MEDTECH INSIGHT
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EU Regulatory Roundup, March 2024: Busy Agenda In Broad Range Of Key Areas

by Amanda Maxwell

March was an important month for EU medtech regulation with an interesting spread of news relating to the Medical Device and IVD Regulations, the Batteries Regulation, the Artificial Intelligence Act and more.

The good news for the medtech sector is that *European harmonized standards are to be free* of charge for the first time. To date, standards have been priced at a few hundred Euros per copy, and several might apply just to one product. It is expected to take a while before the standards organizations can provide them free of charge.

On the same topic, a *few new harmonized standards have been published*. The not so good news is how slowly these documents are being harmonized and adopted in the context of the Medical Device and IVD Regulations. A harmonized standard is one that manufacturers can use to claim compliance with the general safety and performance requirements of the regulations with which the standard is linked.

Looking to other key documents supporting the implementation of the MDR and the IVDR, the European Commission's *updated list of ongoing and planned guidance development* showed that the medtech sector can expect 19 new guidance documents to be endorsed by the commission's Medical Device Coordination Group by the end of June and nearly 50 by the end of 2024. This is testimony to the level of work needed to support the implementation of the two regulations.

Notified Bodies

Turning to the rate of implementation of the MDR and IVDR, there is evidence that notified body capacity has increased significantly and is showing results in terms of processing the backlog of applications. Despite such positive-sounding reports, there are persistent concerns about notified body capacity to manage the MDR and IVDR deadlines.

Figures presented in the *Notified Bodies Survey on Certifications and Applications (MDR/IVDR)*, In the four months to the end of October last year, show there had been a 44% growth in the number of conformity assessment certificates issued by notified bodies in the context of the MDR and 40% under the IVDR as compared with the totals awarded as of June 2023.

Another piece of good news was the arrival of a new notified body under the MDR, *RISE Medical Notified Body*, the second such organization designated in Sweden.

Batteries

Looking to other regulations that impact the medtech sector, news about the new EU's Batteries Regulation has been popular with Medtech Insight's readers. Following the publication of news at the end of February that the *EU's Batteries Regulation is now applicable and of its compliance dates*, lawyers at Hogan Lovells spoke in detail about *how the medtech industry would be impacted*, and about the differences between the former EU Batteries Directive and this Batteries Regulation.

AI

The EU's AI Act (AIA) is an even more critical regulation that overlaps with medtech regulation. It has just one hurdle to cross before becoming EU law now it has been *signed off by the European Parliament*, but is already making big waves.

One of the big concerns for medtech, highlighted in a *position paper by industry association COCIR*, is that it could expose medtech companies to delays and lead to product removals due to overly onerous demands. The paper warns that the AIA could result in the EU in "extended certification procedures, increased development costs, prioritization of other markets, and diversion of resources from research and development."

MedTech Europe also published a series of recommendations to ensure "a clear and practical applicability" of the AIA to the medical technology sector. The trade association is alarmed that elements of the act's wording leave room for diverging interpretations among medical technology manufacturers and will lead to "confusion, inconsistency, and ultimately delays to the delivery of safe and effective products to patients and healthcare systems."

Again in the area of the AIA, Medtech Insight looked at the regulatory grey area around *clinical summarization large-language models* which help clinicians generate and summarize medical records.

Swiss/EU News

In other news, the Swiss and EU have begun negotiations aimed at renewing the close trading relationship and barrier-free mutual market access between the two markets. Local industry

association Swiss Medtech said it "emphatically" welcomes this, while urging the Swiss Federal Council to press ahead with "the long overdue MRA update."

German Interpretation Of EU Rules

In Germany, meanwhile, the Hamburg court looked at the appropriate risk classification of a teledermatology software platform, Dermanostic, which the company had placed in class I, the lowest risk class.

The case is expected to rumble on and potentially a higher court.

It has also generated a heated online debate over whether the product should even be regulated as a medical device which is focused on the interpretation of classification rule 11 in the MDR.

This case may have wider-reaching implications for other health-related software apps.

Top Ten

The following table shows the most popular EU regulatory stories in the month to 26 March 2024:

Rank	Titles
1	*Harmonized Standards Under Medical Device and IVD Regulations Trickle Through*
2	*Great News For Medtech Industry: European Harmonized Standards To Be Free-Of-Charge*
3	*EU Batteries Regulation: Who Is Exempt And Why New Rules Could Force Product Redesign*
4	*Could AI Act Lead To Reduced Access To Medical Technologies?*
5	*40% Plus Growth In Notified Body Certificates Issued Under EU Medtech Regulations*
6	*AI Clinical Summarization Tools Sit In 'Regulatory Grey Area', Experts Warn*
7	*German Row Over Classification Of Telemonitoring Software Looks Set To Rumble On*

8	***European Parliament Adopts AI Act, But Success Hangs On The AI Office***
9	***New Swedish Notified Body Designated Under The EU's Medical Device Regulation***
10	***MedTech Europe Calls For Swift Answers In Areas Where AI Act Threatens MedTech***

- For last month's top 10, see: *EU Regulatory Roundup February 2024: Progress, Trepidation And Promises*.