Slovak Patients Must Not Lose Access to Modern Medical Technologies

POSITIONING PAPER | AmCham Slovakia

European Medical Devices Regulation Is Under Revision

The **revision of the EU regulatory framework for medical devices and in vitro diagnostic medical devices is already underway**. The European Commission's proposal recognises the key shortcomings of the current MDR/IVDR framework: complex and unpredictable certification, disproportionate administrative burden, pressure on notified body capacity, increased costs, and shortages or withdrawals of certain medical technologies from the European market.

AmCham Slovakia *welcomes the objective of making the system more proportionate, predictable and efficient while maintaining a high level of patient safety. What is needed now is a swift and balanced adoption of the proposal to address these shortcomings without further delaying patient access to safe and innovative technologies.*

This is particularly important for smaller markets such as Slovakia, where lengthy, costly or uncertain procedures may lead manufacturers to prioritise larger countries. **Slovak patients, hospitals and healthcare professionals must not face delayed or limited access to modern diagnostic, therapeutic and digital health technologies due to regulatory inefficiencies.**

Slovakia Needs a Fast and Efficient Adoption of the EU COM Revision Proposal on MDR/ IVDR

Slovakia therefore needs a the newly proposed and improved regulatory environment that preserves a high level of patient safety while enabling faster and more predictable access to innovation. It is necessary to reduce unnecessary administrative burden, support digitalisation and modern regulatory tools, strengthen proportionality and risk-based approaches, and ultimately improve Europe's competitiveness in healthcare technologies.

We therefore support a targeted revision of the MDR/IVDR framework that will streamline certification processes, improve predictability of the system, support the use of real-world evidence, enable greater digitalisation of regulatory processes, strengthen support for breakthrough and orphan technologies, and ensure the long-term sustainability of the regulatory framework.

We particularly support the following measures to reduce administrative duplications:

- **Open-validity certificates with periodic risk-based reviews**: removing fixed five-year recertification cycles eliminates an artificial bottleneck while maintaining ongoing oversight proportionate to the device's risk profile.
- **Risk-based sampling in conformity assessment:** proportionate scrutiny for lower and medium-risk devices removes duplicative procedural steps.
- **Broader recognition of clinical evidence:** explicit recognition of well-established technologies, and acceptance of non-clinical evidence including modelling and simulation.
- **Balanced approach to reprocessing rules:** avoid reversing the burden of proof that would make reuse the default, as this creates disproportionate administrative burden and may undermine

patient safety for devices designed as single use. The framework should instead preserve transparency, clear liability and appropriate safeguards for reprocessing, while reflecting existing evidence gaps on safety identified by the Commission.

- **Labelling and traceability for procedure packs and re-distributors:** ensure notification of manufacturers when label changes are made to maintain oversight, traceability and effective post-market surveillance.
- **In-house device exemptions for health institutions:** ensure balanced conditions by reinstating the "no equivalent device" requirement, limiting the exemption period to 3 years and clarifying scope to protect fair competition and patient safety.
- **Equivalence assessments:** reduce administrative burden by removing contractual requirements, while ensuring robust post-market follow-up, maintaining own clinical data for high-risk implantables and supporting innovation through data exclusivity.

To remain competitive in tomorrow's digital healthcare system, **AmCham Slovakia** seek to strengthen the proposed revision proposal by:

- **Including proportionate AI requirments into MDR/IVDR:** Inclusion of AI requirements into a single MDR/IVDR conformity assessment process is the right approach. To bring legal clarity, a time-bound process to reflect AI Act requirements should be included in the legislation.

Key Concerns to Be Addressed

AmCham Slovakia supports the simplification of the MDR/IVDR framework. However, the reform must deliver real improvements in patient access, certification predictability and innovation.

