Notified Body Perspective on Future Governance in the EU Medical Device Sector

July 2025

Abstract

The EU medical device regulatory framework faces fragmentation and inconsistent implementation, hindering safety, innovation, and timely access. This paper presents a notified bodies' perspective on future governance, proposing centralised support, improved coordination, and sustainable funding. It draws on recent EU policy developments and feedback of notified bodies.

NBCG-Med Executive Committee & Team-NB Executive Committee

Content

Introduction

The EU medical device regulatory framework (Medical Devices Regulation 2017/745 and In Vitro Diagnostic Medical Devices Regulation 2017/746) is at a pivotal moment. Fragmentation, inefficiencies, and inconsistent application of rules are undermining the goals of safety, innovation, and timely access.

This paper proposes a future governance model that integrates centralised support mechanisms, enhanced scientific and regulatory coordination, and sustainable funding. It draws on the July 2025 EU Commission Communication "European Commission's Life Sciences Strategy"[1], the July 2025 Consensus Statement of CAMD/HMA[2] and notified bodies' input in the MDCG Annex VII / governance workshops on 20 February, 3 April and 4 June 2025.

1. Proposed Governance Model

1.1 Central Coordination and Support Mechanism

A central EU-level coordination and support structure should be established, tasked with

- Coordination of designation, monitoring and reassessment of notified bodies
- Coordination of classification and qualification decisions
- Development and dissemination of structural guidance ('how the legal system should work')
- Development and dissemination of technical and clinical guidance and Common Specifications
- Coordination of Consultation Procedures with
    - other (i.e. non-device) authorities, such as pharma, cell/tissue, animal tissue authorities
    - expert panels, as established by MDR art 106
    - EU reference laboratories, as established by IVDR art 100
- Maintenance of a structured overview of sources for relevant scientific and clinical data
- Facilitation of early dialogue and special pathways for innovative or high-need devices
- Vigilance coordination
- Technical and Administrative Secretariat activities for MDCG and its Working Groups

[1] European Commission. (2025). *Choose Europe for life sciences: A strategy to position the EU as the world's most attractive place for life sciences by 2030* (COM (2025) 525 final). Brussels. Retrieved from https://eur-lex.europa.eu

[2] CAMD & HMA. (2025, July). *European medical device competent authorities' statement on reform of the EU regulatory framework for medical devices*. Consensus Statement, Utrecht. Retrieved from https://www.camd-europe.eu/events/publication-of-a-consensus-statement-from-the-eu-competent-authorities/

This central coordination and support structure shall be named **Medical Device Coordination Office (MDCO).**

The establishment of the **MDCO should not add to the already complex governance** of the EU medical device sector **but rather simplify it**. By centralising coordination functions and consolidating guidance development, the MDCO can reduce duplication, streamline decision-making, and provide a single, coherent interface for stakeholders across the regulatory landscape.

1.2 Role of notified bodies in a Centrally Coordinated Regulatory System

The important role of notified bodies as technical, regulatory and clinical 'extended arm' of the authorities should be maintained. Notified bodies are not only assessors of compliance—they are key contributors to a well-functioning regulatory system. Their unique expertise, combining regulatory knowledge with deep technical and clinical insight, makes them indispensable to a science-driven and responsive regulatory framework.

Across the EU, notified bodies collectively employ over 6,200 professionals, including more than 3,700 technical experts, over 900 clinicians, and more than 1,600 administrative and support staff[3]. This expert base is not only technically and clinically proficient but also deeply embedded in the operational realities of the sector. Notified bodies assess thousands of devices annually, giving them profound visibility into clinical practices, emerging technologies and real-world challenges faced by manufacturers and healthcare providers.

This **proximity to implementation and innovation** enables notified bodies to:

- Identify trends and risks early in the product lifecycle
- Provide practical, evidence-based input into guidance development
- Ensure that conformity assessments are both scientifically rigorous and proportionate
- Support innovation through early dialogue and structured dialogue.

Moreover, notified bodies operate under strict designation and oversight criteria, ensuring independence, competence, and impartiality. Their involvement in a centrally coordinated system - such as through the proposed Medical Device Coordination Office (MDCO) - would enhance consistency and efficiency without compromising the decentralised strengths of the current model.

[3] Austrian National Public Health Institute, Areté, & Civic Consulting. (2025). Study supporting the monitoring of the availability of medical devices on the EU market: Survey results of the 12th NB survey (MDR/IVDR) with data status 31 October 2024. Retrieved from https://health.ec.europa.eu/document/download/59b9d90e-be42-4895-9f6f-bec35138bb0a_en?filename=md_nb_survey_certifications_applications_en.pdf

Notified bodies should not be seen merely as stakeholders but as essential contributors to the regulatory ecosystem. A governance system that would integrate notified bodies, in an advisory role, into its decision-making structures would benefit from:

- **Operational insight** into how regulations are applied in practice
- **Technical and clinical depth** across all device types and risk classes
- **Scalability, sustainability, and continuity**, efficient expansion, long-term resilience, and preservation of institutional and regulatory knowledge is achieved by building on existing systems, resources, and expert networks within and between notified bodies.

