Is the new Medical Device Regulation (MDR) killing the innovation

The EU, once a world leader in medical innovation, now faces tremendous challenges in implementing the new Medical Device Regulation (MDR).
This framework, supposed to improve safety and transparency, has become a major hurdle for companies in the sector, holding back innovation and considerably increasing development costs.
Perceived as bureaucratic and costly, the MDR has imposed an additional burden on 80% of companies, who have been forced to hire additional staff or redirect resources from research and development (R&D). This has resulted in an average 20% reduction in available product portfolios, 28% higher development costs, and an average 8% increase in device prices - which is probably just the tip of the iceberg[1]. These alarming trends illustrate how well-intentioned regulation is, paradoxically, hindering both rapid access to care and technological advancement.

Meanwhile, the United States is positioning itself as a growth haven for companies in the sector. With faster, less complex certification processes, the FDA is attracting more and more innovations to their first stage on the market[2]. Almost 20% of Swiss companies now prefer to launch their devices in the USA first, while 30% certify their products on both continents, despite much longer lead times in Europe. This trend highlights a lag in product availability that threatens to undermine Europe's attractiveness as a market for medical technologies.
Another pernicious effect of MDR could be its disproportionate impact on patients living in peripheral regions or with limited resources. As a result of the increased costs and constraints imposed on manufacturers, they could concentrate on certain markets only, and abandon others that are less buoyant, which could restrict choice on the one hand, but also limit chronic patients' access to devices they use on a daily basis.
While manufacturers appear to be fairly well informed about the challenges of introducing MDR, the same cannot always be said of patients and healthcare providers.

Faced with this situation, Switzerland offers a glimmer of hope. By allowing FDA-certified devices on its territory, as proposed by Swiss Medtech, the country is strategically positioned to avoid the pitfalls of European regulation. Such a measure would not only guarantee faster access to care for Swiss patients, but would also enhance the country's attractiveness to international players.
However, the success of this strategy depends on swift and pragmatic implementation. Swiss authorities must act decisively to prevent bureaucratic inefficiencies that could undermine the initiative, as emphasized by Damian Müller, President of Swiss Medtech. If excessive red tape is allowed to creep in, the proposal risks becoming a mere “paper tiger”—a lost opportunity in a rapidly evolving industry.

In conclusion, Europe needs to reassess the implementation of the MDR to ensure that it does not sacrifice innovation on the altar of regulation. Switzerland's adoption of a more agile strategy, inspired by the US model, should serve as an example for rethinking the balance between safety and efficiency. The future of patient care and the competitiveness of the sector in Europe are at stake.

[1] Swiss Medical Technology Industry Sector Study 2024
[2] Rosapeak Advisors analysis, US Classification based on 21 CFR Part 866, sub Chapter Medical devices