

Proposals for the Simplification of the EU Medical Device Regulations (MDR/IVDR)

Background

The current Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR) have resulted in a significant increase in complexity, cost, and unpredictability of regulatory processes for medical devices in the EU. This has weakened Europe's competitiveness and delayed innovation, particularly for small and medium-sized enterprises and in priority areas such as pediatrics.

The following concrete proposals aim to strengthen predictability, cost-efficiency, and competitiveness while maintaining high safety standards for patients.

1. Cost Burden

Problem:

The cost of an MDR conformity assessment via a notified body is significantly higher than the equivalent U.S. FDA 510(k) process. In the U.S., SME:s and priority areas such as pediatrics benefit from reduced or waived fees. No such relief exists in the EU, creating structural disadvantages for SME:s and innovators active in rare or specialized fields.

Proposal:

- Introduce **subsidized regulatory processes for SME:s**, with differentiated or reduced fees.
- Establish **fee exemptions for priority areas** in line with the EU Life Science Strategy, including pediatrics, rare diseases, and sustainable health technologies.
- Attract international investment by creating an advantageous market to operate in, enhance market comparability, and strengthen predictability in terms of costs.

Expected impact:

Lower entry barriers for all companies and priority areas, strengthening innovation, competitiveness, and diversity in the EU medtech sector. Creates an equal market opportunity in Europe for innovation, more balanced with the U.S. market opportunity.

The national life science strategy emphasises that conditions for SMEs to establish, develop and grow in Sweden need to be strengthened, as retaining such companies is a critical competitive advantage for the research and innovation ecosystem. By reducing regulatory cost barriers for SMEs and priority areas, this proposal directly supports

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objective 8.2 of the strategy and would aid in creating the proportionate regulatory framework the Government envisions, which in turn would encourage increased direct investments in Sweden, thus creating opportunities for greater benefits for patients.

2. Timelines for the Approval Process

Problem:

Notified bodies hold disproportionate influence over timelines and costs. Companies are often forced to accept costly “expedited review” options to secure predictable timelines, creating inequality and discouraging innovation. Both new product launches and continued availability of existing devices are at risk in the EU.

Proposal:

- Introduce **fixed and legally mandated review timelines**, for example a 90-day maximum response time as used by the FDA.
- **Regulate or prohibit “accelerated review” schemes** based on additional fees to ensure fair treatment.
- Ensure **transparency in pricing and review timelines** across all notified bodies.
- Actively facilitate, from a regulatory perspective, the introduction of new innovations to the European market, ensuring it is more accessible compared to other regions.

Expected impact:

Creates predictability, fairness, and efficiency in the conformity assessment process, preventing unequal treatment and supporting timely patient access to new technologies.

The Government has identified the medical technology area as particularly important and recognised the need to support companies in meeting regulatory requirements. Predictable timelines are fundamental to enabling companies, particularly SMEs, to plan investments and bring innovations to market. This proposal supports objectives 5.1 (medical technology development) and 8.2 (creating framework conditions that facilitate rather than hinder business operations) of the national life sciences strategy.

3. Efficient Dialogue with Notified Bodies

Problem:

The absence of structured pre-submission dialogue leads to uncertainty regarding expectations, clinical data, and documentation requirements, increasing costs and delays.

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Proposal:

- Introduce a **pre-submission process** between companies and notified bodies, mirroring the FDA “Pre-Submission” model.

Expected impact:

Improves clarity, reduces rework, and allows earlier alignment between companies and regulators, ensuring more predictable and efficient development pathways.

The national life sciences strategy explicitly calls for early stakeholder dialogue to support companies in meeting regulatory requirements. This proposal operationalises that vision by creating structured pre-submission processes between manufacturers and notified bodies, reducing uncertainty and accelerating time to market. Importantly, such dialogue would enable both companies and notified bodies to streamline their processes, requiring fewer resources from all parties, a win-win that increases efficiency across the entire regulatory ecosystem. This proposal directly supports objectives 5.1 (development and implementation of new medical technology) and 3.3 (ensuring regulatory and technological developments remain in alignment).

4. Evidence Requirements and Proportionality

Problem:

The Qualified Authorities (MDR’s) evidence requirements for prototype device are often disproportionate to the product’s risk, creating excessive cost and administrative burden. Risk assessed prototype devices face challenges to be approved for clinical pilots and feasibility which delays early technical evaluation in a clinical environment.

