MEDTECH INSIGHT
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EU Regulatory Round-Up, January 2023: Cautious Optimism As New MDR Proposal Unveiled

by Eliza Slawther

All eyes were on the European Commission in January as it edged closer to adopting new legislation that will see the Medical Device Regulation transition deadlines extended.

The new year began with a flurry of excitement among those active in the EU medtech sector. The European Commission, true to its promises at the meeting of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) in December, published its *official proposal to extend compliance deadlines* for the MDR on 6 January.

High risk devices (class III and class IIb) will now have until 31 December 2027 to comply with MDR rules while for medium and lower risk devices (class IIa and class I devices needing the involvement of a notified body), the compliance date is 31 December 2028.

Comments Received On Proposal

This initial proposal was followed by the *opening of comments from stakeholders*, which lasted for a period of eight days and resulted in 246 responses. Initially, the commenting period was expected to be open for eight weeks, but this was *suddenly reduced to just eight days* in light of the need for the proposed amendments to be implemented urgently.

During this commenting phase, feedback from industry suggested that many *remain concerned* that the MDR will still negatively impact innovation despite the proposed changes.

However, these worries are unlikely to change the commission's trajectory. It was revealed at the end of the month that the *European Parliament is expected to vote* on the text of the European Commission proposal to amend the MDR without making any changes at first reading.

This would avoid the need for a second reading. The vote is scheduled to take place during the parliament's 13-16 February plenary session and done through an urgent procedure.

Warning Signs Removed

The removal of potentially misleading *warning signs that were against MDR-designated notified bodies* on the commission's Nando database was another top story from January.

It appeared that there was a problem with these notified bodies, which were well-known in the context of the MDR. This, however, was not the case and the signs were removed.

UK Announcements

The UK Medicines and Healthcare Products Regulatory Agency (MHRA) currently forecasts that, within the next year, a further eight approved bodies (scopes unspecified) will be operating in the UK. That would make 12, with the four currently designated.

The capacity challenge – whether there will be enough approved bodies to serve the Great Britain market—is *due to be addressed by the MHRA in February*. The agency will also focus on new ways innovation can reach the market; and recognizing devices already approved in certain other jurisdictions.

Alongside that, a UK Treasury group will look at how to expedite emerging life sciences technologies onto the market. It will deliver its proposals in the first quarter of 2023.

Still awaited is an official announcement of the one year's deferral of the standstill period – during which EU-approved devices still have access to the UK market – to 30 June 2024. The UK will also establish compliance transition periods, but they are not coterminous with the EU's

Avoiding Cybersecurity Pitfalls

Manufacturers of medical devices must comply with cybersecurity rules under the MDR, but a cautionary tale was outlined by Christian Rosenzweig, a medical device consultant at Germany's Johner Institut, in January.

He told *Medtech Insight* *about a case study* whereby a notified body had rejected a manufacturer's application for recertification of a device as the product had a USB port. Despite not having a direct internet-connectivity function, the notified body insisted that this USB port meant the product could be open to cyberattacks.

Because of this, the manufacturer was required to produce technical documentation relating to cybersecurity, which it did not have at the time of the conformity assessment.

AI And Digital

The beginning of this year has also seen continued developments in artificial intelligence (AI) and digital health. European Commission group Label2Enable *called on regulators* to implement official assessment processes for health and wellness apps, to bring rules for some apps more in-line with the MDR.

Label2Enable claimed that corporations such as Apple and Google are becoming *de facto* regulators in lieu of official third-party organizations being established to assess the efficacy of health apps.

Meanwhile, *a report spanning more than 200-pages* by Belgian researchers outlined just how inconsistent reimbursement and payment schemes are for digital technologies across EU member states and other nearby countries, such as the UK.

The researchers found that digital medtech products tend to be reimbursed only in single markets – and not across multiple member states—which could reflect difficulties in gaining market access across the continent due to large variations in funding schemes available in different locations.

The EU announced plans to utilize AI under a *new project known as the Cancer Imaging Initiative*, which forms part of the umbrella Beating Cancer Plan. The scheme will see a database of annotated images of cancer created that researchers and clinicians can access for use in diagnosing or treating patients.

Top 10 Articles In January 2023

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

Rank	Title
1	*Commission Adopts Proposal For EU MDR Changes, Sets Out New Transition Deadlines*
2	*Commenting On The EU MDR Proposal? What You Need To Know About Finer Details*
3	*European Commission Invites Comments On Its Critical MDR Proposal*
4	*European Commission Suddenly Reins In MDR Proposal Feedback Period To One Week*

5	*Commission Removes Warning Signs Relating To Four EU MDR Notified Bodies*
6	*Moves For Go Ahead For MDR Proposal To Be Discussed At European Parliament*
7	*Innovation To Suffer Unless Revised MDR Addressed Now*
8	*European Commission's 2023 Schedule: Timetable Features Stakeholder Meetings This Year*
9	*February Announcements On UK's Medtech Regulatory System Change Awaited*
10	*Avoiding MDR Pitfalls On Cybersecurity: How EU Rules Could Catch Manufacturers Out*