

(English version)

**Question for written answer E-002192/24
to the Commission
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(21 October 2024)**

Subject: Reform of Medical Devices Regulation required to foster innovation and competitiveness

The implementation of the Medical Devices Regulation (EU) 2017/745 (MDR) in 2021 has placed an immense bureaucratic burden on manufacturers and clinicians, slowing down processes, increasing costs and stifling innovation in the medical sector ⁽¹⁾. Instead of enhancing patient safety, these regulations have led to delays in the availability of life-saving devices, forcing clinicians to use riskier alternatives ⁽²⁾ ⁽³⁾. This bureaucratic overload not only jeopardises the well-being of countless patients but also threatens the EU's competitiveness in the global medical industry, with potentially devastating consequences, including the loss of lives.

Given the severity of this situation:

1. When will the Commission propose a revision of the MDR to eliminate unnecessary bureaucratic hurdles, especially for small and medium-sized enterprises, and ensure that patient safety and innovation is genuinely prioritised?
2. What steps will it take to address bottlenecks in the work of assessment bodies, which have led to dangerous delays and limited access to life-saving devices?
3. What lessons has it learned from the implementation of the MDR, and how will it ensure that future policies are developed and implemented in a way that prevents similar regulatory burdens and unintended negative consequences?

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**Answer given by Mr Várhelyi on behalf of the European Commission
(7 January 2025)**

The transition to the EU regulatory framework for medical devices has proved to be challenging.

The recent extension of the transitional periods has given manufacturers and notified bodies more time to carry out the conformity assessment to reduce the risk of acute shortages of devices.

In addition, the number of notified bodies has significantly increased since the regulations have become applicable. As part of the actions financed under the EU4Health Programme ⁽¹⁾ to support the implementation of the regulations on medical devices, the Commission funds a project to increase the capacity of notified bodies and the preparedness of manufacturers, and to facilitate access to notified bodies, especially for small and medium-sized enterprises ⁽²⁾.

Moreover, the Commission has launched a targeted evaluation of the medical devices legislation in 2024 that will assess its performance, to optimise its implementation and pave the way for identifying options to address persisting shortcomings.

Having regard to the importance and urgency of the matter, President of the Commission has included in the Mission letter to the Commissioner-designate for Health and Animal Welfare ⁽³⁾ the need to ensure the availability and competitiveness of medical devices, including by stepping up the implementation of the current framework and evaluating the need for potential legislative changes.

In this regard, the Commission will prioritise the ongoing targeted evaluation of the medical device Regulations to take informed decisions about the way forward, including about potential legislative changes.

¹ <https://www.degruyter.com/document/doi/10.1515/bmt-2023-0325/html?lang=en>.

² <https://onlinelibrary.wiley.com/doi/10.1111/apa.16919>.

³ <https://pubmed.ncbi.nlm.nih.gov/37068279/>.

⁽¹⁾ European Health Union — helping the transition to the new rules on medical devices and *in vitro* diagnostics: https://health.ec.europa.eu/document/download/1b817e65-89c8-4235-ab74-c147aeff34db_en?filename=mdr_in-vitro-factsheet_1.pdf

⁽²⁾ NoBoCap: <https://nobocap.eu/about/>

⁽³⁾ https://commission.europa.eu/document/download/b628b5a2-ac1e-4b9c-bbdd-35b82da0ac6b_en?filename=mission-letter-varhelyi.pdf