European Commission Draft Implementing Act on Joint Clinical Assessments of Medical Devices and In Vitro Diagnostic Medical Devices

Comment from the Institute for Quality and Efficiency in Health Care (IQWiG)
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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 medicinal products, medical device interventions, and other interventions (e.g., screening). IQWiG is part of the EU Member State Coordination Group on Health Technology Assessment (HTACG) and actively involved in producing Joint Clinical Assessments (JCAs) at Union level.

IQWiG fully supports the Commission's aim to "ensure the highest scientific quality of the joint clinical assessment" (JCA) – not only for medicinal products (MPs), but also for medical devices (MDs) and in vitro diagnostics (IVDs). Therefore, it is justified and consistent to state in Annexes I and II of the Implementing Act that "evidence in the dossier shall follow international standards of evidence-based medicine". However, these standards are unnecessarily weakened for health technology developers (HTDs) who produce MDs or IVDs compared to those who produce MPs. This issue is evident when comparing the Implementing Act on MP JCAs (http://data.europa.eu/eli/reg_impl/2024/1381/oj) and the Draft Implementing Act on MD/IVD JCAs:

MP version "*The results presented in the dossier shall follow international standards of evidence-based medicine and take into account, if available, the methodological guidance adopted by the HTACG […]. Any deviations shall be described and justified.*"

MD/IVD version *„The results presented in the dossier shall follow international standards of evidence-based medicine. The HTD may consult, if available, the methodological guidance adopted by the [HTACG] and describe and justify any deviations from that guidance."*

This obvious discrepancy, which appears several times in the text, raises questions for several reasons: From the patient perspective, it is unclear why the well-accepted methodological standards for drug assessment should not also apply to medical devices. The comparative effectiveness and safety of any type of medical intervention must be established, especially for high-risk interventions. Also from a scientific perspective, the standards of evidence-based

medicine are the same for MPs and MDs. The fact that device evaluation sometimes has specific challenges (e.g., due to the impossibility of placebo controls or learning curve effects in specific cases) is already addressed in the methodological guidance. Finally, from a practical point of view, inconsistent JCA standards would unnecessarily consume staff resources, because manufacturers could produce analyses that are irrelevant to HTA, and HTA agencies would have to deal with insufficient data.

In conclusion, all health technology developers, whether in the pharmaceutical or medical device field, must be required to use the HTACG's methods guidance.