Implementing the Medical Devices Regulation (MDR)

An urgent call on EU institutions to make the MDR work

April 2022

The combination of ageing populations, the rise of chronic diseases, and the ongoing COVID-19 pandemic increasingly strain healthcare systems. Medical devices are indispensable in all areas of healthcare and hence, the continuity and fair access to the existing and new innovative medical devices is critical to meet the industry's healthcare commitment to patients in Europe.

The medical technology industry firmly believes that a robust and predictable regulatory framework is essential to ensure the availability of safe and innovative technologies in the European Union (EU) and beyond. For manufacturers to meet their duty to patients, healthcare professionals and healthcare systems, it is more critical than ever that bold, EU-level action be taken to address the ongoing Medical Devices Regulation (MDR) implementation hurdles.

The medical technology industry therefore *urgently* calls on the EU institutions to put concrete solutions in place *as soon as possible* prior to the end of the 'transition period' on 26 May 2024 to address these roadblocks. Industry fears that without immediate action, the continued availability of much-needed medical devices is threatened, which endangers healthcare delivery to patients both in Europe and around the world.

State of Play

On 26 May 2021, the MDR came into full application. The medical technology industry has always supported the MDR's goals, and manufacturers have intensively been working to transition to the new regulatory system's strengthened rules and offered support to make the system work. However, despite intensive efforts, the new system itself is still not functioning in a way that is predictable or sustainable for all.

The medical technology industry remains seriously held back by the late and incomplete implementation progress in several critical areas of establishing the new system and accompanying processes. The collective effect of this continues to create lengthy and unpredictable conformity assessment timelines for Notified Bodies. Many manufacturers also face resource challenges, especially the sector's many small and medium enterprises (SMEs). Furthermore, the ongoing COVID-19 pandemic has exacerbated this situation by creating supply chain disruptions, issues with conducting on-site audits and with clinical investigations.

Major challenges

1. **Severely insufficient Notified Body capacity.** Although Notified Body capacity continues to increase incrementally, it remains insufficient to conduct all MDR work needing to be completed by 26 May 2024. As of Q3 2021, these Notified Bodies were overseeing more than 25,000 CE certificates issued under the old Directives. The vast majority of them will expire in the January-May 2024 period and need to be fully replaced by MDR certificates before 26 May 2024 for the related devices to remain available on the market. Nevertheless, as of September 2021[1] only about 502 MDR certificates have been issued. Notified Bodies foresee "*inevitable extreme certification bottlenecks",* which *"will most probably prevent high number of devices currently certified under Directives from timely transition by 26 May 2024[2]"*.

2. **Challenges affecting existing ('legacy') devices.** Medical Devices with long track records of safety and performance continue to experience major challenges in transitioning to the MDR because of, for example, strengthened clinical evidence requirements that are not straightforward to meet in practice.

3. **Innovation backlog in Europe.** MDR-designated Notified Bodies lack the spare capacity needed to evaluate files for new products at the required speed. This is creating an innovation backlog, which puts the fate of SMEs in jeopardy and poses a risk that European patients experience delayed access to innovative care as compared to patients elsewhere in the world[3].

4. **Guidance documents whose impacts are insufficiently assessed.** Guidance documents from regulators do not consistently consider stakeholder involvement and input in the drafting process and are being applied without practical or transparent transition timelines (or implementation plans). New guidance may come belated, may invalidate past regulatory decisions, and may jeopardize already achieved MDR certifications. For some, the content is even seen as going beyond the boundaries of the MDR legal text.

5. **Lack of harmonised rules.** Various MDR provisions are still not applied and/or interpreted consistently across EU Member States and Notified Bodies, creating an uneven playing field for stakeholders. As with all EU Regulations, consistent interpretation and enforcement of the new rules are needed.

Proposed solutions to make the MDR work and ensure continued patient care

The medical technology industry sees value in exploring a range of possible solutions, *including but not limited to:*

- **Adopting more pragmatic clinical evidence expectations**, for example, by accepting robust and objective historical and/or post-market clinical data and reconsidering the requirements allowing the use of data collected with the equivalence principle.

- **Adjusting aspects of the conformity assessment procedures**, for example, by allowing Notified Bodies to adopt a conditional certification approach, and fully allow the use of remote audits.

[1] Notified Body Survey, September 2021
[2] Team NB, *Notified Body position paper on MDR/IVDR Implementation*, December 2021
[3] Boston Consulting Group, *For Cutting-Edge Innovations, the US Pulls Ahead of the EU in Medtech Regulation*, March 2022

- **Better allocation of resources at Notified Body level, refocusing on non-administrative tasks**, e.g., dropping scope-extension audits for known manufacturers, avoiding repeated reviews of the same legacy devices when reviewing non-significant changes.

- **Granting manufacturers early dialogue opportunities** before they file for MDR certification of new/innovative devices.

- **Ensuring equal access to Notified Bodies for manufacturers**, and/or communicating clear emergency pathways for manufacturers who are prevented from accessing any Notified Body.

- **Giving more time for the above solutions to be implemented and for the system to be ready**, e.g., by extending the 26 May 2024 deadline and/or the validity of Directive certificates and/or deleting the 26 May 2025 end date for the "selling off" of Directive devices already placed on the market.

Conclusion

The medical technology industry urges the EU institutions to rapidly start discussing, scenario-planning and impact-assessing actions to make the MDR work. We stand ready to collaborate and discuss solutions that address the many complex challenges. Solutions are needed now to support the integrity of healthcare systems in Europe and to safeguard access to needed medical devices.