MAR. 23

INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Proposed amendments to transitional periods provided for MDR and IVDR

The European Commission has adopted a proposal for legislative amendments to Regulation (EU) 2017/745 of 5 April 2017 ("**MDR**") and Regulation (EU) on In Vitro Diagnostic Medical Devices 2017/746 ("**IVDR**").

The aim of this proposal is to give market players more time to ensure compliance of medical devices in order to address concerns about shortages of these devices and thus ensure patient access to them.

Some changes are made to the transitional provisions of these regulations. In particular, the proposal provides for an extension of the periods granted to manufacturers to ensure the transition from the previous legal framework to that established by the new regulations.

These extensions vary according to the category of medical device concerned.

Specifically, for medical devices and in vitro diagnostic medical devices covered by a certificate or declaration of conformity issued before 26 May 2021, the transition period will now be as follows:

i) Until 31 December 2027 for high-risk devices - Class III and Class IIb implantable devices. There are some exceptions, such as sutures, staples, dental fillings, dental braces, dental crowns, screws, wedges, plates, wires, pins, clips and connectors.

ii) Until 31 December 2028 for medium and low risk devices - Class IIb devices other than those referred to in the previous paragraph, Class IIa devices and Class I devices

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The proposal provides for an extension of the periods granted to manufacturers to ensure the transition from the previous legal framework to that established by the new regulations.

These extensions will only apply to devices that are considered safe and for which manufacturers have already taken steps to transition to the rules of the new regulations. In other words, they must have started the conformity assessment process and implemented a quality management system by 26 May 2024 at the latest.

A transition period until 26 May 2026 is also proposed for custom-made Class III implantable devices to allow manufacturers some additional time to achieve certification by a notified body. This transition period is also conditional on the manufacturer submitting an application for conformity assessment before 26 May 2024.

This measure, motivated by the current shortage of supply, will ensure that healthcare systems and patients continue to have access to safe medical devices already on the market.

The proposal also includes the abolition of the "sell-off period", i.e. the period after which medical devices certified under previous legislation and already placed on the market but not yet delivered to the end user would have to be withdrawn. This measure, motivated by the current shortage of supply, will ensure that healthcare systems and patients continue to have access to safe medical devices already on the market.

The proposal must now be adopted by the European Parliament and the Council. ■