MedTech Europe
from diagnosis to cure

PRESS RELEASE

EU Regulation on Health Technology Assessment (HTA)

Integrating the specificities of medical technologies for a successful long-term implementation

Brussels, 24 November 2022 – Ahead of the Member State Coordination Group Meeting of 28 November 2022, MedTech Europe calls for the set up of a dedicated medical and digital technologies methods subgroup to develop, in due time, "Adaptive" Joint Clinical Assessments methodologies applying the latest scientific developments.

MedTech Europe welcomes advances in the assessment of the value of medical technology innovations, especially those that enable timely, accelerated and equal access linked to funding and reimbursement. However, the current implementation of the HTA Regulation does not provide clear safeguards to fully guarantee this in the long term.

The ongoing development of Joint Clinical Assessments (JCA) methodologies by EUnetHTA 21 has not yet included provisions to address the specificities of medical technologies, as recommended by several EU Research and Innovation studies and projects [1, 2, 3] and the EUNETHTA Joint Actions[4]. We call for the development of appropriate methodologies, in due time, for "adaptive" joint clinical assessments of medical technologies of added value for JCA in Q4 2026.

We support the ongoing efforts by the EU institutions to bring in further expertise to ensure the development of a full JCA process.

Concretely, the medical technology industry calls now on Member States to ensure that medtech-specific configurations are created and meet in practice, both for the Member State Coordination Group and for its methods subgroups. These subgroups should be equipped with the expertise necessary to understand the specificities of medical technologies and embrace the latest scientific developments in medical and digital technology assessments.

MedTech Europe is ready to collaborate with Member States and the European Commission to ensure a successful implementation of the Regulation. We look forward to an inclusive, open and flexible approach that can capture the latest innovations in the medical technology sector as well as medical technologies' funding and reimbursement mechanisms.

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[1] Tarricone R et al. Key recommendations from the MedtechHTA project. Health Econ.2017 :26(Suppl1) :145-152

[2] Torbica et al. Economic Aspects of the Evaluation, Diffusion and Use of Medical Devices. Health Econ. 2022:31(Suppl1): 1-206

[3] Van der Wilt et al on Behalf of the VALIDATE-HTA Consortium (2022). Health technology assessment: A matter of facts and values. International Journal of Technology Assessment in Health Care, 38(1), e53, 1–2

[4] *https://www.eunethta.eu/wp-content/uploads/2021/09/FMC-HTA-WHITE-PAPER-FOR-PUBLICATION.pdf*

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.

www.medtecheurope.org.

For more information, please contact:

Caroline Moulins

Senior Manager Communications

MedTech Europe

c.moulins@medtecheurope.org