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INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Extension of the transaction period of the MDR

The European Commission has announced its intention to propose amendments to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices ("**MDR**"), in particular regarding the transition period for the MDR.

Concerns have been raised over recent months by various industry stakeholders who argue that the demanding challenges posed by the MDR's implementation may endanger the continued availability of the various medical devices needed by healthcare systems and patients in the European Union.

In addition to accessibility, implementing the MDR within the proposed time frame could also endanger research and innovation by delaying and compromising access to innovative medical devices in EU countries.

A meeting of the Employment, Social Policy, Health and Consumer Affairs Council ("**EPSCO**") was held in December 2022. At this meeting, through Commissioner for Health Stella Kyriakides, the European Commission undertook to adopt a set of measures to mitigate the foreseeable shortage of medical devices in the European Union caused by the challenges and difficulties posed by the implementation of MDR and IVDR.

The following proposals for amendments to the MDR and IVDR were announced to the EPSCO:

- The transition periods for medical devices approved under Directive 93/42/EEC (Medical Devices Directive) will be extended until 2027 for high risk devices, and until 2028 for low risk medical devices.

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The European Commission undertook to adopt a set of measures to mitigate the foreseeable shortage of medical devices.

- Only medical devices considered safe will benefit from the extension. Moreover, the possibility is still on the table that these transition period extensions will only be accessible to manufacturers that have already started to adapt and certify their medical devices under the MDR.

- The expiry date for medical devices authorised under the Medical Devices Directive – May 2025 – will be revoked, in order to avoid the withdrawal of safe medical devices from the market.

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- Medium and long term solutions will be developed to meet the needs of rare disease patients, which will both address their needs and reduce the bureaucracy associated with this type of medical device.

- The Commission will run a pilot project to provide medical device manufacturers with qualified scientific advice. In particular, it will set up expert panels to advise manufacturers of innovative medical devices for the treatment of rare diseases.

Despite the announcement of these measures, the legislative changes that will implement them have not yet been revealed. We also do not yet know whether they will also apply to in vitro diagnostic medical devices that have not yet adapted to the IVDR.

Nevertheless, it is expected that the legislative cycle to introduce these changes will begin in 2023. ■