RA news round-up
CW 05 of 2023

Europe

Extension of Transition Periods

The new year starts with a bang: the proposal to extend the transition periods of the MDR is now before the European Commission. The chances that this proposal will actually be adopted are now relatively high. This is not least due to the fact that the European Commission and its member countries are aware that there is still a lot of catching up to do in the implementation of relevant structures.

As soon as the proposal is adopted and really binding information is available, we will inform about it. Until then, however, we have created a graphic that illustrates possible scenarios for medical technology manufacturers:

https://www.qtec-group.com/wp-content/uploads/2023/01/qtec-Transition-from-MDD-to-MDR-Expiration-of-Certificates.pdf

The proposal can be found right here:

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13684-Medical-devices-transition-period-extension_en

MDCG on Periodic Safety Update Report

The last MDCG guidance of the past year deals with the Periodic Safety Update Report (PSUR), which manufacturers must prepare for Class IIa, IIb and III medical devices.

This guidance includes some practical advice for devices approved under the MDR as well as so-called legacy devices, which are still circulating in the market under MDD conformity. Particularly pleasing should be the presented template for the PSUR.

https://health.ec.europa.eu/system/files/2023-01/mdcg_2022-21_en.pdf

Guidance on In house Devices

The first MDCG Guidance of the new year deals with Article 5 of the Medical Device and In Vitro Diagnostic Regulation. More precisely, it is about in house devices.

The document describes the requirements of both regulations in great detail and healthcare facilities should urgently check whether they are considered to be manufacturers of in-house devices according to the corresponding article.

https://health.ec.europa.eu/system/files/2023-01/mdcg_2023-1_en.pdf

Standard Fees of Notified Bodies

The MDCG has published a short document to make it easier for Notified Bodies to publish their fees. It contains some definitions and a table that should be used to show the costs of individual activities of the notified body.

https://health.ec.europa.eu/system/files/2023-01/mdcg_2023-2_en.pdf