MEDTECH INSIGHT
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EU Roundup August 2024: Need For MDR Changes Continues To Absorb Sector

by Amanda Maxwell

Now European businesses are returning to “normal” after the summer break, they will find key developments have occurred in the EU during the traditional holiday season.

August can be relatively quiet in the EU. But the traditional summer holiday month was punctuated by the arrival of some key documents. However, it also allowed for a period of reflection on some of the critical events of late in the medtech space.

The topic of how the checkered implementation of the EU’s Medical Device Regulation can be improved continues to absorb the sector. Indeed, Medtech Insight’s most popular piece in August was *an interview with renowned medtech experts*, Erik Vollebregt and Tom Melvin.

Both the lawyer and the former clinician now academic agreed that there could soon be an opportunity for the EU institutions to put together a new proposal for a medical device regulation based on a more science-driven, methodological approach to device regulation at the same time they address the points in MEP Peter Liese’s initiative.

Vollebregt explained that the intention in the Liese document, a proposal to amend the MDR, was to a “politically feasible” response to create better regulation at the earliest opportunity.

Liese had commissioned the Dutch legal expert to do a rewrite of the MDR to “course-correct” rather than work from the ground up, which would be a lengthier process, he explained.

EU competent authorities are also on board with such an approach. The Competent Authorities for Medical Devices (CAMD) association issued a *statement* endorsed by authorities in 20 countries recognizing the urgent need to develop and improve the medtech regulatory system. But it warned that “doing so reactively and without a thorough analysis and evaluation could

lead to significant further disruption and impairment to progress towards an effective EU regulatory system."

CAMD said in its statement that "further system development should be carefully and methodologically evaluated through evidence-based decision making and assessment of the impact of the existing requirements or any proposed developments."

Article 11

The second stage of a *court case* related to the risk classification of an app that diagnoses skin conditions, Dermanostic, highlighted just how complex the interpretation of Rule 11 of the MDR on software is. While the regional court had ruled last summer that the product should be regulated in the lowest risk class, class I, the Hanseatic Higher Regional Court (OLG) in Hamburg ruled this summer that it must be class IIa and pass through a notified body in the latest ruling.

But while many have claimed Rule 11 is impenetrable and not fit for purpose, Cesare Magri, CEO of 4Better Devices, argues against such criticism.

He produced *a guide on How To Use MDR Rule 11*, which took him 300 hours to complete, which is available on request. There had been over 500 requests for the guide within the first month of launch, despite it having no official nor legal standing.

Orphan Devices And Notified Body Fees

In other news, the European Medicines Agency introduced a pilot program for expert panels to assist with the *development and evaluation of orphan medical devices*. This program provides free advice to selected manufacturers and notified bodies on orphan device status and the data needed for their clinical evaluation.

Also, the European Commission posted a long overdue list of *links to the fees charged by notified bodies* under the MDR and IVD Regulation. The document features links to fees from all 49 notified bodies designated under the MDR and all 12 under the IVDR. It could be even more useful if there were uniformity of presentation of the fees structures and tables for comparison, Medtech Insight notes.

Strict New Criteria Proposed For Seven Types Of IVDs

During August, Medtech Insight reported on how the European Commission had issued a proposed text amending the 2022 implementing regulation that laid down common specifications for certain class D IVDs (the highest risk products) in the context of the IVD Regulation.

The updated proposed text outlines new detailed CS for detection of: hepatitis E virus;

Toxoplasma gondii; Plasmodium spp; and four types of arboviruses – Chikungunya virus, dengue virus, West Nile virus and Zika virus.

Interested parties have until September 16 to comment.

Exciting Opportunities

Also on the medtech agenda at present, is the opportunity for interested parties to respond, by 10 October, to the Innovative Health Initiative call to present a proposal to model regulatory sandbox mechanisms and enable their deployment to support breakthrough innovation in the EU.

This is one of four topics that have been launched in an eighth call from the IHI. The others are as follows: They have the same deadlines and are as follows (with links to further details): *a city-based approach to reducing cardiovascular mortality in Europe*; *novel endpoints for osteoarthritis (OA) by applying big data analytics*; and *patient-centred clinical-study endpoints derived using digital health technologies*

Finally, on the topic of cybersecurity, *a new European Commission report* has warned that without new tools, cyber security risks related to the ongoing digitization of healthcare will remain unmonitored and under-researched. It says there is a notable discrepancy regarding whether and to what extent cyber-attacks affect the health of patients since there is considerable variation and inconsistency concerning the characterization of cyber incidents and potential health-related consequences.

For the previous month's regulatory round-up, read: *EU Regulatory Roundup, July 2024: Medtech Ponders AI Act As Debate Over MDR Fix Continues*

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