European Commission
Proposal for a Regulation COM(2025) 1023
Targeted revision of EU rules for medical devices and in vitro diagnostics

Comment from the Institute for Quality and Efficiency in Health Care (IQWiG)
31 July 2026

The Institute for Quality and Efficiency in Health Care (IQWiG) is Germany's independent agency for health technology assessment (HTA, https://www.iqwig.de/en/). IQWiG produces scientific reports on various topics, including medical device interventions. These HTA reports are used to decide about reimbursement within Germany's statutory health care insurance. Thus, IQWiG's reports affect the medical care of approximately 76 million people in Germany. In addition, IQWiG is a key contributor to HTA activity at the EU level, as defined in the Health Technology Assessment Regulation (HTAR; Regulation 2021/2282).

The proposed targeted revision of EU rules on medical devices (MDs) and in vitro diagnostics (IVDs) contains major amendments to the Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR), i.e., Regulations (EU) 2017/745 and 2017/746. From IQWiG's point of view, it is essential that these revisions

i) do not weaken the involvement of independent scientific and clinical expertise and
ii) do not restrict the scope of EU HTA as laid down in Regulation (EU) 2021/2282.

On i): IQWiG supports the requirement that independent clinical experts should assess the clinical evidence on new high-risk devices before they enter the EU market. Currently, this so-called Clinical Evaluation Consultation Procedure (CECP) is implemented in Article 54 of the MDR for certain class III and class IIb devices. A comparable procedure, the Performance Evaluation Consultation Procedure (PECP), exists for IVDs. However, the new proposal would limit the CECP to class III MDs and abolish the PECP for IVDs. These changes would run counter to the EU's aim of deeper involvement of independent scientific and clinical expertise. Reducing the level of clinical oversight in the assessment of high-risk devices is unwise, as the risk of unsafe or ineffective devices in the EU market increases. Furthermore, fewer CECPs and PECPs would reduce the transparency of conformity assessments. Currently, the list of

opinions provided under the CECP[1] is a useful source of information to learn more about the (sometimes weak) clinical evidence supporting new MDs.[2]

On ii): Article 7 of the HTAR (Regulation (EU) 2021/2282) provides that MDs and IVDs can only be selected for joint European assessments if the relevant expert panels have issued a scientific opinion (CECP) or a view (PECP) on a given new device. Consequently, HTA is explicitly linked to the CECP and the PECP. Restricting these consultation procedures to class III MDs would reduce the scope and value of EU HTA, as the number of eligible devices would decrease. In consequence, the proposed revisions to the MDR and IVDR contradict key HTAR aims such as "to produce high-quality and timely results, and foster greater collaboration between Member States on HTA for medical devices and *in vitro* diagnostic medical devices".

It appears as if these unintended downstream consequences have not yet been identified or addressed properly. IQWiG therefore recommends either maintaining the current scope of the CECP and PECP in the MDR and IVDR, or adding additional selection criteria for MDs and IVDs in the HTAR. It is essential that the MDR and IVDR, which regulate market access, remain appropriately aligned with the HTAR, which forms the basis for reimbursement.

[1] European Commission: List of opinions provided under the CECP. https://health.ec.europa.eu/medical-devices-expert-panels/experts/list-opinions-provided-under-cecp_en

[2] Watson C, Richmond FJ: EU's Medical Device Expert Panels: Analysis of Membership and Published Clinical Evaluation Consultation Procedure (CECP) Results. Ther Innov Regul Sci 2024; 58(5): 910-916. https://doi.org/10.1007/s43441-024-00632-7