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European Regulatory Roundup February 2022: Major Push Now On IVD Regulation Preparedness

by Amanda Maxwell

With three months to go until IVDR date of application, the European Commission is pushing hard for a more solid implementation structure. In the UK, meanwhile, industry is concerned at the slow rate of progress in the development of new medtech regulations.

UK medtech regulatory news was under the spotlight in February. Industry association, ABHI, called for more certainty about ongoing progress at the UK regulator, the MHRA, on the new medtech regulations. *Concerned about progress and about the loss of many well-respected staff* at the agency, it is collating industry views to create unique position paper on individual topics which it intends to use to provide input on the future secondary legislation that will be needed to flesh out the primary Medicines and Medical Devices Act (MMDA) 2021.

Notified Body Progress Stalled

Who would have expected that in the nine months running up to the 26 May date of application of the IVD Regulation that no new notified bodies would have been designated besides the six already listed in August 2021?

Now, with just under three months to go, the only names featured on the European Commission's Nando webpages of designated bodies are: BSI (Netherlands); DEKRA Certification (Netherlands) DEKRA Certification (Germany); GMed (France); TÜV Rheinland LGA Products (Germany); and TÜV-SÜD Product Service (Germany).

Concerned by the shortfall in notified body capacity, in early February *the European Commission called*, in the context of its updated *Joint Implementation And Preparedness Plan for the IVDR*, for "further reflection to identify and concretely address root causes of lacking notified body capacity."

It has invited its Medical Device Coordination Group to find solutions that could help secure more notified body availability by the IVDR date of application, and has demanded a particular focus on avoiding delays in the notified body designation process.

The plan also set out where limited resources should be focused in the short term to ensure delivery of the key essential and high-priority actions needed for the IVDR implementation.

New Implementation Documents

Many new documents supporting the implementation of the IVDR continued to be issued in February.

The latest documents, which come on top of an already *very busy three months of IVDR-related publications*, focus on clinical evidence and on *how notified bodies must assess the highest risk IVDs* which fall into class D and are subject to additional testing criteria, including batch testing by an EU reference laboratory (EURL). The guidance explains in detail what is required in the agreement between the notified body and the manufacturer, and how a EURL should be chosen

The *31-page document, MDCG 2022-2*, on clinical evidence for IVDs underlines that performance evaluation should be regarded as a continuous process to generate and maintain the clinical evidence needed to support an IVD's intended purpose.

Common Specifications

Also in February, the commission also published the *first draft Implementing Regulation for common specifications* which would apply to the highest risk, class D, IVDs in the context of the IVDR. It is proposing an unexpected two-year gap until these common specifications, detailed technical specifications, will be mandatory.

While the regulators aim to adopt the text by the end of March, with the new Implementing Regulation entering into force 20 days later, the new common specifications are not due to become mandatory for a further two years, i.e in April 2024, when the new Implementing Regulation fully applies. Interested parties have until 9 March 2022 to comment on the proposed text.

Legacy Devices

Separately, focusing now on medical devices rather than IVDs, *new guidance sheds light on the type of auditing notified bodies need to do for legacy products* certified under the former Medical Devices Directive or Active Implantable Medical Devices Directive and how they may best manage these duties alongside responsibilities to perform MDR audits.

It also talks of what notified bodies must do when they decide to couple MDR audits and legacy

product surveillance audits.

Virtual Manufacturing

And in an interview that proved popular with our readers in February, Elisabethann Wright, partner at Cooley law firm, explained why *the scale of responsibilities for a virtual manufacturer* under the EU's new Medical Device and IVD Regulations may deter many companies from taking on this role.

MDR and IVDR requirements applying to a virtual manufacturer are the same as for a manufacturer and, in addition to increased requirements relating to technical file submissions, virtual manufacturers must fulfil post-market surveillance and vigilance activities. There are liability considerations too.

The EU Innovative Health Initiative

In further news which admittedly is European rather than regulatory, MedTech Europe's Patrick Boisseau explained how manufacturers can get involved in new cross-sectoral medtech/pharma projects in the context of the *EU Innovative Health Initiative* that are predicted to revolutionize European healthcare innovation. He described this as "the first time that the medtech industry is being considered as critical for the deployment of health care delivery in the context of EU research and funding programming. We now hope to be able to deliver truly integrated solutions by joining forces with the pharma industry."

For last month's round-up, and more news of the implementation of the MDR and IVDR, see our top piece for January: *European Regulatory Roundup January 2022: EU's Year Gets Off To Highly Productive Start*

Top 10

The following is a list of the 10 most popular EU regulatory pieces in February 2022:

Rank	
1	***European Regulatory Roundup January 2022: EU's Year Gets Off To Highly Productive Start***
2	***UKCA Marking Debate Moves To Next Level: All Eyes On The MHRA***
3	***Time To Address Root Causes Of IVDR Notified Body Capacity Shortfall, Commission Says***
4	***IVDR Clinical Evidence: EU Guidance Document Spells Out What Is Required***