

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2023/502

of 1 December 2022

amending Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the frequency of complete re-assessments of notified bodies

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ⁽¹⁾, and in particular Article 44(11) thereof,

Whereas:

- (1) Regulation (EU) 2017/745 establishes a new regulatory framework to ensure the smooth functioning of the internal market as regards medical devices. That Regulation significantly reinforces the supervision of notified bodies and conformity assessment procedures.
- (2) Article 44(10) of Regulation (EU) 2017/745 provides that 3 years after notification of a notified body, and again every fourth year thereafter, a complete re-assessment of notified bodies is conducted to determine whether the notified body still satisfies the requirements set out in Annex VII of that Regulation.
- (3) The limited number and capacities of notified bodies currently designated under Regulation (EU) 2017/745 has created bottlenecks for the certification of medical devices during the transitional period provided for in Article 120(3) of that Regulation.
- (4) In order to allow the authorities responsible for notified bodies of the Member State in which the notified body is established to focus on the assessment of new applications for designation as notified body and to allow notified bodies to process a high number of certifications during the transitional period provided for in Article 120(3) of Regulation (EU) 2017/745, the timing of the first complete re-assessment of a notified body after notification should be deferred to 5 years after notification.
- (5) Given that notified bodies are subject to continuous monitoring and assessment activities in accordance with Article 44(4) of Regulation (EU) 2017/745, the frequency of subsequent complete re-assessments should also be changed to every 5 years.
- (6) The authority responsible for notified bodies should have the possibility to conduct a complete re-assessment earlier than at the timing of the normal cycle, where it is justified by the results of the annual assessment activities of the notified body or when requested by the notified body.

⁽¹⁾ OJ L 117, 5.5.2017, p. 1.

- (7) Complete re-assessments that have started, in principle, should continue to be conducted in order to optimise the use of resources already spent. However, the authority responsible for notified bodies of the Member State in which the notified body is established, after having heard the notified body in question, may decide to suspend or terminate an ongoing complete re-assessment, taking into account resources already spent on the re-assessment and the results of the annual assessments already conducted.
- (8) Regulation (EU) 2017/745 should therefore be amended accordingly.
- (9) In light of the overriding need to immediately enhance the capacities of notified bodies in the interest of public health, this Regulation should enter into force as a matter of urgency,

HAS ADOPTED THIS REGULATION:

Article 1

In Article 44 of Regulation (EU) 2017/745, paragraph 10 is replaced by the following:

'10. 5 years after notification of a notified body, and again every 5 years thereafter, a complete re-assessment to determine whether the notified body still satisfies the requirements set out in Annex VII shall be conducted by the authority responsible for notified bodies of the Member State in which the body is established and by a joint assessment team in accordance with the procedure described in Article 39.

The authority responsible for notified bodies of the Member State in which the notified body is established may conduct a complete re-assessment prior to the dates referred to in the first subparagraph, upon request by the notified body or where, based on the results of the annual assessments conducted in accordance with paragraph 4 of this Article, it has concerns regarding the continued fulfilment by the notified body of the requirements set out in Annex VII.

Complete re-assessments that have already started prior to 11 March 2023 shall continue to be conducted, unless the authority responsible for notified bodies of the Member State in which the notified body is established decides to suspend or terminate the ongoing complete re-assessment, taking into account its own resources and the resources of the notified body already spent on the re-assessment, as well as the results of the annual assessments conducted in accordance with paragraph 4 of this Article. Before suspending or terminating an ongoing complete re-assessment, the authority responsible for notified bodies shall hear the notified body concerned.'

Article 2

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 1 December 2022.

For the Commission
The President
Ursula VON DER LEYEN