1. Patient Access and Availability

Slovak patients must not face delayed or limited access to modern medical technologies because of lengthy, costly or unclear regulatory procedures. This risk is particularly serious for smaller markets such as Slovakia, where manufacturers may prioritise larger countries and where startups and academic researchers often have limited funding and scarce human resources. MDR reform is therefore necessary to **ensure that promising innovation from early-stage developers, founders and the academic sector is not unintentionally blocked** by overly complex, costly and slow compliance pathways. Digital solutions, including digital labelling, digital implant cards and electronic instructions for use, should be supported where they improve accessibility, usability and sustainability while maintaining patient safety. Safe and well-established technologies should not be subject to unnecessary repeated evidence requirements.

2. Certification, Costs and Notified Body Capacity

Certification must become faster, clearer and more predictable. As a top priority, **fixed five-year recertification cycles should be removed**, as they create recurrent administrative burden, capacity pressure on notified bodies and uncertainty for manufacturers. Device safety should continue to be ensured through regular notified body audits and post-market surveillance rather than unnecessary repeated evidence requirements for safe and well-established technologies. An **immediate stop-the-clock mechanism for time-limited certificates** should also be introduced until the revised MDR enters into force, in order to prevent a new certification bottleneck. Simplification must not create new administrative layers, unclear timelines or EU-level bottlenecks. **Notified bodies need sufficient capacity, sustainable resources and workable oversight rules.** Higher or unpredictable certification costs may be passed on to healthcare systems and may discourage manufacturers from bringing technologies to smaller markets.

3. Governance, Legal Clarity and Patient Safety

The **roles of the EMA, MDCG, national authorities and expert panels must be clearly defined to avoid duplication, inconsistent interpretation and legal uncertainty.** The simplification proposal preserves

patient safety through a sufficiently robust post-market surveillance framework. However, for AI-enabled and digital technologies the sectoral approach should be reinforced by aligning AI Act requirements with the MDR so that relevant AI obligations are integrated coherently within the existing medical devices framework without duplication.

Patient safety rules and market surveillance safeguards should be maintained. In particular, the **28-days prior notification obligation** under **Article 16** should be preserved to ensure appropriate regulatory oversight and reduce risks, including those linked to parallel trade. At the same time, a 10-year in-house derogation would be disproportionate and could undermine fair market conditions; a shorter **maximum duration**, such as **3 years**, would be more appropriate.

For Slovakia, the MDR/IVDR revision is not only a regulatory reform. It is a patient access issue. As a smaller market, **Slovakia is particularly vulnerable to delayed certification, higher costs and limited manufacturer prioritisation.** If the revised framework does not deliver faster, clearer and more predictable procedures, Slovak patients may wait longer for modern diagnostic, therapeutic and digital medical technologies. **Slovak patients should not lose access to innovation because the regulatory system remains too slow, too complex or too costly**

4. Article 17 – Reprocessing of Single-Use Devices

AmCham Slovakia considers it important that any revision of **Article 17 MDR** preserves the current balanced framework for the reprocessing of **single-use medical devices**. Under the existing rules, Member States may decide whether reprocessing is permitted within their healthcare systems, while the entity that reprocesses the device assumes full regulatory responsibility as manufacturer, including traceability, risk management and safety obligations. This allocation of responsibility is important for patient safety and legal certainty, because accountability remains with the actor that decides to reprocess and place the reprocessed device into use.

AmCham Slovakia does not support changes that would effectively presume that single-use devices are reprocessable by default or shift the burden onto original manufacturers to justify single-use designation. Such an approach would introduce new administrative and technical documentation burdens without demonstrated cross-category evidence of safety, environmental or economic benefit across all device types. Reprocessing is primarily a healthcare system decision that depends on national organization, hospital capabilities and economic conditions, rather than a product-intrinsic issue that can be uniformly redefined at EU level.

Any **revision** of **Article 17 should** therefore f**ocus on** maintaining clear accountability, patient safety and regulatory consistency, while avoiding unnecessary new burdens for manufacturers and preserving Member State flexibility in this area.

Media contact:
Dominika Komárová, American Chamber of Commerce in the Slovak Republic, dominika.komarova@amcham.sk, +421 947 939 030

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