MedTech Europe
from diagnosis to cure

STATEMENT

Call to address key challenges for the implementation of the Health Technology Assessment Regulation

Need for a clear and comprehensive roadmap

Ahead of the initial application of the Health Technology Assessment Regulation (HTAR), outstanding questions remain on whether its implementation in the field of medical technologies can support key European policy objectives favouring innovation, competitiveness and timely access to novel care.

For the HTAR to be of added value to patients and health systems in Europe, it is crucial to ensure that methods, processes and timelines adapt to the specificities of the novel medical technologies in scope for joint clinical assessment (JCA). Guidance and implementing act preparatory documents released so far have not accounted for these specificities. Furthermore, the content of Joint Scientific Consultation (JSC)/JCA Implementing Acts, templates and guidance documents currently under development will be critical for a successful implementation but would not suffice to enable readiness for the successful application of the regulation.

MedTech Europe and its members are dedicated to contributing to a successful application of the HTAR by continuing to highlight the shortcomings and uncertainties around the added value of proposed processes, from the selection of technologies to the effective use of JCA reports at the national level. Hence, we call on the HTA Coordination Group, its subgroups, and the European Commission to recognise the specificities of novel medical technologies and to issue a clear and comprehensive roadmap to foster system readiness.

The roadmap should be rolled out in a timely manner and should aim to:

- Provide clarity and predictability on processes in the different phases of the JCA (pre-, during and post) and on avenues for multi-stakeholder participation.
- Provide clarity on the definitions and the application of the provisions in the implementing acts.

For instance, further clarifications are needed regarding the identification of and planned reporting on emerging health technologies; the possibility for early dialogue and involvement of health technology developers; definitions of ‘expected major impact’ and ‘organisational-financial consequences’; the capacity to account for the evolving nature of evidence generation plans during the JSC process; and the approach to select technologies to undergo JCA and to identify the appropriate time for the assessment. Furthermore, it remains unclear how Member States’ access and reimbursement pathways will effectively use JCA reports conducted for medical technologies and how this creates value compared to competitive products undergoing national HTA processes.

In order to unlock the HTAR for the creation of a favourable environment for medical technology innovation, the following principles are to be followed: (i) create opportunities for early dialogue with health technology developers and involvement of other stakeholders; (ii) mitigate the risk for extra administrative burden; (iii) increase predictability of processes and timelines; and (iv) apply an adaptive approach for JCA reports that comprehensively incorporate all available evidence sources and effectively inform national access pathways.

MedTech Europe and its members remain committed to ensuring that Europe’s patients and healthcare systems benefit from the latest technology innovations with a major impact in a timely manner. A clear Roadmap taking into consideration the above outlined objectives and principles can help all interested parties prepare for changes ahead.

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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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