Notified bodies' expertise and experience could, in particular, add value to

- Existing and new scientific and technical expert committees
- Development of guidance and common specifications
- Early advice and special pathway procedures
- Classification and delineation discussions

In parallel, the role of NBCG-Med (Notified Bodies Coordination Group for Medical Devices) should be significantly enhanced. As the formal coordination platform for notified bodies, NBCG-Med is uniquely positioned to consolidate expertise, identify systemic challenges, and support harmonised implementation. With an expanded mandate - supported by MDCO - NBCG-Med could enhance their contribution to guidance development and to harmonised positions on ad-hoc and strategic issues and also participate in planning of activities at central level. This would ensure that the practical experience and technical and clinical depth of notified bodies are consistently reflected in the EU regulatory system.

1.3 Resourcing and Financial Sustainability of Medical Device Coordination Office (MDCO)

To execute its important tasks and responsibilities, MDCO must be equipped with adequate resources. A sustainable budget for MDCO could be structured through a hybrid funding model, combining contributions by stakeholders and contributions paid from EU budget. This approach would ensure long-term financial stability.

Stakeholder contributions could be collected through modest fees associated with activities in EUDAMED. This model appears to offer a proportionate reflection of the benefit from the support by MDCO.

Additional fees could also be introduced for specific services such as early advice for manufacturers and the designation / audits of notified bodies. If designation of notified bodies would be coordinated via MDCO, national fees to notified bodies could be abolished.

2. Special Pathways and Early Advice

2.1 Introduction

Notified bodies support the establishment of a special pathway to assist devices that face disproportionate challenges under current MDR/IVDR - such as those intended for special populations (paediatric, orphan) or breakthrough innovations. However, such pathways must not be implemented solely between manufacturers and individual notified bodies, as this could lead to inconsistencies and regulatory uncertainty. Instead, a coordinated process with clear guidance and oversight is essential.

2.2 Regulatory Framework for Special Pathways

A new **Annex "Special Pathways"** will be added to MDR/IVDR, defining:

- Eligibility criteria for devices allowed to follow the "Special Pathways" route.
- Minimum data requirements, acknowledging that pre-market data collection as required by MDR/IVDR may not be feasible.
- Optionally, criteria and datasets may be tailored per device group (e.g. orphan, paediatric, breakthrough).
- Alternatively, this new section could be added to MDR **Annex XIV (Clinical Evaluation)** and IVDR **Annex XIII (Performance Evaluation)**.

A **Special Pathways Working Group**, coordinated and supported by the **MDCO**, shall be established. The Working Group shall be composed of national authority experts. The Working Group shall establish its rules of procedure.

2.3 Pre-Certification Special Pathway

1. **Eligibility Identification**: Manufacturers apply for "Special Pathway Status" with a notified body, based on the eligibility criteria stipulated in the MDR/IVDR new Annex "Special Pathways". Notified bodies check if the eligibility criteria are met and inform the Medical Device Coordination Office (MDCO) of an upcoming "Special Pathway" procedure.
   MDCO establishes an ad-hoc group of experts that will review the precertification report of the notified body.
   Any dispute between the notified body and the manufacturer whether the eligibility criteria are met, will be referred for decision to the ad hoc group of experts of the "Special Pathways Working Group".
2. **Initial Review by the notified body**: The notified body assesses the data and documentation provided by the manufacturer.
3. **Pre-Certification Report**: The notified body drafts a report, identifying evidence gaps and recommending how these could be addressed post-market (e.g. PMCF, PMPF).
4. **Special Pathways Working Group Review**: The Special Pathways ad-hoc group reviews the pre-certification report, may amend the recommendations for post-

market data collection, including the timeframe in which the manufacturer needs to complete the post-market obligations.
The Special Pathways ad-hoc group may consult the relevant expert group, the notified body, the manufacturer or any combination of these.

5. **Special Pathways Working Group Decision**: The Special Pathways Working Group issues a positive, negative, or conditional opinion.
6. **Notified body Action**: The notified body acts on the MDCO's decision (e.g. issues a certificate with post-market conditions or rejects the application).

2.4 Early Advice Pathway

A similar pathway via the **Special Pathways Working Group** could be utilised for manufacturers wishing **early advice** meetings with a notified body. In this case, the ad-hoc group reviews the draft early advice report of the notified body and may make amendments. In this way, the early advice activities of the notified body are supervised by experts on behalf of the national competent authorities.
This early advice would be different to structured dialogue and would focus on (clinical) data generation.

2.5 Follow-up and Regulatory Learning

The Special Pathways Working Group, supported by MDCO, gathers valuable insights from early-stage development devices. If these insights have broader relevance and could lead to regulatory learning, they may trigger New Work Item Proposals (NWIPs) for guidance documents via MDCG or NBCG-Med. Once such a guidance document is published, affected devices no longer qualify for the Special Pathway route.

2.6 Confidentiality

All information submitted and exchanged during the Special Pathway or Early Advice procedure is treated as strictly confidential. This includes manufacturer data, notified body assessments, and Special Pathways Working Group deliberations. Disclosure is limited to involved parties and governed by applicable EU confidentiality and data protection rules.

3. Structured overview of sources for scientific and clinical data

MDR/IVDR Annex VII Section 4.10, 2nd bullet, requires notified bodies to maintain procedures for screening scientific and clinical data. The implementation of this requirement varies depending on each notified bodies' scope.

A centralized, MDCO-maintained repository of relevant sources would simplify compliance, promote consistency, and support proportionality. It would also benefit expert panels and manufacturers by providing a shared, reliable foundation for evidence-based assessments.