MEDTECH INSIGHT
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European Regulatory Roundup, December 2022: Repositioning The MDR For A Better Year In 2023

by Amanda Maxwell

2022 ended on as positive a note as could have been wished for in terms of setting the scene for a more effective implementation of the MDR. But has too much damage already been done?

As 2022 drew to a close, the European Commission, after much persuasion by all stakeholders in the medtech sector, came up with proposals intended to address some of the greatest challenges with the implementation of the Medical Device Regulation. This was mainly in a bid to prevent the unnecessary removal of even more medtech products from the EU market.

Its proposals, if enforced as expected in early 2023, will effectively change of the course of implementation of the MDR.

Council of EU Supports Commission Proposals

There was a flurry of activity on 8 and 9 December.

Following much speculation, the Council of the EU published *the European Commission's proposals* on 8 December.

These contained the detail of what the commission then put to *the meeting of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO)* meeting the following day.

Its mix of proposals were unanimously supported by the health ministers present at the Council of EU meeting, namely to:

1. Extend the MDR compliance deadline for legacy class III and class IIb products to 26 May 2027.

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2. Extend the MDR compliance deadline for legacy class IIa, and class I products needing the involvement of a notified body, to 26 May 2028.

3. Extend the validity of certificates issued under the former Medical Devices Directive and Active Implantable Medical Devices Directive if needed for legal and practical reasons (including for access to third country markets).

4. Remove the sell-off date of 26 May 2025.

Transitioning Between Certificates When There Are Gaps

The European Commission's Medical Device Coordination Group then issued, immediately after the 9 December meeting, its *MDCG 2022-18*: Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of an MDR certificate.

The position paper explains a way forward for such devices where, despite reasonable efforts undertaken by the manufacturer to obtain certification under the MDR, the relevant conformity assessment procedure involving a notified body has not been concluded in time. It explains what information a manufacturer or authorized representative needs to submit to the competent authority to apply for such products to remain on the market.

Competent authorities can agree to an extension of certificates for legacy devices on case-by-case basis. In general, the period must not exceed 12 months and the manufacturer's application for conformity assessment under the MDR should have been accepted by a notified body and a written agreement signed by the notified body and manufacturer.

The MDCG says the intention is to make use of Article 97 to provide a "legally sound, coherent, consistent and controlled" period of the non-compliance of devices which are impacted by the limited capacity of notified bodies and for "which no unacceptable safety concerns are identified."

MDR Implementation Woes Leave Littered Battlefield

This is a huge turnaround by the commission which has long resisted making further changes to the MDR date of implementation. But coming this late in the day, significant damage has already been done.

A glance at some of the news being published in the last month or so shows the casualties on the European battlefield. There are also moves by non-EU European countries, which can make their own medtech regulatory arrangements, to adopt new strategies that could further fragment the future of what was a European single market.

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Switzerland had already voted in late November to pursue proposals to accept FDA-approved medical devices. And as *Medtech Insight* went to press, there were suggestions that the UK is now considering a similar option.

Could we even be on the verge of seeing the EU, too, decide in 2023 to accept FDA-approved devices? There is little doubt that this topic will at least be on the agenda of high-level EU meetings next year.

There has been a turnaround in reports about medtech regulations in the lay press too.

The British Medical Journal, Channel 4 Dispatches and the International Consortium of Investigative Journalists have all alleged in the past that the EU's medtech regulations were too lax.

But now, news agency, *Reuters*, has *published a piece in mid-December* which highlights how the new, more stringent, EU medtech regulation "sows chaos" and how "a law created to stop one criminal company's actions 10 years ago now endangers patients' lives, including children, and European manufacturing sites."

This piece is measured and will strike a chord with everyone in the sector. It presents examples of critical devices, otherwise considered safe, being pulled from the market, companies struggling, doctors facing shortages of critical devices and innovation stymied, all because of the MDR.

MDR Seen As Necessary

But where there is seemingly a backlash now against the MDR because of the severity of the problems it has caused, Graeme Tunbridge, SVP global regulatory and quality, medical devices at BSI Group told *Medtech Insight* just ahead of the festive break, that the MDR is so much more than a reaction to the PIP breast implant scandal, as some are suggesting.

"We're still seeing manufacturers that fall short of having applied the regulations appropriately, and where this has been happening in the past, it will be picked up earlier with the MDR," he argued.

"The MDR will make a demonstrable improvement," Tunbridge added, and "manufacturers will be held to account."

2023

The sector is now waiting with bated breath to see the European Commission's legislative proposals to introduce the proposed changes discussed at the Council of the EU on 9 December. While they were promised for January, some reports suggest that they will not be ready until

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March.

There is speculation whether the action will be enough to put the EU on a better footing to prevent further devices being removed from the EU market. Will it result in a sufficiently wide bandwidth at notified bodies given the extra time proposed now beyond the current 26 May 2024 MDR final deadline for legacy devices?

The industry will also be monitoring closely developments regarding the recognition of US FDA approval in Europe. Just how far is this likely to go?

Top Ten Articles In December 2022

The following table lists the most popular European regulatory articles among our subscribers in the last month of 2022. They explore the themes mentioned above in significantly more detail

Rank	Title
1	*European Commission Proposal To Extend MDR Deadlines As Far As 2027 and 2028*
2	*Council Of EU Supports Urgent MDR Action By European Commission*
3	*How Legacy Devices Can Remain On Market Once Former Certificates Have Expired*
4	*European Regulatory Roundup, November 2022: EU MDR Situation Now Critical*
5	*European Parliament Calls For Risk-Related Extensions Under MDR And IVDR*
6	*Crucial Council Of EU Debate On Medical Device Regulation Crisis Countdown*
7	*European Commission Proposal To Free Up Notified Body Time And Extend Reassessment Deadlines*
8	*Medtech Experts Voice Mixed Reactions To European Commission's New MDR Proposals*
9	*Heads Of Medicines Agency Group Adds Another Authority Voice To Intense EU MDR Debate*
10	*View From German Industry: MDR At The Turning Point*

- A separate piece *Medtech Insight* piece is being published focusing on AI, digital health, data and cybersecurity regulatory changes in the EU.

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