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.

II. Quotations

The proposal addresses the minimum information to be collected by a notified body (NB) (and submitted by the manufacturer) and the different elements to be included in a quote issued by a NB.

NB feedback:

1. Quotation Accuracy

Providing more detailed information will help NBs give more accurate price quotes, which is welcomed.

1.1 SME Status Verification

Currently, NBs cannot easily confirm if a manufacturer is a Small or Medium-sized Enterprise (SME). Most NBs only check the number of employees, not the company's turnover. NBs do not have the resources or expertise to review financial statements. This would create extra work, slow down application processing, and increase costs. Self-declarations from manufacturers are not validated and are therefore unreliable.

Team NB suggests that SME status should be verified and recorded in EUDAMED during user registration. This would allow a transparent verification mechanism of a manufacturer (whether SME or not) for all stakeholders, including NBs.

2. Fee Transparency and Cost Estimates

2.1 Fee Publication

Current Annex VII of MDR and IVDR already requires all NBs to publish their fees. Links to the current NB fees are published on the EC website.

2.2 Factors Affecting Costs

The total cost of conformity assessments depends on many factors, such as:

- How well the manufacturer is prepared
- The quality of technical documentation
- How quickly the manufacturer responds to NB questions
- The complexity of the device

Many of these factors are outside the NB's control. It is also hard to predict future costs, such as for surveillance audits, because these depend on changes at the manufacturer, device portfolio, inflation etc.

2.3 Quotation Practice

NBs support giving detailed quotes for initial certification. For estimated costs, NBs recommend continuing to provide indicative prices with clear conditions. These estimates cannot be guaranteed and may change.

Team NB proposed that only if the actual cost changes by more than ±20% from the original estimate, NBs should inform the manufacturer and explain the reason. This approach reduces administrative work and keeps the process transparent.

3. Travel and Accommodation Costs

NBs have staff located worldwide. It is not possible to give an exact estimate for travel and accommodation costs at the time of quotation, as these costs vary by location of the necessary NB employees, travel provider, travel time etc. NBs have only limited control on these costs.
Team NB recommends removing the requirement to specify travel cost at time of quotation.

III. Timelines and clock-stops

The proposal introduces maximum timelines and clock-stops for various certification activities, including initial certification, changes, and recertification. Feedback on recertification timelines is addressed separately. The proposed key timelines are:

- Initial Certification
  - Application Review: 30 days, 1 clock-stop
  - QMS Assessment: 120 days, 3 clock-stops
  - Technical Documentation (TD) Assessment: 90 days, 3 clock-stops
  - Final Decision and Certificate Release: 15 days, no clock-stops
- Changes
  - Assessment of Change Request: 30 days
  - NB Conformity Assessment and Approval (for substantial changes): 90 days
  - Maximum of 3 clock-stops allowed across both steps

NB feedback:

1. General observations

NBs acknowledge that specific timelines for conformity assessment activities could improve predictability and speed of certification. Such timelines must be realistic and improve current mechanisms. NBs agree with starting the clock from the initiation of a given activity rather than a single point (i.e. date of the written agreement). The proposal also recognises that conformity assessments can happen in parallel instead of a sequentially. The timelines proposed for TD assessments apply per device (instead of the full application that may comprise of multiple devices) allowing a planned and staggered start of activities associated with each device.
The proposed timelines for different activities are challenging and unrealistic. The proposal does not consider differing processes across NBs or the need for flexibility in a system with thousands of types of devices varying in complexity. In some cases, several reviewers with different competencies are involved in each assessment to meet the competency requirements. This is very hard to achieve with the proposed timelines especially with multiple parallel submissions ongoing at any time.

2. TD assessment

90 days for TD assessment is challenging, especially for complex devices with multiple competencies involved. GÖG surveys recognise TD assessment as the limiting step in the certification process. NBs suggest that this is changed from 90 days to 150 days. 90 days would significantly affect small/new NBs who train their new staff on live files (under supervision). In shorter timelines, NBs would be forced to use experienced staff for only for work, with no time left to train new staff. 90 days would also be challenging where external experts are utilised. All these factors could also lead to higher costs for TD assessment.

3. Decision making step

No clock-stops are allowed. NBs recommend adding one clock-stop for cases where additional information from the manufacturer is needed.
The 15-day limit for decision-making is restrictive due to the limited number of qualified staff. NBs suggest increasing to 25 days, especially when the Final Review and Decision-Making steps are combined.

4. Proposal: **Consistent Timelines Across All Certification Activities**

Team-NB strongly emphasize that the current approach—using different timelines for initial certification and changes—creates unnecessary complexity for NBs when implementing and monitoring these processes.
To address this, Team-NB recommends establishing specific, consistent timelines for each step of the certification process, regardless of whether the step is part of initial certification or a change approval.

Proposed consistent timelines:

- Application Review: 30 days
- QMS Audit: 120 days
- TD Assessment: 150 days
- Final Review and Decision making: 25 days

By applying these timelines uniformly, NBs can streamline their procedures, reduce administrative burden, and ensure greater predictability for all stakeholders.

IV. Monitoring of timelines and costs

The proposal discusses monitoring of: fulfilment of the mandatory timelines, durations of conformity assessments and monitoring of costs. Several KPIs are proposed. NBs are required to publish annual reports with this data on their websites and provided to the EC.

NB feedback:

The proposal to monitor and report is against the recommendation from MDCG 2022-14 to reduce administrative burdens for NBs. Team NB understand the need for accountability and supports monitoring of KPIs related to timelines and costs.

- Team-NB is against the publication of such KPIs in the public domain. Instead, the KPIs may be audited by the designating authorities.
- Monitoring of timelines and costs should replace the existing NB surveys conducted by GÖG (and other bodies).
- The KPIs to be monitored should be defined and kept to a minimum that do not add burden.

V. Recertification

The proposal introduces information to be submitted by the manufacturer to support the recertification of certificates. It also requires NBs to notify a manufacturer at least one year in advance of their certificate expiry. Once the manufacturer has submitted their information, the NB must complete reviewing that information within 60 days, including clock stops.

NB feedback:

- It should be the manufacturer's responsibility to monitor the expiry dates of their certificates and request recertification, if required, at least 1 year prior to the expiry date.
- The proposal does not specify timelines for manufacturer submissions for recertification. This should be defined to provide predictability to the process and avoid delayed submissions close to the expiry date of the certificate. NBs typically need at least 9 months to conduct recertification.
- 60 days for the NB to review the information provided by the manufacturer is very short. This does not consider the complexity associated with some devices and multiple certificates held by the manufacturer, sometimes expiring simultaneously. We recommend the overall timeline for NB review of information is extended to 100 days.

VI. Transitional provisions

The proposal includes the transitional provisions for the implementation of these proposals.

NB feedback:

- No transition timeline is provided for the implementation of the changes to the quotation process. NBs propose at least a 6-month transition period for these changes to allow NBs and manufacturers to adjust processes to collect/submit more information during application.
- The proposed 3-month transition period for introduction of the timelines is extremely short. NBs propose at least 12 months transition period for the implementation of these changes.