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Policy Brief

Strengthening the implementation of the Regulation on medical devices and the Regulation on in vitro diagnostic medical devices in Romania

JANUARY 2026

Strengthening the implementation of the Medical Devices Regulation and the In Vitro Diagnostic Medical Devices Regulation in Romania

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Executive summary

The implementation of the European Union Regulation on medical devices and the European Union Regulation on in vitro diagnostic medical devices represents one of the most extensive regulatory reforms in the field of health at European level. This policy brief analyzes the main obstacles and opportunities associated with the application of these regulations in Romania, based on the results of a questionnaire administered to 1,685 respondents, relevant actors from industry, research, hospitals, and the regulatory field, both nationally and internationally. The analysis highlights a central problem: the significant difference between the ambitious objectives of the new regulations and the existing institutional, technical, and financial capacity in Romania. The lack of a national notified body, the shortage of specialized expertise, the complexity of compliance requirements, the high costs for small and medium-sized enterprises, and the absence of clear support mechanisms and institutional dialogue are identified as the main barriers. These difficulties pose real risks to patients' access to essential medical devices, to the competitiveness of the local industry, and to the efficient use of European funds.

BEHEALTH International Hybrid Event in Healthcare 8th Edition

Co-funded by the European Union

At the same time, respondents highlight the long-term benefits of the new regulations:

- **increasing patient safety,**
- **improving device quality,**
- **increasing market transparency,**
- **strengthening public confidence.**

The document points out that Romania can transform compliance from an administrative burden into a factor for development through strategic investments in institutional capacity, digitization, professional training, and the intelligent use of European health and research programs. The general recommendation is to adopt a coordinated, medium-term approach that combines legislative reforms, support infrastructure, and financial mechanisms dedicated to industry and the health system.

Introduction

The European Union regulations on medical devices and in vitro diagnostic medical devices were introduced to correct the shortcomings of the previous regulatory framework, placing emphasis on patient safety, robust clinical evidence, and post-market surveillance of devices.

Although these regulations are directly applicable in all Member States, their impact is deeply influenced by national implementation capacity, the level of preparedness of the actors involved, and the existence of institutional support mechanisms.[1]

In Romania, the implementation of the new regulations represents a major public policy challenge, with direct implications for the healthcare system, the medical device industry, research, and innovation. Compliance difficulties particularly affect small and medium-sized enterprises, hospitals, and niche device manufacturers, increasing the risk of essential products being withdrawn from the market and limiting patients' access to safe and innovative medical technologies.

The main objective of this policy brief is to summarize the perceptions and experiences of relevant actors regarding the implementation of regulations and to formulate public policy recommendations for the period 2026–2028.

The main recommendations presented in this document are the result of working sessions and panel discussions held during the BEHEALTH 2025 event, organized by RoHealth – the Health and Bioeconomy Cluster, supplemented by the analysis of responses to the questionnaire on the implementation of European regulations, completed by 1,685 respondents. The target audience includes policy makers, health authorities, medical universities, and European organizations.

Context. Presentation of the problem

At the European Union level, new regulations on medical devices[2] have introduced much stricter requirements regarding clinical evaluation, technical documentation, traceability, and

post-market surveillance. Although these requirements aim to protect patients, they have created a structural imbalance between the volume of certification requests and the capacity of the institutions responsible for assessing compliance.

In Romania, these difficulties are exacerbated by specific national factors. The results of the questionnaire indicate the absence of a national notified body, which forces manufacturers to resort to bodies in other Member States, with high costs and very long assessment times. At the same time, the competent national authority is perceived as having limited resources, both in terms of the number of specialists and its ability to provide consistent and predictable guidance.

The national legislative framework is considered insufficiently clear, and the lack of practical guidelines adapted to the local context[3] leads to inconsistent interpretations of compliance obligations. Furthermore, the national digital infrastructure is not fully interoperable with the European database for medical devices, which hinders reporting and surveillance.

