*(English version)*

**Question for written answer E-002957/25**
**to the Commission**
**Liesbet Sommen (PPE)**
*(17 July 2025)*

*Subject:* The urgent need to revise the MDR and the IVDR: towards a workable framework for innovation and patient safety

Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) aim to achieve a high level of patient safety. In its resolution of 23 October 2024, the European Parliament called on the Commission to put forward proposals for delegated and implementing acts by the end of the first quarter of 2025 and to prepare a systematic revision of both regulations.

In practice, complex procedures currently compromise the availability of life-saving devices. According to a study by Qualix, the Medical Devices Regulation is more stringent than regulations in Australia, the UK and the US, among others, which hinders innovation.

It is therefore crucial to find a workable balance between patient safety and reducing unnecessary administrative burdens.

1. Taking into account the call for input from 12 December 2024 to 21 March 2025, will the Commission also provide a timetable for the revision of both regulations or any delegated and implementing acts?

2. What specific measures does it intend to take to facilitate the access of SMEs and software producers to the market and to revise downward the qualification and classification of software as a low-risk medical device (SaMD)?

3. Is the Commission considering an accelerated authorisation procedure for innovative devices that can meet medical needs or offer solutions in the event of a health crisis?

Submitted: 17.7.2025

**Answer given by Mr Várhelyi on behalf of the European Commission**
*(17 October 2025)*

As mentioned in its replies to P-002033/25 ([1]) and E-002807/25 ([2]), the Commission is working to address challenges identified regarding the regulatory framework for medical devices and *in vitro* diagnostics.

It has been conducting a targeted evaluation of the regulations (EU) 2017/745 (Medical Devices Regulation 'MDR') and (EU) 2017/746 (In Vitro Diagnostics Regulation 'IVDR').

To follow up on the evaluation, and respond to calls from the European Parliament, Member States and stakeholders, the Commission will present by the end of 2025 a legislative proposal for a revision of the MDR and IVDR ([3]).

As part of this revision, among other objectives, the Commission aims to reduce the administrative burden including reporting obligations, enhance the predictability and cost-efficiency of the certification processes of notified bodies, and make the conformity assessment requirements more proportionate, especially for low- and medium-risk devices and those that cater to special patient needs.

In line with the political priorities of the Commission, a revision of the MDR and IVDR will aim to simplify the legislation and lighten the regulatory burden for the actors subject to the regulations, also for small and medium-sized enterprises, software producers and manufacturers of innovative devices, without compromising patient safety and public health.

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([1]) https://www.europarl.europa.eu/doceo/document/P-10-2025-002033-ASW_EN.html.
([2]) https://www.europarl.europa.eu/doceo/document/E-10-2025-002807-ASW_EN.html.
([3]) https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14808-Medical-devices-and-in-vitro-diagnostics-targeted-revision-of-EU-rules_en.