MAR. 23

INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Amendments to the frequency of full reassessments regarding MDR and IVDR

On 8 March 2023, **Commission Delegated Regulations (EU) 2023/502** and **503**, both dated 1 December 2022, were published.

Delegated Regulation (EU) 2023/502 amends **Regulation (EU) 2017/745** of 5 April 2017 ("**MDR**") on **medical devices**, while **Delegated Regulation (EU) 2023/503** amends **Regulation (EU) 2017/746** of 5 April 2017 ("**IVDR**") on **in vitro diagnostic medical devices**.

The European Commission has taken this measure following serious difficulties in the certification of medical devices during the transitional periods of the new regulations.

The changes made concern the frequency of **full reassessments of notified bodies**. As originally drafted, a complete re-assessment was mandatory **three years after the notification of a notified body** and **every four years thereafter**. With the entry into force of the new regulations, this will only become mandatory **five years after the notification of a notified body** and **every five years** thereafter.

The European Commission has taken this measure following **serious difficulties in the certification of medical devices during the transitional periods of the new regulations**, taking into account the limited number and capacity of notified bodies. However, full re-evaluations started before 11 March 2023 should continue in order to optimise the use of resources already invested.

Both Regulations will enter into force on 11 March 2023.

In this context, the European Commission had already announced on 6 January 2023 a proposal for a legislative amendment aimed at extending the transition periods provided for in the MDR and the IVDR, as explained in this Informative Note. ■

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