European Commission - Targeted revision of the EU rules for medical devices and in vitro diagnostics

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 medical device (MD) interventions. These HTA reports are used by the Federal Joint Committee (G-BA), the main decision-making body in the German health care system, 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 an essential contributor to HTAs at EU-level, as defined in the HTAR (Regulation 2021/2282 on HTA).

Clinical application of a new MD intervention requires **adequate scientific data,** not only on safety and performance, but also on effectiveness, including patient-relevant benefits. Therefore, the new MDR (Medical Device Regulation) was a key step towards better patient care. It is essential that MDR (regulating market access) and HTAR (forming the basis for reimbursement) remain well-linked. Only if the requirements concerning clinical evidence for new MDs remain at a high level, will HTA be able to provide EU member states with useful information to guide national reimbursement decisions on new technologies. As such, IQWiG strongly supports the EU position, which requires that the "level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose" (MDR Article 61). This essentially means that for the vast majority of first-in-class high-risk MDs, randomised controlled trials (RCTs) have to be conducted. According to our own analysis of MD clinical investigations, such high-level evidence has already become a well-accepted and common standard throughout the last decade (https://pubmed.ncbi.nlm.nih.gov/30798319/). These standards of high-quality evidence and patient safety are feasible and must not be given up in future revisions of the MDR.

As a second key requirement, **full transparency** is needed, for utilising the MDR-required information on new high-risk MDs for HTA purposes. The clinical investigation report, which has to be published within 1 year after the investigation ends (MDR, Article 77), is crucial for HTA and other clinical purposes. Of similar importance is the public availability of the summary of safety and clinical performance (MDR, Article 32). It is of great importance that the European database on MDs ('EUDAMED') soon becomes fully functional.

The **example** of a new transcatheter tricuspid valve replacement system (Evoque, Edwards Lifesciences) illustrates our two main points well: A new, first-in-class, high-risk MD received CE mark approval in October 2023 and was selected for pilot testing the EU HTA process (see: https://health.ec.europa.eu/publications/pico-exercises_en, Exercise 4). In Germany, transcatheter tricuspid valve replacement had to be assessed by IQWiG and G-BA, because of the novelty of the MD (https://www.g-ba.de/bewertungsverfahren/verfahren-137h/58). Unfortunately, the HTA process could not progress as planned, because the results of the pivotal studies (TRISCEND and TRISCEND II) were not fully available when the device received CE mark. The 1-year results from the TRISCEND II study were published as late as October 2024 (https://pubmed.ncbi.nlm.nih.gov/39475399/) – 1 year after market access. Furthermore, the clinical investigation report for this study (TRISCEND II) has not been made publicly available until today. Accordingly, patients in Europe were being treated, although the evidence on this new heart valve was preliminary and opaque (https://www.iqwig.de/presse/presse-mitteilungen/pressemitteilungen-detailseite_131520.html). This shows that the MDR requirements for high-quality clinical evidence and full transparency should be strengthened rather than loosened.

In conclusion, a high level of evidence and a high level of transparency are essential for a functioning European system that governs market access and reimbursement decisions. If this requires more work, both from the manufacturer's and the regulator's side, this extra work is fully compensated and justified by the improved safety and effectiveness of patient care. If changes in the MDR are necessary in order to reduce the regulatory burden, these alleviations should be limited to low-risk devices and re-certifications.