

Revision of the EU Medical Devices Regulation (MDR)

Less regulation

As part of the EU health package, the European Commission is finally proposing a revision of Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR). The aim of the amendments is to remedy existing enforcement and application deficits in the MDR that have arisen from the high regulatory complexity and the associated administrative burdens.

In particular, the aim is to simplify the conformity assessment and approval procedures for medical devices in low and medium risk classes in order to ensure the functioning of the internal market and accelerate market access.

Another key component of the reform is to strengthen EU-wide coordination through closer cooperation between the competent national authorities and the European Medicines Agency (EMA).

Protecting patient safety is a priority

Further harmonisation of procedural requirements and evaluation criteria is intended to reduce divergent enforcement



practices and increase legal clarity and predictability for economic operators. Notwithstanding the planned simplifications, protecting patient safety remains the guiding principle; To this end, market surveillance is to be strengthened and more precise requirements for post-market surveillance and risk management are to be introduced.

Relief for small and medium-sized enterprises

In addition, the revision takes technical progress into account by making the regulatory framework for innovative medical devices, in particular for digital and AI-based applications, more flexible without compromising safety and performance. A special focus is placed on reducing the burden on small and medium-sized enterprises (SMEs) by eliminating disproportionate administrative requirements. Accompanying adjustments to the IVDR are planned in order to streamline approval procedures in the field of *in vitro* diagnostics and improve the availability of diagnostic products throughout the EU.

Assessment

The EU health package combines preventive approaches with innovation and industrial policy measures and responds to structural deficits in the regulatory framework of the MDR. This sets the tone for the health policy agenda in the coming months. The proposals mark the beginning of legislative deliberations in the European Parliament and the Council, which are expected to take at least a year. From the perspective of the dental profession, the announced revision of the Medical Device Regulation (MDR) is particularly welcome. This is in line with a long-standing and repeatedly voiced demand by the CED and the BZÄK, as the previous regulations have led to considerable burdens and supply risks in practice. The MDR revision and the planned Biotech Act also appear to be capable of gaining majority support and are likely to progress relatively quickly through the legislative process.

On the other hand, it is critical to question the fact that, despite the declared preventive aim, the cardiovascular plan does not address any binding fiscal measures to reduce sugar consumption. This had been repeatedly called for by the CED and other patient associations and could have contributed to caries prevention and the containment of non-communicable diseases.

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BDIZ EDI welcomes progress on the MDR

For years, the BDIZ EDI has been campaigning to make the EU Medical Device Regulation (MDR) more practical. Its demands focus on significantly longer transition periods, more functional notified bodies, and realistic implementation of the MDR requirements. For this reason, the association welcomes the European Commission's efforts to revise the regulation.