International Diabetes Federation Europe

IDF Europe's Response to the Targeted Revision of the EU rules for Medical Devices and In vitro Diagnostics

Medical devices have become an essential component of diabetes management. Yet, despite their increasing availability, **many of the 34 million people living with diabetes in the EU do not achieve their treatment targets.** This highlights the need to foster more innovation and facilitate the introduction of new devices that better meet people's needs.

We strongly support the initiative's objective to reduce the administrative burden and enhance predictability and cost-efficiency **while preserving a high level of public health and patient safety**. These goals are particularly critical given reported performance issues with some CE-marked devices. **It is, therefore, imperative that the CE-marking process is robust enough** to lower the risk of dangerous devices making it to market. While post-marketing surveillance data provides valuable data on device performance and safety, it cannot replace rigorous pre-market assessment. We, therefore, recommend **strengthening EU-wide oversight and requirements for all medium to high-risk devices through:**

- Expanding the role of the EMA, leveraging its scientific expertise to enhance oversight of pre-market approvals and post-market surveillance for thorough and consistent clinical evidence evaluation
- Developing uniform, EU-wide standards for Notified Bodies (NBs) to reduce variability in the quality of conformity assessments. Clearer frameworks and minimum requirements for assessing required clinical evaluation and investigation standards would ensure that safety, effectiveness and real-world performance are rigorously evaluated, while simplifying processes and improving predictability. This would also include the development of common study design approaches.
- Addressing resource gaps by increasing funding and training for NBs

These measures should be complemented by:

- **clear mechanisms for reporting post-marketing safety and effectiveness issues**
- **robust guidelines** on communication, corrective actions and follow-up of these issues
- **improved awareness and training of healthcare professionals (HCPs) and citizens** on reporting safety and effectiveness issues

As innovation quickens, robust mechanisms are required to identify devices' real value, enhance trust in medical devices among citizens, HCPs and policymakers, and support informed decision-making. We therefore recommend increasing transparency for CE-marked devices (class IIb and above) by:

- Mandatory disclosure of all submitted clinical evidence and performance data
- Easy and clear access to this data to help citizens and clinicians make informed decisions about device use
- Publication of real-world performance data from post-market surveillance, with continuous updates on device safety and efficacy

This approach should be complemented by increasing involvement of people with lived experience in device assessment and, generally, embedding their voice in regulatory governance.

We also welcome the aim to support innovation and thus increase the availability of medical devices to patients. To this effect, we suggest creating an Innovation Pathway for transformative devices. This would expedite approval of breakthrough devices addressing significant unmet needs or offering transformative health benefits. This pathway should balance the need for speed with rigorous safety and efficacy evaluations; tailor requirements for devices serving small or underserved populations to facilitate timely market access without compromising safety; and provide technical guidance and support for manufacturers (including SMEs) to encourage investment in critical healthcare technologies.

In conclusion, we support the initiative's goal of reducing the administrative burden and enhancing predictability and cost-efficiency. However, efficiency and speed must not compromise safety and effectiveness. We, therefore, strongly urge the Commission to strengthen governance and assessment processes, with greater engagement of people with lived experience.