Proposal:

- Create a **streamlined route for early clinical pilot studies** with simplified regulatory requirements to support innovation and safe exploratory research.
- Clarify and simplify the GSPR list by identifying the most relevant requirements for an early clinical pilot or feasibility pilot study.
- Ensure that activities conducted in Europe are compatible with FDA expectations, allowing companies to reuse key documentation and maintain comparable regulatory processes.
- Consider whether “feasibility pilot study” better captures the intended purpose than “early clinical pilot study”.

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Expected impact:

Accelerates responsible innovation, reduces development cost and time, and enables earlier access to clinically valuable technologies for European patients.

The Government's objective is to significantly increase the number of clinical trials in Sweden, recognising that clinical trials are crucial for enabling early access to new treatments and advancing knowledge in healthcare. By creating a streamlined pathway for early feasibility studies with proportionate evidence requirements, this proposal makes Sweden and the EU more attractive for early-stage clinical innovation, which directly contributes to patient benefit. This proposal supports objectives 4.1 (more high-quality clinical trials) and 3.3 (regulatory frameworks that promote dynamic development).

5. Evaluator Expertise and Independence – Avoiding a Catch-22 for Innovation

Problem:

Under MDR/IVDR, notified bodies must use personnel with “relevant knowledge, experience, and competence” while ensuring independence. Although no fixed number of years of experience is required, in practice this creates a **catch-22** for breakthrough technologies: the limited pool of true experts often includes individuals with prior collaboration in the field, making them ineligible under current independence interpretations. This delays reviews and limits EU capacity for novel technologies and rare specialties.

Proposal:

- **Clarify competence criteria** to include documented training, adjacent-domain expertise, and structured casework, not only long tenure in the same technology area.
- Establish an **EU Innovation Reviewer Pool** allowing notified bodies to access vetted independent experts under transparent conflict-of-interest rules.
- Permit **managed independence**, allowing experts with prior non-design exposure to participate under disclosure and dual-review oversight.
- Require **transparency in evaluator competence and independence criteria** published by all notified bodies.

Expected impact:

Ensures access to qualified and independent expertise for innovative technologies, removes hidden barriers based on “years-in-niche” experience, and strengthens Europe’s capacity to evaluate and approve cutting-edge medical devices efficiently.

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The national strategy welcomes development and implementation of groundbreaking technologies in clinical research and care delivery. However, evaluating truly innovative technologies requires access to qualified, independent expertise. Ensuring good options for certifying new products through notified bodies is essential infrastructure for innovation. This proposal addresses a critical bottleneck and directly enables objective 5.2 (development and implementation of groundbreaking technologies).

6. Clarifying regulations handling In-House Manufacturing in Healthcare – Ensuring Fair Competition and Legal Clarity

Problem:

Advances in technologies such as 3D printing have enabled hospitals to produce patient-specific medical devices directly within healthcare facilities. While this supports innovation and individualized care, it takes place in a regulatory grey zone under the MDR and IVDR “in-house manufacturing” provisions. Key terms, such as what constitutes an “equivalent device,” are ambiguously defined, leading to inconsistent national interpretations. This creates uncertainty regarding what hospitals are permitted to manufacture and under what conditions.

Commercial manufacturers, who must meet full conformity assessment and post-market requirements, face unfair competition from hospital-produced devices that are not subject to equivalent regulatory scrutiny. This not only distorts competition but may also undermine patient safety and reduce incentives for industrial innovation.

Proposal:

- Clarify the MDR/IVDR provisions on in-house manufacturing to ensure consistent interpretation across Member States.
- Define “equivalent device”, “legal entity”, and “commercially available alternative” through harmonized EU guidance.
- Establish clear boundaries between legitimate in-house manufacturing for unmet clinical needs and de facto commercial production.

Expected impact:

Creates a level playing field between healthcare institutions and commercial manufacturers and ensures that new technologies like 3D printing can be safely and fairly utilized within healthcare. Promotes legal clarity, innovation, and sustained industrial investment in Europe’s medtech ecosystem.

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The Government's view is that rules governing entrepreneurship should be proportionate, transparent and well-motivated, and that it should be easy for companies to do the right thing and follow the rules. Unclear rules on in-house manufacturing create regulatory uncertainty and potential unfair competitive advantages that particularly disadvantage SMEs who must meet full conformity assessment requirements. Clear, proportionate rules ensure both patient safety and fair competition. This proposal directly supports objective 8.2 (better regulation and framework conditions).

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