

(English version)

**Question for written answer E-000515/26
to the Commission
Cynthia Ní Mhurchú (Renew)
(9 February 2026)**

Subject: Delays in CE marking for medical devices under the EU Medical Device Regulation and their impact on patient access

Under the Medical Device Regulation ⁽¹⁾ (MDR), significant delays in notified body assessments are reportedly preventing EU patients from accessing well-established medical technologies, such as a femoral hip stem used in over one million patients worldwide and manufactured in the EU, despite completed documentation for CE marking.

What specific steps is the Commission taking to reduce MDR backlogs and processing times, introduce prioritisation or simplification measures, address notified body capacity constraints, and provide indicative timelines or transparency measures to improve planning and prevent patient-access disruptions?

Submitted: 9.2.2026

**Answer given by Mr Várhelyi on behalf of the European Commission
(14 April 2026)**

The Commission is aware of certain problems and challenges related to the implementation of Regulations (EU) 2017/745 on medical devices ⁽¹⁾ and (EU) 2017/746 on *in vitro* diagnostic medical devices ⁽²⁾. It has been taking decisive actions to improve the situation, aiming to ensure more timely patients' access to medical technologies.

Specifically, on 16 December 2025 the Commission adopted a legislative proposal for a revision of the current regulations ⁽³⁾. The proposed revision aims to simplify the rules for medical devices and *in vitro* diagnostics to make them easier, faster and more effective, while keeping the highest standards for patient safety.

It will make the sector more competitive in the internal market and globally by supporting innovation. The Commission counts on the European Parliament and the Council to prioritise this proposal and ensure a swift adoption.

In addition, the Commission is finalising an Implementing Regulation laying down certain procedural requirements for the conformity assessment activities carried out by notified bodies ⁽⁴⁾.

The main elements of this Implementing Act are maximum timelines for notified bodies to complete the certification procedure.

This will enhance the predictability of the process, speed up access of medical devices to the market and guarantee their continuous supply. The act was supported by the Medical Device Committee in March 2026 and will be adopted in April.

The Commission has also prepared Delegated Regulations to expand the lists of well-established technologies referred to in Regulation on medical devices to make the application of some legal requirements for these technologies more proportionate, without compromising health and safety. These acts have been adopted in March 2026 ⁽⁵⁾.

¹ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>).

⁽¹⁾ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

⁽²⁾ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EEC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

⁽³⁾ Proposal for a regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and *in vitro* diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I, COM(2025) 1023 final, 2025/0404 (COD); https://health.ec.europa.eu/medical-devices-sector/new-regulations_en#simpler-and-more-effective-rules-for-medical-devices--commission-proposal-for-a-targeted-revision-of-the-medical-devices-regulations.

⁽⁴⁾ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14471-Medical-devices-uniform-application-of-the-requirements-for-notified-bodies_en.

⁽⁵⁾ Currently under the scrutiny procedure by the European Parliament and the Council until June 2026, see <https://webgate.ec.europa.eu/regdel/#/delegatedActs/2643> and <https://webgate.ec.europa.eu/regdel/#/delegatedActs/3061>.