EHA's position on the IVDR revision proposal

June 2026

In Vitro Diagnostic Medical Devices Regulation (IVDR) proposed targeted revision December 2025 (COM(2025)1023)

The European Hematology Association (EHA) welcomes the proposed targeted revision of the In Vitro Diagnostic Medical Devices Regulation (IVDR) and supports measures to improve regulatory proportionality, reduce unnecessary bureaucracy, and safeguard patient access to essential diagnostics while maintaining high standards of safety and performance.

EHA strongly supports the proposed **removal of the requirement** under Article 5(5)(d) to **demonstrate the absence of an equivalent CE-marked device**, as well as the **increased flexibility** for the use and limited **transfer of in-house diagnostics** (Article 5(5)(a)). These amendments reduce unnecessary burden on healthcare institutions and support continued access to specialized diagnostics developed and used within accredited laboratories.

While welcoming these changes and recognizing the importance of appropriate safeguards at EU level, EHA continues to stress the need for a fit-for-purpose regulatory treatment of IH-IVDs, to better reflect the specific nature of in-house IVDs.

Important considerations:

- In-house IVDs are developed and used within healthcare institutions and are already subject to established quality and accreditation systems, including ISO 15189. Experience from clinical laboratories suggests that some IVDR requirements create significant additional administrative workload without clear added value for patient care.
- The regulatory framework should move towards a complementary, proportionate regime that avoids duplication with ISO 15189-based systems and national oversight. Diagnostics developed and used within a single, ISO 15189 or equivalent accredited, institution for targeted individual patient care should be subject to minimal additional regulatory burden beyond participating in external quality assessment programs for the relevant category of tests.

With regard to the **public declaration** requirements under Article 5(5)(f)(iii), namely, that devices comply with the **general safety and performance requirements** set out in Annex I of this Regulation, and, where applicable, that any unmet requirements are accompanied by a reasoned justification, EHA considers that these should be implemented in a harmonized manner throughout the Union. This would ensure their consistent application by the Member

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States, while avoiding unnecessary duplication of conformity assessment or quality review procedures.

Beyond Article 5(5), EHA welcomes the proposed amendments, including the introduction of **priority pathways for breakthrough and orphan diagnostics**, a more flexible performance evaluation consultation procedure with an **early scientific expert advice mechanism** for high-risk diagnostics from an appropriately reinforced **IVD expert panel(s)**, improvements to **conformity assessment procedures**, enhanced **regulatory efficiency**, and measures aimed at strengthening **innovation**, improving predictability and facilitating the development of complex tests, including molecular and companion diagnostics. EHA supports strengthened EU-level coordination, including **crisis response tools** and mechanisms to address shortages, as well as the introduction of regulatory **sandboxes** to facilitate innovation.

In conclusion, EHA supports a revised IVDR that is more flexible, predictable, and better aligned with clinical practice. While the proposed amendments to Article 5(5) are a step in the right direction, further efforts are needed to ensure a truly proportionate approach to in-house diagnostics. The goal must be a framework that sets high standards of patient safety while enabling innovation, supporting accredited laboratories, and ensuring that patients across Europe continue to have timely access to high-quality, specialized diagnostics.