MEDTECH INSIGHT
CITELINE COMMERCIAL

28 Feb 2023 | **News**

EU Regulatory Round-Up, February 2023: EU Closes In On Adopting MDR Proposal

by Eliza Slawther

The European Commission's legislation to extend compliance deadlines for legacy devices under the Medical Device Regulation has remained top of the agenda for the second month running after it was given the formal go-ahead by the European Parliament in February.

The EU is just a stone's throw away from formally adopting laws that will postpone Medical Device Regulation compliance transition deadlines and remove the sell-off period for both the MDR and In Vitro Diagnostics Regulation after a 16 February vote by the European Parliament *in favor of the proposal*, which was published in early January.

The new measures are intended to go some way towards addressing capacity issues being experienced by notified bodies, and the speed at which the legislation has been pushed through the EU system is testament to the pressures created by the implementation of the original MDR plans. However, the proposal is yet to be formally adopted by the Council of the EU. It is anticipated that the amending regulation will be published in the Official Journal of the EU in mid-March.

While MDR updates have been the most closely followed and anticipated announcements of 2023 so far, these changes are unlikely to solve all the challenges posed by the implementation of the MDR.

One of *Medtech Insight's* most-read articles among subscribers this month was an *expert interview* in which medtech regulatory lawyer Erik Vollebregt detailed exactly what the amendments mean, and where their limitations lie.

Vollebregt pointed out that the commission's extension of the MDR compliance deadlines do not provide for a blanket extension of time for all manufacturers and said implementing the amendment will be "messy."

Clinical Evidence Concerns

More stringent clinical evidence requirements for high-risk devices under the MDR when compared to the former Medical Devices Directive is one aspect of the regulation that will not be changing once the new legislation is adopted.

This has proved a sticking point among industry, particularly for manufacturers and health care professionals in the rare disease and pediatric fields. An expert interview entitled "*How Can The EU Get Clinical Evaluations For High-Risk Devices Right?*" was the fifth most popular EU regulatory article among *Medtech Insight* subscribers in February.

In this article, Alan Fraser, Professor of Cardiology at Cardiff University and chair of the BioMed Alliance in Europe's medical devices task force, told *Medtech Insight* how greater transparency around the outcomes of clinical investigations could improve patient safety and empower physicians to make better treatment choices.

On the penultimate day of the month, the European Medicines Agency's expert panel pilot *opened for applications from medtech companies* who wish to gain scientific advice on their clinical development strategies for certain high-risk devices in the context of the MDR.

Just 10 manufacturers will be selected during the pilot phase, during which fees for the advice will be waived. However, the scheme is expected to be launched in full next year for those who are either not yet in a position to apply or who are not accepted onto the pilot scheme.

AI And Data Regulation

While some of the debate and criticism around the EU's regulatory plans for digital products, artificial intelligence and data has been overshadowed by MDR developments in recent weeks, MedTech Europe *published its official stance* on the European Health Data Space towards the end of the month.

The trade body made several recommendations in relation to the scope of the MDR/IVDR and the EHDS/AI Act. Manufacturers should not have to undergo multiple conformity assessments, it argued. Instead, single conformity assessments should be undertaken by notified bodies listed under the MDR/IVDR.

UK Shaping Up Regulatory Structure

Developments from UK medtech regulator the Medicines and Healthcare products Regulatory Agency (MHRA) also proved popular among *Medtech Insight* readers in February. The new regulatory structure will be based on seven pillars, one of which is dedicated to IVDs.

According to diagnostics industry association BIVDA, there have been *encouraging developments*

in the IVD space from the MHRA, particularly around supporting innovation. However, the regulator should set out its intentions more clearly and collaborate with the US FDA and EU, BIVDA head of regulatory affairs Ashleigh Batchen told *Medtech Insight*.

If the UK is to attract more SMEs, its regulatory processes *should be simplified*, according to a UK medtech market access report, "Challenges and Opportunities for the UK HealthTech Industry." Many businesses rely on expensive external consultants to navigate the regulatory pathway, the report revealed, which can hinder companies from entering the market.

The new UK regulatory system is expected to apply from 1 July 2024, after the original date was extended by a year last October, but dates have yet to be confirmed formally.

Not all UK developments are likely to be welcomed by industry, though. The MHRA announced that *regulatory fees will increase* from 1 April, with the device registration fee set to increase 140% to £240 ($295).

Top 10 Articles In February 2023

The following table lists the most popular European regulatory articles among our subscribers in February 2023. They explore the themes mentioned above in significantly more detail.

Rank	Title
1	*EU Gives Final Thumbs Up To Altering Transition Deadlines For MDR Legacy Products*
2	*European Parliament Edges Closer To Adopting MDR Transition Proposal*
3	*Implementing The EU MDR Amendment: "Messy" And "A Lot To Figure Out On The Hoof"*
4	*Diagnostics Industry Helps MHRA Shape IVDs Roadmap As Part Of Future UK Regulation*
5	*How Can The EU Get Clinical Evaluations For High-Risk Devices Right?*
6	*When Is An IVD A CDx? EU IVDR Guidance Updated To Include Flowchart*
7	*UK MHRA's New And Increased Medtech Fees In Force in April*
8	*Industry Calls For Single Conformity Assessments To Cover EU MDR, EHDS And AI Act*
9	*Medtech SMEs Set Out Regulatory Needs As UK Advances Post-EU*

	System
10	*Another Notified Body Designation Coming Down The Line Under The EU MDR*