

(English version)

**Question for written answer E-002807/25
to the Commission
Jan-Peter Warnke (NI)
(9 July 2025)**

Subject: Medical devices regulation (MDR)

The Commission received an obligation to submit a proposal to Parliament to revise the current MDR by the end of November 2025. It has been requested so urgently as the application of the current regulation is having devastating consequences for patients, doctors and medical device manufacturers in the EU, in particular SMEs.

1. When will a revision of the valid MDR be provided?
2. To what extent has the Commission been informed of the wide range of initiatives in Europe through associations, patient organisations, doctors' organisations and, for example, the hearing held in Parliament on 28 March 2025?
3. What influence does the excessive level of red tape currently in place in the EU have on the revision of the MDR?

Submitted: 9.7.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(5 September 2025)**

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

It is conducting a targeted evaluation of the regulations (EU) 2017/745 ⁽²⁾ and (EU) 2017/746 ⁽³⁾ which will be finalised in the fourth quarter of 2025 ⁽⁴⁾.

Based on this evaluation, the Commission will, by the end of 2025, propose legislation that strikes a balance between simplifying EU regulations related to medical devices and *in vitro* diagnostics, with a view to facilitate businesses' operations across the EU single market, and effectively protecting patient safety and public health ⁽⁵⁾.

In the context of the targeted evaluation of the regulatory framework for medical devices, the Commission conducted a public consultation and call for evidence focused on identifying problems in the current legal framework.

It is therefore well informed about the positions of various stakeholders, including representatives of industry, patients and healthcare professionals.

The Commission also regularly discusses this matter with the European Parliament and Member States. Through an additional call for evidence, the Commission will gather input for addressing the identified problems by means of a targeted revision of the regulations on medical devices.

⁽¹⁾ https://www.europarl.europa.eu/doceo/document/P-10-2025-002033-ASW_EN.html.

⁽²⁾ <http://data.europa.eu/eli/reg/2017/745/oj>.

⁽³⁾ <http://data.europa.eu/eli/reg/2017/746/oj>.

⁽⁴⁾ See EU rules on medical devices and *in vitro* diagnostics — targeted evaluation. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14155-EU-rules-on-medical-devices-and-in-vitro-diagnostics-targeted-evaluation_en.

⁽⁵⁾ See Medical devices and *in vitro* diagnostics — targeted revision of EU rules: 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; see also Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Choose Europe for life sciences: A strategy to position the EU as the world's most attractive place for life sciences by 2030, COM(2025)525 final, 2.7.2025.