MEDTECH INSIGHT
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EU Regulatory Roundup, November 2023: Notified Body Advances But Sector Still Demands System Rethink

by Amanda Maxwell

There is currently a melting pot of ideas concerning the future of the EU's medtech regulatory system due to its shortfalls. All the while progress is being made, especially in the area notified bodies.

EU medtech industry association, MedTech Europe, published *a position paper calling for reform of the medtech regulatory system* during November.

The document is part of a growing crescendo of calls for remedying problems associated with the MDR and IVDR.

The paper highlights how "at least 17% of today's IVDs and 20% of the MD product portfolios are expected to be discontinued in Europe," due to the expectation that costs of the transition to the IVDR or MDR outweigh product revenue, particularly among SMEs.

One of its key points is that an unpredictable process makes it "highly difficult" for medical technology companies to adequately plan, prepare, and allocate resources effectively.

Among other things it wants to see a single, dedicated structure to oversee and manage the regulatory system, including the designation and oversight of notified bodies, with the authority to make system-level decisions. It is also calling for the introduction of an innovation principle that swiftly connects the latest medical technologies to European patients and health systems through dedicated assessment pathways and early dialog with developers.

Regulators are no strangers to these arguments and some of the shortfalls with the MDR and IVDR were discussed at the *Council of the EU EPSCO meeting* on 30 November. There, EU member states called for the May 2025 deadline for high-risk IVDs under the EU's IVD Regulation to be

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postponed, as well as action to accelerate the date by which the Eudamed medical device database becomes fully functional in the context of both regulations.

Commission Figures Highlight Scale Of Challenges

Figures published by the European Commission in November supported the urgency for action to improve the implementation of EU medtech rules. While there has been a leap in the number of conformity assessment certificates issued under the MDR as of the end of June of 32% on the previous quarter's figure, the number of applications has also jumped by 22%, adding to the numbers of products that need reviewing.

Indeed, the number of outstanding applications and the length of time they are likely to need to be processed indicates ongoing challenges ahead for notified bodies certifying all devices – even within the new deadlines under the *MDR*.

When it comes to the IVDR, the figures show that, proportionately, the situation is expected to be even more challenging.

Notified Body Appointments

There have been three new notified body appointments during November, with the European Commission now hinting that another is imminent in December. The following were designated last month under the MDR:

- *Notice Belgelendirme, Muayene ve Denetim Hizmetleri Anonim Şirketi*, based in Istanbul, Turkey.
- *UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San .ve Tic AS*, based in Ankara, also in Turkey.
- *Scarlet NB*, based in the Netherlands, which specializes in certifying medical software.

These appointments came hot on the heels of *two designations under the IVDR in October*.

In addition to news about the recent appointments, the notified body association, TEAM-NB, has *highlighted how far small manufacturers are behind large manufacturers in submitting their technical documentation* to notified bodies under the MDR and IVDR. In all, 50% of large manufacturers have already submitted technical documentation for 75-100% of their portfolio, compared with just a quarter of SMEs having reached this stage.

AI

With AI is a *regular and popular feature in medtech regulatory news*, the medtech sector remains a

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key contributor to discussions on the EU's AI *Act[YA2]* .

MedTech Europe's director for international affairs, Jesús Rueda Rodriguez, spoke out at a recent meeting of the European Medicines Agency (EMA) *on how other relevant regulations, including medtech, should be a main priority for the European Medicines Agency* when developing its guidance to avoid "significant confusion" going forward.

Other Newsworthy Topics

- In other news:

- A *recent Elemed report on gender distribution* shows a more equal number of women are promoted into managerial roles in the medtech industry compared to other industries. Yet, relative to the total workforce, more men appear to be employed in senior leadership positions, particularly at the director/VP level. There are also major differences in the number of women in different regulatory leadership roles around the globe.

- Austrian company, *Croma-Pharma, received a conformity assessment certificate for its hyaluronic acid-based filler,* Saypha RICH, the first Annex XVI non-medical product to be certified by a notified body, in this case TÜV SÜD of Germany, under the MDR.

- *European Commission data* now show there has been a 25% increase in demand for notified bodies to assess Annex XVI products.

- Two medical device trade associations, MedTech Europe and COCIR, issued a joint statement calling for the *commission's proposed Data Act* to reflect "a balanced and proportionate future-proof framework that preserves incentives for industry to invest in methods of generating value through data." They also requested that the obligation to share data under the Data Act "should in no way contradict or compromise the obligations for medical technologies required under other EU legislation."

Top Ten

The following table highlights the 10 most popular reads among Medtech Insight's subscribers:

Rank	Title
1	***Will Industry Succeed Now In Thrusting Comprehensive Reform Medtech Regulations To Top Of EU Agenda?***
2	***Certificates Issued Under EU's Medical Device Regulation Leap By***

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	Nearly A Third In Just Three Months
3	***First Dermal Filler CE-marked Under Annex XVI Of The EU's Medical Device Regulation***
4	***Twists And Turns Ahead For Medtech In Europe As AI Dominates October Regulatory Debates***
5	***Turkey Notches Up Two Notified Bodies Under EU's Medical Device Regulation In Two Weeks***
6	***Notified Body Designations Under The MDR Hit The 40 Mark With New Turkish Designation***
7	***Notified Body Training Session Highlights Need For More Support For SMEs***
8	***Latest Notified Body Designated Under the EU's MDR Is A Software Specialist***
9	***Medtech Industry Weighs In On EMA's AI Regulation Proposals***
10	***Shattered Glass Or Broken Ladder: Is The Medtech Industry Becoming More Equal For Women***

- For October's roundup, see: *EU Regulatory Roundup, October 2023: Notified Bodies Fire On All Cylinders To Manage Challenges*

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