DiaLab Danish Diagnostics & Laboratory Association

**The European Commission**
Rue de la Loi 200
1049 Brussels
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**DiaLab's Feedback on the Commission Proposal for a Regulation: The Revision of the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR)**

DiaLab welcomes the opportunity to provide feedback to the European Commission's proposal for a revision of the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR).

DiaLab is a Danish industry association for companies who are manufacturers and/or distributors of in-vitro diagnostic devices as well as laboratory equipment.

Reflecting the nature of our member base and the insights from our members, this feedback mainly addresses the proposed revision of IVDR. DiaLab further supports the feedback of Dansk Erhverv (The Danish Chamber of Commerce) and Medtech Europe.

**Specific remarks**

Patient safety
Patient safety must remain the cornerstone of the MDR and IVDR. IVDs play a critical role in modern healthcare, informing clinical decisions and enabling timely and accurate diagnosis.

DiaLab supports the Commission's ambition to simplify and improve the regulatory framework without compromising the high level of safety established by the MDR and IVDR. A more proportionate and risk-based regulatory system will allow competent authorities and notified bodies to focus their resources where they have the greatest impact.

Effective regulation and patient safety go hand in hand. A well-functioning and predictable regulatory framework is essential both to safeguard patients and to ensure continued innovation.

Safeguarding the Purpose of the In-House Exemption
DiaLab recognizes the important role of the in-house exemption in enabling health institutions to develop and use diagnostic tests where no suitable CE-marked alternative is available. The exemption is an essential mechanism for addressing genuine unmet clinical needs and should remain an integral part of the IVDR.

However, DiaLab is deeply concerned by the Commission's proposal to remove the requirement under IVDR Article 5(5)(d) that health institutions must demonstrate that no equivalent CE-marked device is available before relying on the in-house exemption. This safeguard ensures that the exemption remains targeted while maintaining CE-marked diagnostics as the standard for patient care.

Removing this requirement risks creating a two-tier regulatory system in which commercially available CE-marked IVDs and in-house tests are subject to fundamentally different regulatory standards despite serving the same clinical purpose. Allowing health institutions to routinely use in-house tests where equivalent CE-marked devices exist would weaken incentives to invest in innovative diagnostics, create an uneven regulatory playing field, and ultimately undermine the CE-mark system.

The proposed expansion also raises important patient safety concerns. CE-marked IVDs are subject to independent conformity assessment and continuous regulatory oversight to ensure consistently high standards of safety and performance. While in-house tests play an important complementary role, they should not become the default where equivalent CE-marked alternatives are available. Maintaining CE-marked diagnostics as the standard is essential to ensuring a high level of patient safety.

DiaLab therefore strongly urges the Commission to **reinstate IVDR Article 5(5)(d) and maintain the current requirement** that the in-house exemption may only be applied where no equivalent CE-marked device is available and where its use is clearly justified.

Breakthrough and Orphan Pathways

DiaLab welcomes the introduction of dedicated breakthrough and orphan pathways under the MDR and IVDR. These measures have the potential to accelerate patient access to innovative diagnostic technologies, particularly in areas of high unmet medical need and rare diseases.

To ensure the framework delivers its intended benefits, DiaLab encourages alignment of the proposed orphan device threshold of 1 in 12,000 individuals per year with the existing EU definition of rare diseases (5 in 10,000), thereby ensuring consistency across the European regulatory framework without the risk of excluding critical diagnostics such as tests for rare blood groups.

Removing the fixed five-year recertification cycles and replacing it with a risk-based approach

DiaLab welcomes the Commission’s proposal to remove the maximum period of validity of certificates (currently 5 years), replacing it with a more targeted and risk-based approach with periodic reviews proportionate to the risk of the device. This change will be a substantial step towards a more proportionate and efficient regulatory system where the resources are used where the risk is greatest.

A More Proportionate Approach to IVD Regulation

DiaLab welcomes the Commission's efforts to introduce a more proportionate and risk-based regulatory framework for in vitro diagnostics. Unlike many medical devices, IVDs do not interact directly with the patient. This distinct risk profile should be more clearly reflected in the regulatory framework.

In particular, DiaLab supports greater regulatory clarity for well-established technologies and routine procedures, ensuring that commonly used diagnostics and

procedures such as routine blood draws and finger pricks are not subject to unnecessary regulatory requirements. A more proportionate approach will reduce unnecessary administrative burdens while maintaining high standards of quality, safety, and patient care.

Specifically, we propose to amend Article 58(1) IVDR to clarify that full authorisation requirements apply only when an invasive procedure presents significant clinical risk.

International cooperation
DiaLab welcomes the introduction of a dedicated chapter on international regulatory cooperation. Closer cooperation with regulatory authorities in jurisdictions with comparable standards will reduce unnecessary duplication and strengthen the global recognition of the CE marking system.

We remain at your disposal for any further elaborations or questions.

Best regards,

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Head of Secretariat