9 November 2026

Patient and healthcare professionals' organisations warn against weakening clinical evidence requirements for high-risk devices

Joint Statement of the European Patients' Forum and BioMed Alliance on the proposed revision of the Medical Devices and In-Vitro Diagnostics Medical Devices Regulations (MDR/IVDR)

As negotiations in the Council and the European Parliament continue on the Revision Proposal of the MDR and IVDR, our organisations are concerned about the possibility that the European Commission's proposed changes to the rules on equivalence under Article 61 and Annex XIV of the MDR may be retained in the final text.

Broadening the equivalence pathway for high-risk medical devices could expose patients to serious and unacceptable safety risks, undermining the progress achieved in recent years. The proposed changes would allow manufacturers to rely more extensively on clinical evidence from another device and avoid conducting clinical investigations to demonstrate the safety and performance of their own device. At the same time, the Commission proposed removing the requirement for a contract ensuring full access to the technical documentation of the reference device, further undermining the reliability of equivalence claims.

In view of the serious risks these changes would pose on patient safety and users' trust in the system, BioMed Alliance and EPF call on the co-legislators to:

- **Revert to the original wording of Article 61(5) and Annex XIV paragraph 3 of the MDR,** preserving the existing safeguards, including the requirement for a contract between manufacturers ensuring full access to the relevant technical documentation when equivalence is claimed for implantable or Class III devices
- **Maintain strict criteria for demonstrating equivalence**, requiring devices to have the same technical, biological and clinical characteristics, rather than allowing reliance on devices with merely similar characteristics
- **Preserve robust pre-market clinical evidence requirements for high-risk devices**, particularly Class III and Class IIb implantable devices given the potentially serious and long-lasting consequences of safety failures

Background

As part of its efforts to simplify the regulatory framework and reduce administrative burdens, the Commission proposal aims to relax the requirements for establishing equivalence for implantable and Class III devices (see MDR Article 61.5 and Annex XIV paragraph 3). The new provision allows manufacturers of high-risk implants to claim equivalence to another device in their conformity assessment application, permitting them to rely on clinical data for that specific alternative device, and removing the requirement to perform a clinical investigation. This will be achieved by removing the requirement for a contract between manufacturers and by lowering the evidence threshold for demonstrating equivalence, allowing devices with 'similar'

rather than the 'same' clinical and biological characteristics. As a result, new high-risk implantable devices may be marketed without any form of pre-market clinical investigation. There is also a risk of predicate creep, which indicates that in a gradual accumulation of changes, devices can be approved based on equivalence to 'older models', which were themselves also approved based on equivalence[1].

This represents a fundamental reversal of policy developed under the MDR to improve the evidence base for the highest risk medical devices, and a step backwards for the EU regulatory framework. It also disregards the European Commission's own conclusion in 2012 which noted that "'*equivalence' with another implantable or class III device is not a sufficient justification to omit clinical investigations*." [2] The revision proposal justifies this change because similar device data is 'available', however no further justification has been provided for this fundamental change to clinical evidence requirements for high-risk implants.

Safety risks

There are many examples of devices approved based on claims of equivalence under the previous medical device directives, with serious complications occurring after their approval. In some cases, their use led to the deaths of patients, and in other cases to the need for urgent re-operation with removal of the faulty device and replacement by a safer alternative. In these cases, equivalence had been accepted by the notified body but was inappropriate because of a change or difference in design or manufacture. For instance, examples include heart valves that caused numerous complications including thrombus formation or embolisms, metal-on-metal hip implants with high revision rates, and transvaginal meshes that caused infection, pain, and other complications[3]. Since the MDR came into force, there have been significantly less similar incidents, most likely due to its stricter conditions for claiming equivalence.

Facilitating the reliance on data for equivalent devices is not a technical 'simplification', but a demonstrated safety risk. Standards of clinical evidence are already often insufficient and lack of clarity remains among manufacturers and notified bodies as to what constitutes sufficient evidence. The EU funded Co-ordination of Research and Evidence for high-risk Medical Devices (CORE-MD) Project found that many high-risk medical devices used in cardiology, orthopaedics and diabetes care rely on insufficient clinical evidence, including studies with small sample sizes, non-randomised design or retrospective control groups, or no clinical studies at all[4]. The consequences for patients can be seen in areas such as diabetes care, where significant accuracy and quality issues with continuous glucose monitors have been identified, affecting patients who rely on these devices to manage their condition. The consensus

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[1] Lefkovich C, Rothenberg S. Identification of predicate creep under the 510(k) process: A case study of a robotic surgical device. PLoS One. 2023 Mar 28;18(3):e0283442. doi: 10.1371/journal.pone.0283442. PMID: 36976820; PMCID: PMC10047502.

[2] See: COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT ON THE REVISION OF THE REGULATORY FRAMEWORK FOR MEDICAL DEVICES /* SWD/2012/0273 final */
Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52012SC0273

[3] See pages 28-30 of the BioMed Alliance Position paper for specific examples and sources: https://www.biomedeurope.org/news/healthcare-professionals-share-views-as-negotiations-on-mdr-ivdr-revision-continue/

[4] See: page 32 of https://www.biomedeurope.org/wp-content/uploads/2025/07/BioMed-Recommendations-MDR-IVDR-2025.pdf

recommendations from the CORE-MD project[5] also stated clearly that manufacturers of a new high-risk device entering an existing market must be able to state with confidence that their device is at least as good as those that have already been approved, which will necessarily require pre-market clinical investigations. A claim of equivalence without robust pre-market clinical investigations for high-risk implants is unacceptable on ethical and evidentiary grounds.

Way forward

We propose to retain the wording that was provided in the original MDR Article 61.5 and Annex XIV paragraph 3. While allowing the use of equivalence for lower risk devices with the same characteristics could be justifiable with appropriate oversight, Class IIb implantable devices and Class III devices pose greater risks to patient safety and should be subject to clinical investigations as a general rule. For Class III or implantable devices which may safely be marketed without any clinical investigations, the use of equivalence should only be permitted under strict conditions, including the requirement for a contract between manufacturers ensuring full access to the relevant technical documentation of the equivalent device.

Safety risks cannot be mitigated by merely strengthening PMCF or improving the monitoring of clinical safety and performance in real world conditions, as the risks for patients particularly with class IIB implantable and class III devices are simply too great. Implants (such as the abovementioned case of vaginal mesh) are often implanted in the body for a long time, and safety issues may only become apparent after several years. The only way to protect patient safety is to limit the equivalence pathway only to low-risk devices, or cases where there is demonstrated access to high-quality data to demonstrate the same technical, biological and clinical characteristics.

EPF and the BioMed Alliance remain committed to working with the EU institutions to ensure that the final legislation safeguards patient safety while supporting availability of safe and high-performing medical devices across Europe.

[5] See: Fraser et al, Lancet Regional Health Europe, 2025, https://www.thelancet.com/journals/lanepe/article/PIIS2666-7762(25)00252-2/fulltext