Compliance & Risks

Kennedys

In Practice Series

How To Prepare For The European Medical Devices and In Vitro Diagnostics Regulations

9 Step Checklist to Avoid Legal Risks

On 6 January 2023, the EU Commission published its draft legislative proposal to amend the transitional provisions in Regulation (EU) 2017/745 for medical devices ("MDR") and Regulation (EU) 2017/746 ("IVDR") for in vitro diagnostic medical devices, hereafter "the Regulations".[1]

The proposed amendments introduce an extension to the transitional periods established in the Regulations to provide medical device manufacturers more time to bring their devices into conformity with the requirements of the Regulations.

This is still a proposal and needs to go through the EU legislative procedure. However, in order to address the urgent requirements to provide more time to certify medical devices and mitigate the risk of device shortages, it is expected that the proposed amendment will be adopted by the European Parliament and the Council through an accelerated co-decision procedure.

Companies should always refer to the specific regulations and guidance in place in the jurisdictions they are operating. However, the following general principles may provide some helpful pointers:

- [ ] If not already, manufacturers should undertake an urgent "readiness" review of their product portfolio to include an analysis of the implications of MDR and IVDR on device categorisation, the expiry period of any existing certificates and begin contracting with notified bodies and testing houses in light of the substantially increased demand being placed on a limited resource.

- [ ] Particular attention should be given to products that may require a specialised notified body with specific technical skills, given the shortage of resources is still more acute for such devices.

- [ ] Manufacturers whose medical device certificates are due to expire should contract with a notified body as soon as possible for a conformity assessment prior to the certificate's expiry. In this way, if a certificate expires prior to the enforcement of the proposed amendment, the validity of such certificate can be extended.

- [ ] Manufacturers whose medical device certificates have already expired or manufacturers who fail to contract with a notified body prior to the certificate expiry may apply for an exemption in accordance with Article 97 or Article 59 (1) to extend the validity of certificates.

- [ ] The extension of the validity of certificates is directly applicable without requiring notified bodies to change the date on the individual certificates. This may pose a problem to manufacturers who export devices outside the EU as competent authorities outside the EU may not accept expired certificates. Therefore, manufacturers need to ensure the certification process in the relevant non-EU market that may support the proposed extension of the validity of certificates in the EU.

- [ ] By 26 May 2024, manufacturers must put in place a quality management system (QMS) in accordance with Article 10(9) of the MDR in order to benefit from the extended transition period.

- [ ] By 26 May 2024, the manufacturer or its authorised representative must lodge a formal application for a conformity assessment for the 'legacy device', and by 26 September 2024, the notified body and the manufacturer must sign a written agreement for such conformity assessment in order to benefit from the extended transition period.

- [ ] During the transitional period, manufacturers and businesses have more time to comply with the MDR and the IVDR, but it's important to start preparing as soon as possible and to keep track of key dates and account for lead times with respect to expiry of device certificates and the end of transition periods.

- [ ] Developing and maintaining good ongoing relationships with preferred notified bodies and testing houses will ensure manufacturers are better placed to respond to future regulatory changes, particularly in times of high demand for these services.

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