The impact on the industry is significant, particularly for small and medium-sized enterprises and innovative start-ups in areas such as medical software and artificial intelligence. The costs generated by clinical trials, performance evaluations, and recertification often exceed the financial capacity of these players, leading to the withdrawal of niche devices from the market.

Analysis and discussion of results

Analysis of the questionnaire responses shows that implementation difficulties are not perceived as temporary problems, but as structural vulnerabilities of the national regulatory system. The lack of institutional capacity and support infrastructure causes significant delays, additional costs, and uncertainty, with direct effects on patient access to medical technologies.

A key issue is the lack of notified bodies. The fact that Romania does not have such a body creates dependence on external structures, reduces the competitiveness of local manufacturers, and discourages investment. At the same time, the extensive clinical evidence requirements are perceived as disproportionate for low-volume devices and manufacturers with limited resources.

At the same time, respondents acknowledge the systemic benefits of the new regulations. Standardization of requirements, increased scientific rigor, and strengthened post-market surveillance are considered essential for improving the quality and safety of medical devices. However, these benefits can only be realized in the presence of public policies that effectively support implementation.

Examples from other Member States show that effective solutions include national competence centers[4], early-stage advisory services for innovators[5], public-private partnerships[6], and the use of European funds to develop testing and training capacities[7].

In the absence of such mechanisms, the new regulations risk exacerbating market fragmentation and inequalities between Member States.

Implications and public policy recommendations

Maintaining the current situation regarding the implementation of European regulations for medical devices may have significant consequences for the healthcare system and the economy.

In the absence of corrective measures, there is a risk of reduced patient access to safe and effective medical devices, withdrawal of essential devices from the market, particularly in niche segments, and a decline in the economic competitiveness of local manufacturers.

Furthermore, inefficient use of European funds allocated to health and research may limit Romania's ability to develop the infrastructure and expertise necessary to comply with European requirements. In contrast, a strategic and coordinated approach to implementation can transform compliance into a driver of economic and institutional development, contributing to the modernization of the health system and the strengthening of the national innovation ecosystem. To achieve this objective, it is necessary to strengthen the legislative and institutional framework by clarifying national legislation and harmonizing it with European requirements, as well as by establishing mechanisms for structured dialogue between authorities, industry, and hospitals to ensure consistent and predictable interpretations.

At the same time, developing skills and human resources must become a priority, by creating national training programs in the field of medical device regulation and by investing in the retention and motivation of specialists in the public sector.

It is also essential to accelerate investment in infrastructure and digitization, including the development of a digital infrastructure that is interoperable with European reporting and traceability systems, and to support clinical centers and testing laboratories in generating evidence that complies with regulatory requirements.

Financial support for industry and hospitals must be ensured by introducing mechanisms dedicated to compliance costs and by integrating regulatory requirements into research projects funded by European programs.

At the same time, the creation of partnerships and the exchange of best practices at European level, including through the development of competence centers and regional clusters in collaboration with other Member States, can significantly contribute to increasing Romania's capacity to implement the new regulations efficiently and sustainably.

Conclusions

The application of new European regulations on medical devices is a major test for Romania's ability to integrate European reforms into national health and innovation policies. The results of the

questionnaire indicate that, in the absence of strategic measures, the implementation process risks generating bottlenecks, excessive costs, and losses in competitiveness, with a direct impact on patients and the health system.

At the same time, these regulations offer a real opportunity to improve the quality, safety, and transparency of the medical device market. Long-term benefits can only be achieved through deliberate investment in institutional capacity, professional skills, and infrastructure.

For the period 2025–2027, it is essential that decision-makers act quickly and in a coordinated manner. Implementing the proposed recommendations can turn compliance with European regulations into a strategic advantage, with positive effects on the healthcare system, the economy, and society as a whole.

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The author remains available for any questions and to participate as a consultant in discussions regarding changes to the text and guidance documents.

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