Published on *The National Law Review* https://natlawreview.com

MedTech Europe Proposes Comprehensive Medical Device Regulatory Reforms

Article By:

Michael Zogby

MedTech Europe has issued a position paper calling for comprehensive medical device regulatory reforms to benefit patients and European health systems.

Over 6.5 years since the third implementation, the In Vitro Diagnostic Medical Devices Regulation 2017/746/EU (IVDR) and Medical Devices Regulation 2017/745/EU (MDR) were intended to establish a “robust, transparent, predictable and sustainable regulatory framework for [in vitro diagnostic] medical devices which ensures a high level of safety and health whilst supporting innovation.” This goal, however, has not been accomplished.

MedTech Europe's position paper presents challenges that medical technologies face under the European regulatory framework, and proposes reforms that fall within three categories:

- **An Efficient CE Marking System**: MedTech Europe requests "a more efficient and resource-effective CE marking system that improves predictability, reduces administrative burden, and adapts to external changes."
- **A System That Works for Innovation**: The organization proposes "the inclusion of an innovation principle that swiftly connects the latest medical technologies to European patients and health systems through dedicated assessment pathways and early dialogues with developers."
- **An Accountable Governance Structure**: Additionally, MedTech Europe suggests "the establishment of a single, dedicated structure to oversee and manage the regulatory system, including the designation and oversight of Notified Bodies, with the authority to make system-level decisions."

These proposed reforms focus on the development of "a robust, transparent, predictable and sustainable regulatory framework that ensures a high level of safety and health while supporting innovation, for the benefit of European patients, health systems and society."

Of the 35,000 medical technology companies in Europe, 92 percent are small and medium-sized enterprises (SMEs), and those entities provide approximately 500,000 medical technologies to European patients. The position paper discusses the range of innovation, which is "the result of continued research and development investment by the industry (the average is estimated to be around 8 percent) in close cooperation with healthcare professionals,

patients, and health systems to identify unmet needs."

MedTech Europe emphasizes that "[m]edical technologies form an integral part of healthcare systems and are crucial for prevention, diagnosis, treatment, and cure." Accordingly, if those "medical technologies do not reach health systems in a timely manner, [then] patients pay the highest price. It is therefore crucial that the framework regulating access of medical technologies to European health systems is fit-for-purpose."

As a European trade association for the medical technology industry, including diagnostics, medical devices, and digital health, MedTech Europe's members are national, European, and multinational companies, as well as a network of national medical technology associations that research, develop, manufacture, distribute, and supply health-related technologies, services, and solutions.

www.medtecheurope.org/...

Source URL:https://natlawreview.com/article/medtech-europe-proposes-comprehensive-medical-device-regulatory-reforms