ROPES & GRAY

ALERT

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European Commission Proposes to Amend Transitional Provisions for In Vitro Diagnostic and Other Medical Devices

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Background

On 6 January 2023, the European Commission ("EC") published the legislative proposal to extend or amend the transitional deadlines for certain medical devices and in vitro diagnostic medical devices ("IVD"). This is in follow up to the discussion within the EU Employment, Social Policy, Health and Consumer Affairs Council (the 'Health Council') on 9 December 2022[1] where the Health Council supported the European Commission's proposal to delay the transitional deadlines to avoid causing harm to EU health systems and, most critically, patient care. The previous alert can be found here.

Legal basis relating to the key proposed legislative amendments

Consisent with the parent EU law instruments respectively governing medical devices and IVDs, the proposed legislative amendments are made on the basis of (a) completing the internal single market and (b) protecting public health by setting high standards of quality and safety of medical devices.

As detailed below, the proposed amendments:

- confer specific powers on Member States to address disruption of product supplies under the so-called subsidiarity principle[2];
- adhere to the basic principle of proportionality to specifically address the supply disruption arising from shortage of Notified Bodies ("NBs") so that the rules are not applied excessively.

The key proposed changes to Regulation (EU) 2017/745 ("MDR") and Regulation (EU) 2017/746 ("IVDR") are set out in the table below for ease of reference.

Consistent with the European Commission's position declared at the meeting with the Health Council in December 2022, the legislative proposal removes the "sell-off" deadline provided in Article 120(4) MDR and Article 110(4) of In Vitro Diagnostic Regulation to avoid devices unnecessarily being removed from the EU market by 27 May 2025.

New deadlines and conditions under MDR	
Product Types and Characteristics New Deadline (in brackets)	**Conformity assessment involving a NB**
Conformity assessment involving a NB	
Class III, Class IIb implantable medical devices with the new deadline extended to 31 December 2027.	Specific conditions • Before expiry date of the certificate, contractual arrangements are put in place between the manufacturer and the NB,

[1] See Ropes & Grey Alert of December 12, 2022, entitled "Reality is Tricky Business in Effective Implementation of the EU Medical Devices Regulation EU Health Council Supports Delay of MDR Transitional deadlines" here.
[2] Subsidiarity principle means that EU action may only be taken if the aims of the envisaged measure cannot be achieved by Member States alone.

The extension applies to certificates issued by NBs according to the Directives governing general medical devices or active medical devices from 25 May 2017, valid on 26 May 2021 and not withdrawn thereafter. Expired certificates will remain valid until the new deadline.	essentially demonstrating the commitment for the conformity assessment under the MDR to be initiated in respect of the medical device covered by the expired certificate. • A national competent authority (a) has granted a derogation from the need for conformity assessment procedure to allow the medical device to be placed on the market on grounds relating to public health or patient safety or health or (b) has requested the manufacturer to perform an evaluation that the medical device does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health. <u>General conditions</u> • The device continues to comply with the Directives governing the general medical devices or active implantable medical devices. • There are no significant changes in the design and intended purposes. • The device does not present an unacceptable risk to the health and safety of patients, users or other persons or to other aspects of the protection of public health. • The manufacturer has put in place a quality management system no later than 26 May 2024. • The manufacturer or an authorised representative has lodged a formal application in respect of the device covered by the initial certificate no later than 26 May 2024; and no later than 26 September 2024 the NB and manufacturer have signed a written agreement with a view to initiating a conformity assessment under the MDR. • The requirements under MDR relating to post-market surveillance, market surveillance, vigilance, and registration of economic operators are put in place. The NB responsible for MDR conformity should assume the role for the surveillance no later than 26 September 2024, and the arrangements for the transfer of the surveillance responsibility from the previously designated NB under the Directives to the NB under the MDR should be covered by a written agreement.
Class IIb (other than implantable medical devices), Class IIa and Class I in sterile condition or having a measuring function with the new deadline extended to 31 December 2028. The extension applies to certificates issued by notified bodies ("NB") according to the Directives governing general medical devices or active medical devices from 25 May 2017, valid on 26 May 2021 and not withdrawn thereafter. Expired certificates remain valid until the new deadline.	
Class III custom-made implantable medical devices with the new deadline extended to 26 May 2026.	• No later than 26 May 2024, the manufacturer, the authorised representative, has lodged a formal application for conformity assessment to be initiated.

	• No later than 26 September 2024, the NB and the manufacturer have signed a written agreement for the conformity assessment to be performed.
Conformity assessment not involving an NB	
Medical devices, which did not involve NBs in the certification, with the new deadline extended to 31 December 2028. The extension applies to the declaration of conformity, under the Directive governing general medical devices, which was drawn up before 26 May 2021, but the conformity assessment under MDR requires involvement of an NB.	<u>General conditions</u> • The device continues to comply with the Directives governing the general medical devices or active implantable medical devices. • There are no significant changes in the design and intended purposes. • The device does not present an unacceptable risk to health and safety of patients, users or other persons or to other aspects of the protection of public health. • The manufacturer has put in place a quality management system no later than 26 May 2024. • The manufacturer or an authorised representative has lodged a formal application in respect of the device covered by the initial certificate no later than 26 May 2024; and no later than 26 September 2024 the NB and manufacturer have signed a written agreement with a view to initiating a conformity assessment under the MDR. • The requirements under MDR relating to post-market surveillance, market surveillance, vigilance, registration of economic operators are put in place.

New deadline under IVDR	
An IVD lawfully placed on the market under the IVD Directive before 26 May 2022 may continue to be placed on the market. An IVD lawfully placed on the market from 26 May 2022 may continue to be placed on the market if a certificate is issued under the IVD Directive and valid within the period indicated on the certificate except for certificates issued according to EC verification procedure under the IVD Directive, which will become void by 27 May 2024. In respect of the above IVD types, the deadline for the IVD Directive to continue to apply until 27 May 2025 is removed.	• The IVD continues to comply with the IVD Directive. • There are no significant changes in the design and the intended purpose.

Rationale for the urgent legislative actions and next steps

- The Commission recognises that the amendments should be adopted by the EU legislature due to exceptional circumstances arising from an imminent risk of shortages of medical devices and associated risk of a public health crisis.
- The amendments must be adopted by the European Parliament and the European Union Council under the co-decision procedure.
- The urgent legislative actions seek to ensure availability of medical devices whose certificates have already expired or are due to expire before 26 May 2024 to provide legal certainty.
- Therefore, the legislative process will likely be truncated for the amendments to be adopted as soon as possible. For this reason, the normal eight-week period for Member States to consult internally under the applicable EU Treaties will be dispensed with.