

# Between aspiration and reality



With the Medical Devices Regulation (MDR), the European Union wanted to send a strong signal: greater patient safety, greater transparency, greater oversight. A noble goal that no one in the industry would question. Yet a gap has opened up between political aspirations and practical implementation, one that is becoming ever wider for manufacturers, hospitals, doctors and dentists, and ultimately for patients as well.

Since it came into force, the MDR has revealed a downside that was long underestimated in Brussels. The costs of recertification are rising massively, the documentation requirements are growing beyond measure, and the administrative burden is tying up resources that should actually be channelled into research, development and patient care. The situation is particularly dire for notified bodies: too few, too slow, too overburdened. Even established products that have been in safe use for decades must undergo lengthy procedures once again—a process that is not only expensive but also risky.

For when certificates expire, products disappear from the market. And that is exactly what is already happening. The MDR is leading to a paradoxical situation: it is precisely those medical devices that have been functioning reliably for years that are no longer being manufactured because recertification is no longer economically viable.

For large corporations, this is annoying but manageable. For medium-sized manufacturers—the backbone of the European medtech sector—this poses an existential threat. Many of them face the choice of scaling back their product range, postponing innovation, or leaving the European market altogether. Some have already done so. As a result, Europe risks losing the innovative strength that has made it a global pioneer for decades.

The MDR was intended to build trust. Yet it threatens to achieve the opposite: start-ups are being put off by the regulatory complexity, medium-sized companies are struggling to survive, and

hospitals are reporting supply shortages. Innovation does not flourish within the straitjacket of excessive bureaucracy, but in an environment that enables both safety and progress in equal measure. It is precisely this balance that has been thrown off course. The European Commission has now recognised that the MDR, in its current form, is not fit for the future. The announced review is long overdue. In this issue, lawyers Ratajczak and Gassner analyse the current situation and the European Commission's proposals, which have been available since mid-December. "The European Commission is pulling—at least by the standards of Brussels bureaucracy—something of an emergency brake on the Medical Devices Regulation," reads the introduction to the article. The commission cites as its objectives the simplification of the regulations and the reduction of the administrative burden, as well as the improvement of the certification process, promote innovation and competitiveness within the EU medical device industry and ensure the availability of safe and innovative products.

But an evaluation alone is not enough. It must incorporate the views of manufacturers, notified bodies, hospitals and patients. The relevant bodies at EU level must have the courage to make structural changes, rather than merely tweaking individual parameters. The question is not whether we need regulation. The question is how much regulation an innovation-driven health-care system can withstand without suffering damage. If Europe wishes to retain its role as a hub for medtech innovation, the MDR must be reformed—streamlined, accelerated and made fit for purpose. The evaluation offers an opportunity to do so.

Anita Wuttke  
Editor-in-Chief