July 2026

HOPE Position

on the revision of the Medical Devices and In-vitro Diagnostic Regulations

HOPE welcomes the proposed revision that aims to simplify the EU regulatory framework, reduce unnecessary administrative burden and support timely access to products. However, those efforts should not weaken the patient protection.

The proposed revision of the Medical Devices Regulation (MDR) concerning artificial intelligence in Recital 23 and in article 4 of should be deleted. It would render inapplicable important requirements and safeguards on high-risk AI systems used for medical purposes. The current regime of the AI Act should continue to apply.

The core of the MDR is the requirement for robust clinical evidence for high-risk medical devices. This was introduced to address the shortcomings of the previous Medical Devices Directives (MDD) framework, which relied too heavily on equivalence claims. The changes in article 61(5) that would relax these requirements, poses significant safety risks.

The amendments of article 2(10) on the obligations in case of interruption or discontinuation of supply chains are welcomed, as they will ensure the administrative efforts are focused where they are really needed, but information about discontinuation or interruption of relevant device marketing should be made publicly available and in a timely manner for service providers for them to be able to adapt to the change.

The changes proposed in article 5(5) to the exemptions for the in-house manufacture and use of devices in healthcare facilities are going in the right direction. However, to ensure that healthcare facilities can make use of the exemptions, significant changes are needed to reduce the burden of formal requirements. HOPE suggests for the same reasons to delete 5.5(e).

HOPE welcomes the proposed amendment to paragraph 1 in Article 17. The obligation for manufacturers to provide sufficient justification as to why a device is classified as a single-use device and cannot be reprocessed is a demand voiced for decades. Manufacturers should provide verifiable reasons for the single-use nature of a product, as there have been sufficient examples of products labelled as single-use products even though they could easily have been reprocessed. In addition, we suggest the introduction of a sanction mechanism.

The definition of reprocessing of devices in accordance with Art. 2 does not differentiate between single-use devices that cannot be reprocessed according to the manufacturer and (reusable) medical devices that have reached the end of their possible reprocessing cycles. In this respect, this distinction in paragraph 3 is also superfluous.

It is not clear why a Common Specification on general reprocessing requirements is required in paragraph 4. The reprocessing of reusable devices has been established for decades, and single-use devices should generally not be reprocessed under the premise of paragraph 1. In this respect, not only should a CS be issued on reprocessing, but also in particular on which verifiable evidence manufacturers must submit in detail in order to be allowed to declare a product as a single-use device.

In annex II HOPE believes that Electronic Instructions for Use (eIFU) could be helpful for healthcare professionals. But IFU should be kept in case of electricity blackout, or no robust digital system. eIFU should not be extended beyond what is foreseen in that Implementing regulation - 2021/2226.

For devices used exclusively with a medicinal product and packaged together with a medicinal product, the instructions for use must be included as part of the co-packaging of the medicinal product with the device. Electronic instructions shall provide approved information only and the software used for the electronic instructions shall comply with regulation 2016/679 (General Data Protection Regulation), and profiling of patients shall be forbidden.

Article 59c on increased reliance on real-world evidence is welcome but requires robust governance to ensure reliability and applicability.

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