RA news round-up
CW24 of 2021

Europe

Transition period until EUDAMED is fully functional

Unfortunately, the latest announcement of the German Federal Ministry of Health is only available in German. Since the full functionality of the European EUDAMED database is not yet given, national specifications and options to meet the requirements of the MDR are introduced. Of course, these also apply to manufacturers from other countries than Germany!

This now means that not only manufacturers, but also importers and distributors must check very carefully what the respective national specifications are until EUDAMED is fully operational. The German solutions can be read in the following document:

https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/B/Bekanntmachungen/210526_Bekanntmachung_BMG_EUDAMED.pdf

Call to Action of In Vitro Diagnostics Stakeholders

Back in May, a high-profile incendiary letter on the implementation of the IVDR was published. The editors are the European Federation of Pharmaceutical Industries and Associations, the European Cancer Patient Coalition and the company Diaceutics.

In view of the known problems in implementing the requirements of the IVDR, the letter calls for an appropriate response from the European Commission. For example, EUDAMED is not yet operational, reference laboratories are not yet available, and there are too few notified bodies to meet the immense demand for certification. One of the concrete demands is a postponement of the Date of Application by one year. If the current situation remains as it is, a large number of patients are likely to be undersupplied.

The letter can be read here:

https://www.efpia.eu/media/602667/call-to-action-to-the-european-commission-to-postpone-and-facilitate-a-phased-implementation-of-the-in-vitro-diagnostic-regulation.pdf

IVDR Join Implementation Plan

As if the European Commission had read the Call to Action of the IVD stakeholders, a Joint Implementation Plan was published shortly afterwards, which is addressed to MDCG, the member states and the Commission itself.

This plan is supposed to be a living document and will be constantly updated to monitor the implementation process. The document identifies and discusses the major hurdles in the implementation of the IVDR. In addition, sometimes more, sometimes less concrete priority actions are proposed. But whether the idea "Make available national experts" really contributes to solving the problem of the availability of notified bodies remains at least questionable.

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_joint-impl-plan_en.pdf

Endorsement of IMDRF Guidance N48

The new MDCG Guidance 2020-10 is more like an announcement. It states that Annexes E to I of IMDRF Guidance N48 will be endorsed. These IMDRF appendices provide examples of how to applicate UDIs and address potential issues. Also, the MDCG adds some explanations to these examples.

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_2021-10_en.pdf

Device Types in Implant Cards

The eleventh MDCG Guidance of this year deals with the implant card and is to be understood as a supplement to Guidance MDCG 2019-8. The document now provides a list of possible Device Types to be entered in the implant card. The list includes 88 entries and can be found here:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_2021-11_en.pdf

International News

Australia

The Australian TGA continues to be busy working on the new regulatory framework for medical devices. Now it's the turn of personalized medical devices, and an official document is open for comment. The consultation process is intended to clarify, among other things, whether the classification of personalized medical devices is appropriate to their risk profile.

Comments can be submitted until July 14. Of course, this all runs through the recently launched Consultation Hub.

https://www.tga.gov.au/consultation/consultation-proposed-refinements-regulation-personalised-medical-devices

USA

By Executive Order, the U.S. president has called for an improvement in the government's cybersecurity. The FDA has responded by publishing a kind of summary of the currently valid guidance and standards on this topic from the medical technology sector. The document is aimed first at the National Institute of Standards and Technology (NIST), which is involved in implementing the order.

Five pages are devoted to answering NIST's specific questions, providing a nice overview of the state of the art on cybersecurity. This starts with the question about the criticality of a software and ends with test requirements for source code. The exciting document can be found on the FDA website:

https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity