MEDTECH INSIGHT
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EU Regulatory Roundup February 2024: Progress, Trepidation And Promises

The European Commission Is Ready To Do Some Stock Taking As Screws Tighten On EU Medtech

by Amanda Maxwell

Good news in February for market transparency and for more time for the regulation of IVDs. But medtech is watching the likely impact of the AI Act and Batteries Regulation with apprehension.

The big news during February has been the European Commission's pledge to *take stock of challenges* in the implementation of the Medical Device and IVD Regulation and listen to the views of stakeholders.

It has promised a public consultation on the MDR and IVDR in the third quarter of 2024; its aim is to adopt a "targeted evaluation" during the fourth quarter of 2025.

The implementation of the two EU rules has been far from smooth, not least given some safe products have had to unnecessarily be withdrawn from the market because of challenges and failures created by the system itself.

During its review, the commission will assess whether the current rules are: effective, efficient and proportionate; meet current and emerging needs; align with other actions; and have added value.

Two Pivotal MDR/IVDR Measures In Wings

In other significant news, the final sign off is now within sight for two important measures, one impacting the entire medtech industry and the other the IVD sector. The news follows the Council of the EU's *adoption of the European Commission's 23 January 2024 proposal*.

The first measure is the proposal to *speed up the launch of the Eudamed electronic database*, with five out of six of the modules now due to become mandatory in late 2025.

The five will require registration in the following areas: actors (companies, authorized representatives etc); unique device identification (UDI)/devices; notified bodies and their certificates; market surveillance/post-market surveillance and vigilance.

The sixth module, covering clinical investigations and performance studies, is further behind in development and will get underway separately to the other five when it is ready.

The second important measure relates to further extending the transition period for certain IVDs an additional 18 months or so. The newly proposed extensions of existing transition periods will mean the following deadlines: class D (high risk), 31 December 2027; class C, 31 December 2027; class B, and A placed on the market in a sterile condition, 31 December 2029.

Both these measures have been introduced as part of a *string of amending regulations* to the original MDR and IVDR.

Instructions For Use

The medtech industry considers that current EU rules require too many paper versions of the electronic IFU, an especially onerous and expensive task given the demand for multiple language versions in a marketplace where there are 24 different official languages.

During February, therefore, MedTech Europe, along with 11 other medtech industry associations put together *a position paper* asking the European Commission's Medical Device Coordination Group to *consider extending the scope of products that are eligible to be provided with eIFU* as a priority for 2024.

The AI Act

All eyes have been on progress of the EU's AI in February and how the final text, which represents the world's first set of comprehensive AI rules, would impact the medtech sector.

On 2 February member states at the Council of the EU, *voted to approve* the compromise text that had already been accepted by the Council of the EU and the European Parliament in December 2023. Then, on 13 February, the two European Parliament committees tasked with examining the proposal *also agreed to it*.

The Parliament will need to adopt the text in plenary next, expected in April, before final sign off by the Council of the EU.

This will be a significant achievement. The AI Act was first proposed by the European

Commission in 2021 and has been subject of fierce debate.

But it represents another set of hurdles for medtech manufacturers who now, in addition to the Medical Device and IVD regulations, will also need to comply with design and development requirements under the AI Act under which they are considered high risk.

Just as with the MDR and the IVDR, the full impact of the new Act will only emerge once the implementation tools are in place.

Indeed, a paper published in Nature Portfolio Journal's Precision Oncology highlighted *how tangible solutions are needed to address regulatory challenges*. They argue how it is essential to optimize safe approval pathways, including adaptations to the regulatory approval process for AI-enabled medical devices and improvements for post-market surveillance to allow for adaptive AI-enabled devices.

Batteries Regulation

Another EU regulation that will impact the medtech industry and which must be implemented alongside the MDR and IVDR is the Batteries Regulation which became applicable on 18 January 2024.

This regulation could prompt the need for medical device design changes.

Most medical devices featuring batteries will need to comply between August 2025, when extended producer responsibility requirements become mandatory, and early 2027, when requirements come into play for the removability and replaceability of batteries.

Key Meetings

Looking forward, there are some key big *EU regulatory meetings* over the next four months. Brussels, Berlin and Vienna are among the host cities that will be welcoming large numbers of medtech regulatory experts.

For last month's roundup see: *EU Regulatory Roundup January 2024: Regulatory Reform Under Spotlight As AI Act Fallout Scrutinized*

The Top 10

Below is the list of the top 10 articles among Medtech Insight's subscribers published in February 2024:

Rank	Title
1	*EU Artificial Intelligence Final Text Confirmed By Parliament*

	Committees
2	Medtech Industry Produces Evidence In Bid For Updated eIFU Rules In Multilingual EU Marketplace
3	European Commission To Cast Its Own Critical Eye Over MDR And IVDR
4	EU AI Act Final Text Approved By European Member States
5	Council Of EU Agrees To Speedier Launch Of Medtech Database And Greater Transparency
6	New EU Regulation Extending IVD Deadlines Expected In April
7	The EU's New Batteries Regulation: When And How Its Requirements Will Impact Medtech
8	Five Key Meetings Offering EU Medtech Regulatory Insights Over Next Four Months
9	Experts Press For New Artificial Intelligence Regulatory Approaches
10	Implementing The MDR And IVDR: Checkered History Signposts Need For Revised Approach