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EU Regulatory Roundup, October 2023: Notified Bodies Fire On All Cylinders To Manage Challenges

by Amanda Maxwell

Are too few manufacturers making their applications to notified bodies right now or are they applying but being turned away? Tensions are rising as notified bodies try to manage their workload and industry feels increasingly under stress.

October saw evidence of the struggles that notified bodies are experiencing in managing their workloads. They are calling for manufacturers to apply to notified bodies now so that they can audit products in a timely and manageable way.

But manufacturers, and especially SMEs, who have suffered the impact of a challenging and piecemeal implementation of the Medical Device and IVD Regulations, are arguing that notified bodies still do not have sufficient capacity to take on more work, leaving them stranded.

Indeed, our most popular article, *Manufacturers' Delaying Tactics With Notified Bodies Threaten To Undermine MDR Extensions*, created considerable controversy on social media last month.

The Debate

The piece highlighted that the number of manufacturers who have taken the necessary preliminary steps towards compliance with the MDR for their legacy products and applied to a notified body remains lower than had been hoped by notified bodies.

The testing and certification organizations argue they need to spread and manage the volume of applications ahead of the new MDR deadline and to work at full speed now while they have capacity to space the workload out.

But reports suggest that they are encountering an increasingly common trend among

manufacturers who, having made applications in time, are then asking to delay submitting their quality system and technical documentation for some three years, i.e., not until late on towards the deadline for compliance. This is what director of the TEAM-NB notified body association, Françoise Schlemmer, told Medtech Insight in October.

In response, Oliver Bisazza, CEO of Medtech Europe, questioned on LinkedIn where the free capacity is?

He has heard from national medtech associations that some SMEs are unable to access an MDR-designated notified body due to capacity issues.

Erik Vollebregt, partner at Axon Lawyers, said, meanwhile, that manufacturers do not intentionally plan delays but struggle with "a system that isn't working or anyone now and has not been for some years now."

Notified Body Designations

The notified body capacity issue is critical to how implementation will unfold and to the management of the industry through the implementation timelines.

Progress on the designation of new notified bodies continues to inch forwards; the European Commission predicted in mid October that there would be *43 notified bodies under the MDR and 12 under the IVDR* by the end of November.

Then, at the end of the month, the second Finnish organization, Sertio Oy, became the *12th organization to be designated under the IVDR*. Medtech Insight understands one more MDR notified body listing is now imminent and another two MDR notified body announcements are in the wings.

Notified Body Call To Action On IVDR

In another bid to persuade manufacturers to make their applications to notified bodies sooner rather than later, this time in the context of the IVD Regulation, TEAM-NB issued *a call to action to diagnostics manufacturers to comply with the regulation now* or risk creating a bottleneck situation further down the line which could impact the successful implementation of the IVDR and cause products to be removed from the market for compliance rather than safety reasons.

Where applications are submitted "in good time," notified bodies have "jointly committed themselves to make time and resources" available to process the device applications and complete the conformity assessments being mindful of the implementation dates." But where they are not, TEAM-NB made it clear that there are no such guarantees.

For class D devices, notified bodies strongly recommended applications are submitted no later

than the end of 2023 to allow technical documentation assessments to start in time.

Notified Body Capacity And Availability

Against this uncertain and unsettled background, and with concerns over the impact of the MDR and IVDR on innovation in the EU, a new notified body initiative, *NoBoCap*, is being set up to ensure that innovative health solutions can reach the EU market more swiftly and efficiently.

NoBoCap wants to ensure that augmented capacity at notified bodies will shorten the go-to-market time and increase the cost-efficiency of taking new innovative technologies to market.

This is among the schemes that the EU is developing to address the challenges that have arisen in getting innovative products through the regulatory labyrinth because of increasingly complex MDR and IVD requirements, and because of lack of readiness of some key features among the new regulations, leading companies to choose launching innovative products in other markets, such as the US, first.

The NoBoCap project aims to increase the number of notified bodies, streamline the conformity assessment process, improve communication between notified bodies and market operators, and ensure notified bodies have the necessary expertise and resources to provide high-quality services.

It also foresees a community of clusters, innovation hubs and partners in Europe for innovators to provide a voice for start-ups and SMEs, as well as a source of expertise for the regulatory ecosystem which has become so complicated it is now frequently referred to as a "regulatory lasagna."

Eudamed

The news that has created the most shock in October relates to proposals for the *launch of EU's medical device database, Eudamed,* to be postponed by an additional two years. This is on top of historic delays to this cornerstone of the EU's medtech regulations. The lack of readiness of the module on clinical investigations and performance studies is being blamed for the delay. Stakeholders are reported to be "speechless" and "stunned" at the proposals for such a long delay.

AI And Regulatory Sandboxes

AI is a topic that is growing in magnitude, even just within the EU medtech regulatory space. Our articles on this topic are becoming increasingly popular, and we will dedicate a separate special monthly round to this topic alone, to follow shortly.

Other key EU documents

Further key EU documents published in October include:

- Guidance *on medical device software (MDSW) intended to work in combination with hardware* or hardware components, *MDCG 2023-4*. This examines and provides clarifications on which specific regulatory considerations apply when the hardware or hardware component incorporating the data collection element (camera, electrical/optical sensors etc.) is a medical device or an accessory to a medical device.

- Commission Delegated Regulation (EU) 2023/2197 as regards the assignment of Unique Device Identifiers for contact lenses

Top 10

The top 10 EU regulatory stories for October are listed below:

Rank	Title
1	***Manufacturers' Delaying Tactics With Notified Bodies Threaten To Undermine MDR Extensions***
2	***How "Regulatory Sandboxes" Offer Hope For New Technologies That Don't Fit The Regulatory Mold***
3	***EU Medtech Sector 'Stunned' And 'Speechless' At Proposals For Further Delays To Eudamed Database***
4	***Explaining The EU Rules For Device Software Working With Hardware***
5	***NoBoCap: The EU's Solution To Its Medtech Notified Body And Innovation Crisis?***
6	*Medtech Could Help Address EU's Worsening Healthcare Workforce Crisis*
7	***Commission Predicts 43 Notified Bodies Under MDR And 12 Under IVDR By End November***
8	***Take Steps Now To Comply With IVDR Now Or Face The Consequences, Industry Told***
9	***How The EU's AI Act Offers Regulatory Sandbox Solutions For Medtech Manufacturers***
10	***Biotech Industry Advised To Prepare For Incoming EU AI Regulation***

- For September's top 10, see: *EU Regulatory Roundup, September 2023: Dismantling Regulatory Barriers To Medtech Innovation*