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EU Regulatory Roundup January 2024: Regulatory Reform Under Spotlight As AI Act Fallout Scrutinized

by Amanda Maxwell

As 2024 began, the clamor of voices calling for regulatory reform, including a new EU governance structure for medical devices, had grown to fever pitch. Hot news in January shows how progress is being made. But the likely imminent adoption of the EU's AI Act could present new issues.

The most exciting news for the medtech industry in January was the proposal by the European Commission to extend the transition periods of most devices under the IVDR Regulation and to see most parts of the Eudamed medical device database implemented ahead of completion of the entire database.

The news came on 23 January, along with a proposal for a requirement for manufacturers to give prior notice before interrupting the supply of certain critical medical devices and IVDs.

The document is testimony to the power of lobbying by the medtech industry and other medtech stakeholders, including representatives of member state competent authorities who spoke at the at the EPSCO Council meeting on 30 November 2023. (Also see "*Member States Want Action Over High-Risk IVDs And Eudamed Medical Device Database*" - Medtech Insight, 1 Dec, 2023.)

Top experts around the EU medtech industry had explained in Medtech Insight's *2024 horizon-scanning piece* how these and other matters were among the most challenging uncertainties they faced as they headed into the start of the new year.

Their statements are based on experience and some insights into facts and figures. But *more accurate data is now being collated* through the EU's *new medtech regulatory dashboard* commissioned by the commission's European Health and Digital Executive Agency.

The experts also commented on how robust the MDR and IVDR were in their view to cope with the changing world of medical technology.

MedTech Europe's Oliver Bisazza had spoken of deficiencies in the system leading to "shortages, blocks to innovation, and a spiraling burden" on industry today. While Sue Spencer, head of IVDs at Qserve Group described 2023 as "the most unpredictable in her 30 years working in the regulated medtech space.

AI Act

Bayard Consulting's Lionel Tussau, meanwhile, spoke about the potentially conflicting vertical (MDR, IVDR) and horizontal European regulations (e.g. on AI and sustainability).

A glance at Medtech Insight's January pages demonstrated why his concerns are so critical. While there is some *good news for start-ups and SMEs* from what we know of the document leaked so far, it also seems that regulatory overlap with the MDR and IVDR is likely to persist in the finalized AI Act text and additional guidance documents will potentially be needed in future to provide clarification.

The Act is scheduled for adoption now; some last-minute concerns raised by Germany, France and Italy look unlikely to derail its progress.

The European Commission has also launched the *EU Artificial Intelligence Office*, its governance structure for overseeing implementation of the EU AI Act. This is one of several initiatives readying the EU for the introduction of the new rules and providing a structure to support EU innovation in this area. There is also, for example, an innovation package introducing several wide-reaching initiatives to provide key resources encouraging innovation from the start-up and SME community, including in the health area.

Clinical Evaluation Guidance And IVDR Project

In other news, a *critical new clinical evaluation guidance document was published which has taken industry by surprise* and which is still causing some discomfort in the sector as to its correct interpretation of the EU's MDR rules.

Nevertheless, the latest interpretation of the permissible use of equivalence in clinical investigations promises to simplify clinical evaluation costs and time. The headline news is that contracts are never required when a company claims equivalence of its products with another firm's device, according to the latest guidance document, MDCG 2023-7 "Guidance on exemptions from the requirement to perform clinical investigations pursuant to Article 61(4)-(6) MDR and on 'sufficient levels of access' to data needed to justify claims of equivalence."

And in separate news, the Medical Device Coordination Group (MDCG) has updated its *Joint*

Implementation and Preparedness Plan for the IVDR, highlighting its priority projects for 2024. Some two-thirds of the nearly 50 projects set out in the original document in 2021 are now marked as complete.

Falsified Medical Devices

One article that attracted a lot of interest in January looked at *whether the current EU medtech regulations are sufficient to address the problem of falsified medical devices*. There were varied and conflicting responses to this question and it seems that there is a much low level of rigor applied to devices than to falsified medicines.

Crowded Regulatory Agenda

As if there is not already enough material for the medtech sector to contend with, there is a myriad of other EU regulations that are now impacting the device area and which need monitoring.

In January we learned that the *EU Data Act is creating new complications* because manufacturers of connected devices will now be required to give users direct access to data and share it with third parties, including competitors.

And the *provisionally agreed EU Product Liability Directive* is set to place the burden of proof on medtech companies and extend the latent damage clause from 10 to 25 years. Both updates will have financial and operational impacts on the medtech industry.

Meanwhile, Medtech Insight also spoke with two key experts on how *further work is needed to address the interplay between the cybersecurity legislation and the MDR*.

Top Ten

The following were the 10 most popular EU medtech regulatory articles in Medtech Insight in January:

Rank	Title
1	*Is EU Medtech Regulatory Reform On The Horizon? Seven Expert Perspectives Entering 2024*
2	*EU Regulatory Roundup, December 2023: Sector Poised For A Rethink*
3	*Surprise Revelation In EU Guidance On Equivalence In Investigations Will Save Time And Money*
4	*Early Version Of EU's Medtech Dashboard Promises To Reflect A Regulatory Data Goldmine*
5	*European Member States Call For Direction On Falsified Medical Devices*