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Open The Champagne! EU Go Ahead For Standards Needed For New Medtech Regulations

by Amanda Maxwell

The EU has the green light to adopt and list standards that will be recognized under the MDR and IVDR. But there will be no escaping the impact of the delays, especially for the IVD sector.

The legal basis is now in force for the EU to start publication in the Official Journal of the European Union of references of harmonized standards in the context of the Medical Device and IVD Regulations (MDR and IVDR) which apply on 26 May this year and next year respectively.

The news follows the EU standards organizations, CEN and Cenelec, accepting the European Commission's mandate to revise some 200 existing standards that had been listed under the current medical device directives and draft 27 new standards to underpin the implementation of the new regulations.

In announcing the update, the European Commission also revealed that "the first lists of MDR/IVDR harmonized standards should be ready by June 2021". They will be periodically updated and enlarged.

This development is a huge relief for the medtech sector. Standards are a foundation stone of the MDR and IVDR; manufacturers who claim compliance with the standards can argue that they have demonstrated compliance with the General Safety and Performance Requirements (GSPRs) to which they are linked in the MDR and IVDR.

Bumpy Ride But Not As Disastrous As It Could Have Been

When it comes CEN and Cenelec accepting the commission's standards request, it has been a bumpy ride. This is the commission's second attempt at having the standards bodies accept its mandate.

The last proposed standards request was rejected. (Also see "*What Next For Standards As CEN/CENELEC Reject MDR/IVDR Commission Request?*" - Medtech Insight, 30 Jun, 2020.)

But with just two weeks until the MDR date of application and no standards harmonized under it, manufacturers who claim compliance with the MDR have had to turn to alternative means of attempting to demonstrate compliance with the MDR and IVDR GSPRs.

While many may have continued using standards under the directives and justified their decision, the lack of harmonized standards under the new regulations potentially slows down notified body auditing. This is because the testing and certification organizations may have to conduct significantly different conformity assessment processes for each product, unless they too can argue the case to continue using current directives and demonstrate how they have taken differences between the requirements of the directive and regulations into account .

All this will mean an individual response by each notified body, and differences overall in how notified bodies operate and assess products. This is a far cry from the harmonization goals of the EU's MDR and IVDR.

The good news is that, because the vast majority of medical devices have made use of the grace period, the delay in having MDR harmonized standards available is not as disruptive as it could have been.

But the situation may be very different for the IVD sector. Only a small proportion of IVD products, estimates suggest less than 20%, will be able to make use of the IVDR grace period. Yet how many IVD standards are likely to be ready in time for when the IVD Regulation applies on 26 May 2022?

With IVDR notified body resources predicted to be stretched to breaking point next year, the lack of harmonized standards will further slow the process and challenge capacity. This is in no one's interest, not least given that the sector has not yet found any workable solution to the predicted IVDR notified body bottlenecks.

It will be important therefore, Medtech Insight notes, that the IVD industry is not left trailing behind in the standards stakes and the IVD standards are prioritized where necessary.

Dates

The commission *Implementing Decision*, which formalizes the standardization request to the standards bodies, was published in the Official Journal of the EU on April 14.

The deadlines for adoption of all the MDR and IVDR standards, new and revised, is 27 May 2024 according to the commission's Implementing Decision. But the hope is that CEN and Cenelec

will be able update and sign off many of the existing directive standards under the new Regulations relatively swiftly where significant updates are not required.

Next Steps

The next job for CEN and Cenelec will be to prepare a joint work program indicating the responsible technical bodies for each standard and a timetable for the execution of the requested standardization activities in line with the deadlines.

They have until 28 May to submit a work program for both the MDR and IVDR standards.

In addition to reporting progress annually to the commission, the standards bodies must submit their first annual report to the commission by 16 April 2022, and then by 31 October every year. They must provide the commission with the joint final report by 30 June 2024, and promptly report any “major concerns relating to the scope of the standardization request.”