Question for written answer E-002192/2024
to the Commission
Rule 144
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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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[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/.