medical technologies:**
   (a) with transparent and adequate selection criteria, focused on those technologies *considered to be significant innovation and with potential significant impact on public health or health care systems* (as proposed by the European Parliament),
   (b) conducted at an appropriate point in time, within a predictable timeframe,
   (c) using the best available and proportional evidence including real world data,
   (d) applying tailored, fit-for purpose methodologies, and
   (e) involving technology developers as knowledge partners from scoping to final assessment.

2. **Ensure the new EU HTA framework in no way interferes with regulatory assessments conducted on medical technologies.** CE marking, as indicated under the *in vitro* Diagnostic and Medical Device Regulations (IVDR/MDR)[4] respectively, shall remain the *only* marketing authorisation process for demonstrating a medical technology's safety, performance and clinical benefit for its intended use.

3. **Secure a pre-defined and clear purpose for how clinical assessment reports will be used** to meaningfully contribute to funding and/or investment decisions within the Member States**,** while appropriately rewarding the value medical technologies bring.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018PC0051&from=EN
[2] In this document, 'medical technologies' refers jointly to medical devices (MDs) and to *in vitro* diagnostics (IVDs)
[3] I.e., those whose regulatory assessment has included an expert panel opinion as per the clinical evaluation consultation procedure of Regulation 745/2017 on Medical Devices Article 54, or as per the performance evaluation consultation procedure of Regulation 746/2017 Article 48 on *in vitro* Diagnostic Medical Devices
[4] I.e., Regulation 745/2017 on medical devices and Regulation 746/2017 on *in vitro* Diagnostic Medical Devices

With these conditions met, joint clinical assessments can help Member States determine the clinical benefits medical technologies bring when used in daily practice. **To have value, however, these assessments must also enable Member States to take appropriate decisions on the funding or reimbursement of medical technologies.** Only by driving these decisions will the future clinical assessment reports bring added value to European citizens, providers, healthcare systems and the medical technology industry.

If joint clinical assessments are not conducted in a tailored way and have no clear purpose, they would serve as a barrier for these innovations to reach citizens and could lead to a reduced availability of medical technology innovations to healthcare systems, especially those developed by European SMEs.

The Characteristics and Access Model of Medical Technologies

Each year, the medical technology sector provides thousands of innovations. Many of these come from European small and medium-sized enterprises (SMEs), which account for approximately 95% of all manufacturers. These innovations keep citizens in good health while fostering more sustainable care.

Medical technologies have unique characteristics and are associated with open, competition-driven, and decentralised market access models. These access models most often differ from those of pharmaceuticals. If an HTA is part of a Member State's access pathway, it is typically conducted in different Member States at different points in time. It is therefore critical that any future EU Regulation on HTA takes these unique characteristics into account.

Towards Joint Clinical Assessments that safeguard Citizen access to Medical Technologies

As a first step, the EU Institutions can mitigate the risks posed by the EU Regulation on HTA by:

1. Introducing specific measures to ensure that work carried out under the EU Regulation on HTA remains distinct from the medical technology CE marking Regulations (IVDR/MDR), which shall remain the "only" marketing authorisation process in EU. The EU Regulation on HTA shall in no way interfere with or slow down regulatory assessments of safety and performance conducted under the IVDR or MDR, i.e., by:
    - Only requiring the most up-to-date and publicly available safety and performance related information to be included in the technology developer's dossier,
    - Assigning an expert reviewer role to the European Commission and the Medical Devices Coordination Group, to ensure during the procedural review stage that joint clinical assessment reports do not overlap with regulatory assessments carried out under the IVDR/MDR, and
    - Explicitly defining, together with the technology developer, an appropriate time to conduct a joint clinical assessment on a given medical technology, namely, after market launch and allowing for the generation and use of clinical effectiveness data, including real world data,

2. Leveraging the unique expertise of medical technology developers, by including them in the full process, from scoping to final assessment,[5]
3. Ensuring that the reports provide only a scientific analysis and (as proposed by the Council) contain no *value judgement or conclusion on the overall clinical added value* of the technology assessed, and
4. Transparently linking available joint clinical assessments to the funding and/or investment decisions.

As a second step, we call for a predictable and fit-for-purpose joint clinical assessment process for medical technologies, by ensuring:

1. That evidence uncertainty is addressed over time with continuous generation and use of real-world data,
2. The acknowledgement of medical technologies' characteristics, whereby the level of evidence available continually evolves in line with the medical technology's lifecycle,
3. The process corresponds to the different points in time (and different purposes for which) Member States conduct HTAs for medical technologies. Here, again, it is critical to involve technology developers when determining the appropriate time to conduct joint clinical assessments on given medical technologies.

MedTech Europe is committed to working with the EU Institutions to find an appropriate framework for medical technologies during the trilogue negotiations.

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.

For more information, visit www.medtecheurope.org

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[5] For details, see https://www.medtecheurope.org/resource-library/the-value-of-industry-involvement-in-hta-november-2011/ and https://www.medtecheurope.org/wp-content/uploads/2017/09/Stakeholder-involvement-in-HTA-cooperation-2-pager-final-11092017.pdf