The European Association of Medical devices Notified Bodies

Team-NB Position Paper

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ANNEX VII - COMMISSION IMPLEMENTING REGULATION DRAFT

I. Executive Summary

The Commission's proposal of 12 December 2025 to amend Annex VII introduces maximum timelines and clock-stops for certification activities under MDR/IVDR. The aim is to streamline conformity assessment processes, enhance predictability, and ensure timely market access for medical devices. The proposal sets out specific deadlines for each step of initial certification, changes, and recertification, with the intention of improving transparency and efficiency across the sector. Team-NB welcomes the Commission's efforts to improve the regulatory framework and acknowledges the potential benefits of clear timelines.

NBs have identified several challenges and risks associated with the proposal:
Complexity and Feasibility: The proposal introduces different timelines for initial certification and changes. This creates unnecessary complexity for NBs, making implementation and monitoring more difficult, especially given the diversity of device types and NB processes.
Resource Constraints: Some timelines, particularly for technical documentation (TD) assessment and decision-making, are considered unrealistic. NBs highlight that these steps often require multiple reviewers with specialized expertise, and that shorter deadlines could compromise quality, limit training opportunities for new staff, and increase costs.
Operational Flexibility: The proposal does not sufficiently account for the need for flexibility in handling complex or high-risk devices, or for parallel processing of multiple submissions.
Transition timelines: these are considered too short and should be replaced by realistic timelines

In response, Team-NB strongly recommends a harmonized and pragmatic approach. Team-NB proposes establishing consistent and realistic timelines for each step of the certification process—regardless of whether the activity relates to initial certification or changes. For recertification, Team-NB proposes timelines that could also address the complexity associated with some devices and multiple certificates held by a manufacturer with simultaneous expiry dates.
This would reduce administrative burden, simplify monitoring, and provide greater predictability for all stakeholders.

Team-NB remains committed to supporting the European Commission and all stakeholders in further improving the regulatory landscape, with the ultimate goal of ensuring patient safety and timely access to innovative medical devices.