

## MedTech Europe calls for stronger recognition of medical technologies' specificities in upcoming trilogue on HTA

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MedTech Europe, the trade association representing the medical devices and *in vitro* diagnostics industries in Europe, acknowledges the European Council's agreement to start trilogue negotiations on the proposed EU Regulation on Health Technology Assessment (HTA).

As decision-makers embark on this critical stage of the legislative process, it will be crucial to ensure that timely access to innovation is safeguarded and improved for patients and health systems across Europe. To achieve this, any joint clinical assessment conducted on medical technologies must have a clear purpose, and their results must also enable appropriate real-life funding or reimbursement decisions taken within Member States. Regrettably, it is unclear how the Council proposal, as it stands now, would contribute to better or earlier patient access to medical technology innovation.

MedTech Europe strongly encourages the co-legislators to address, in the upcoming trilogue negotiations, that medical technologies have unique characteristics and specific access models, both in terms of their regulatory approval and in terms of how they are procured or reimbursed. This is important to preserve patient access, especially for critical conditions which require innovative technologies, to ensure the financial sustainability of our healthcare systems across Europe, and to preserve the competitiveness of our SME-driven sector.

Our industry is facing a major overhaul in transitioning to the stringent requirements of the Medical Device Regulation (MDR) and *In Vitro* Diagnostic Regulation (IVDR). We are committed to doing our part to successfully certify the tens of thousands of medical technologies against the new CE marking rules. It is therefore critical that the EU HTA Regulation do not interfere with regulatory assessments conducted under the MDR/IVDR, as this could lead to delays in patient access to innovation and increased confusion in the market authorisation process in Europe. We therefore call on the EU institutions to ensure these separate legislative frameworks to remain distinct, not only in the recitals of the EU HTA Regulation but also in practice. CE marking shall remain the only process for market approval demonstrating safety and performance for our sector and should not be redone.

When identifying medical technologies to undergo joint clinical assessment at EU level, we call for criteria to select only those technologies that bring considerable and unique transformative healthcare outcomes, for patients and for the delivery of healthcare.

We are further committed to work closely with the EU institutions and stakeholders to help ensure that the specificities of our sector's access pathways and value assessment methods are fully considered.

Specifically, we propose to:

1. Have predictable joint clinical assessments on medical technologies:
  - with transparent and adequate selection criteria (see above),
  - conducted at an appropriate point in time, agreed together with technology developers
  - using the best available and proportional evidence including real world data,
  - applying fit-for-purpose methodologies tailored to medical devices and *in vitro* diagnostics and
  - 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 under the new medical technology regulations (IVDR/MDR),
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.

We look forward to discussing the above with EU institutions **to ensure that a future Regulation can bring added value to European citizens, providers, healthcare systems as well as the medical technology industry.**

## 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](http://www.medtecheurope.org).

### For press enquiries, please contact:

Jerick Parrone  
Senior Manager Communications - External Affairs  
MedTech Europe  
[j.parrone@medtecheurope.org](mailto:j.parrone@medtecheurope.org)