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European Regulatory Roundup, August 2021: New Documents, A Busy Agenda And Thorny Issues

by Amanda Maxwell

August is the traditional holiday season in the EU, and output from Brussels, in particular, tends to reduce significantly. But with the MDR and IVDR center stage, it has remained relatively busy.

While August may not have witnessed the *same document deluge as In July*, it has nevertheless remained eventful in EU device regulatory circles.

During the month, three new guidance documents were issued by the Medical Device Coordination Group (MDCG). *One was on repackaging and relabeling rules for importers and distributors*, which impact those operating under the Medical Device and IVD Regulations. Article 16 of the MDR and IVDR explains how importers and distributors may need to take on the responsibilities of manufacturers under certain circumstances, but even if they do not, there are still strict requirements to ensure ongoing compliance of these devices with the MDR and IVDR, particularly in the area of information supplied, translation and repackaging.

In the IVD area, meanwhile, one of two new guidances explains how *Notified Bodies Assessing High-Risk IVDs May Sometimes Need To Pause Product Reviews*. The reason notified bodies may need to pause product reviews for high-risk IVDs is linked to expert panel review for these or similar products.

Also in the IVD area, the MDCG published *guidance on performance evaluation of COVID-19 tests*. This is for immediate use in the context of the current IVD Directive in addition to being relevant in the context of the forthcoming IVD Regulation, not least because the performance of COVID-19 tests circulating on the EU market has been harshly criticized. The EU's IVD Regulation and its much stricter requirements are still eight months away.

What Is On Post-Vacation Agenda?

On the return from the traditional break, the European Commission has a number of high-profile objectives on its agenda. These include seeing key standards, *especially for risk management (EN ISO 14971) and quality management systems (EN ISO 13485)*, published as harmonized standards at the earliest possible opportunity.

So far, *only five standards have been harmonized in the context of the MDR and four under the IVDR*. But the standards bodies have accepted a 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.

The EU also expects a *flurry of new implementing acts* between its post-August return and the end of September in the areas of: common specifications for Annex XVI products without and intended medical purpose; and more detailed arrangements for the Eudamed medical device database. Under the IVDR, implementing acts are expected by year end to: facilitate the EU reference laboratories (EURLs) fulfilling their tasks; set up fees for EURLs; and establish common specifications for certain IVDs in class D.

New Notified Body

In other EU news French notified body, *GMed, had been designated under the IVDR*. This brings the total number of IVDR notified bodies to six. The latest designation comes with just nine months to go until the regulation fully applies from 26 May 2022.

Thorny Questions

But while these new documents and measures all help with implementation of the new regulations, there are issues that could seriously hamper progress. Politically, the failure of *the Swiss-EU MRA* is going to have far-reaching consequences for manufacturers on both sides, not least in the area of authorized representatives and labeling.

And from a high-level regulatory point of view, *the impasse over remote auditing* combined with the continued COVID-19 pandemic threatens the timely implementation of both the MDR and IVDR.

UK

And in other news, and despite the huge task ahead in implementing new regulations, the UK's Medicines and Healthcare products Regulatory Agency is to lose 20% of its staff in post-Brexit cost-cutting plans.

For last month's round up, see: *European Regulatory Roundup, July 2021: First Expert Panel Opinion Hits Snag Amidst Document Deluge*

Rank	Title
1	*The Unintended Consequences Of The Swiss/EU Medtech MRA Failure*
2	*EU Prioritizes Risk Management And Quality System Standards Now Legal Basis In Place*
3	***New MDR And IVDR Implementing Acts Due Imminently***
4	***UK Regulator To Lose 20% Of Staff In Post-Brexit Cost-Cutting Plans***
5	***European Regulatory Roundup, July 2021: First Expert Panel Opinion Hits Snag Amidst Document Deluge***
6	***Repacking And Relabeling Devices: New EU Guidance For Importers, Distributors And Notified Bodies***
7	***Medtech Sector Keeps Lobbying European Commission As Remote Auditing Becomes More Urgent***
8	***EU Puts Out Urgently Needed Guidance To Tighten COVID-19 Test Standards***
9	***GMed Designated Under EU IVD Regulation***
10	***Notified Bodies Assessing High-Risk IVDs May Sometimes Need To Pause Product Reviews***