MEDTECH INSIGHT
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EU Regulatory Roundup, July 2024: Medtech Ponders AI Act As Debate Over MDR Fix Continues

by Amanda Maxwell

Many in the EU will be taking their traditional summer break in August. They will be leaving much in the political and regulatory melting pot as they go.

The big news in July for medtech was the *publication of the final text of the AI A*ct in the Official Journal of the EU. The act was *published* on 13 July and entered into force on 1 August although it will not generally be fully enforced for products that come under the scope of the Medical Device or IVD Regulations until mid-2027.

A sizeable number of the requirements in the AIA will be new to the medtech industry, and potentially particularly challenging for SMEs who have fewer resources to manage the additional demands.

To help our medtech readership understand how they need to respond to the AIA, Medtech Insight featured a review of a podcast by Marco Caproni of notified body, TÜV SÜD, who *explained how requirements over and above those in the MDR and IVDR impact medtech manufacturers*

The medtech sector will need to start understanding exactly how it is impacted by the AIA. It will need to do this at the same time as it is still dealing with a range of challenges and uncertainties related to the implementation of the MDR and the IVDR as well as a host of other EU regulations, including related to the data space, cybersecurity and the environment.

All this is ongoing against the backdrop of a debate which is now ramping up about how best to improve the troublesome medtech regulations.

How To address The MDR's Problems

Indeed, one of the highlights in Medtech Insight's July's EU regulatory news was a series of articles based on the interview with Tom Melvin, a regulatory expert and associate professor of medical device regulatory affairs at Trinity College, Dublin, Ireland. During this interview, Melvin addressed current problems with implementation of the MDR and IVDR and possible new ways of improving them.

In *response to questions about his views* of the Peter Liese proposals for an amendment to the MDR, Melvin recognized its value in general. However, he called, also, for a "thorough conceptual underpinning of the system" and for the EU to tackle the "fundamental methodological problems," so it can "truly make the system more proportionate, predictable, reproducible and efficient."

He also advised EU decision-makers to look for a more scientific approach to regulation, like those applied in the US, especially around clinical evidence.

His plea for an analysis of the regulations with a longer-term review was also a feature of *recommendations made by the Competent Authorities for Medical Devices group* in a recent statement which shows significant solidarity with the general view among EU medtech stakeholders that revision of the MDR and IVDR is urgently needed.

Innovation

Still with one eye on the other side of the Atlantic, Melvin recommended that the EU, which is know to be falling behind when it comes to medtech innovation due to the nature of its regulations, should *assess certain successful US regulatory strategies*.

In the EU, the lack of predictability, particularly when it comes to clinical evidence requirements, number and length of trials, and costs, creates hurdles for innovation."This ... makes it difficult to secure funding for promising new technologies," Melvin said.

A Passionate Plea

For the most immediate future, Melvin explained *why a plan around derogations for devices falling through the regulatory crack is now critical*.

There could be a fresh wave of casualties from 26 September, he warned, following the deadlines contained in the MDR *amending regulation published in March 2023* where manufacturers that applied in time have failed to sign the necessary agreements with their notified bodies related to these products.

But there is no accurate information on precisely which devices are impacted or how clinicians

can try to compensate with other potential options, if at all. Inevitably, patients will suffer worse treatment as a result, and some could even die, he warned.

Important Appointments In The EU

With so much talk about how the MDR and IVDR should be updated, medtech will be relieved that there is some continuity within key roles at the European Commission and European Parliament. Despite political shifts at EU level, Ursula von der Leyen has been re-elected president of the European Commission.

Industry association, MedTech Europe, issued a *statement on the occasion of her appointment* highlighting the critical importance of reforming the medical device regulations, arguing that the current regulatory system is hindering innovation, increasing costs and delaying patient care.

We also already know that the European Parliament will have two high-profile members who have been involved in the drafting of the EU's medtech regulations and who have clinical backgrounds, *Dr Peter Liese and Dr Vytenis Andriukaitis*.

Revisions To Guidance Documents

Medtech Insight wrote about two new guidance documents were updated and published in July:

- *MDCG 2021-5 Rev. 1* includes new sections on: standards rulings of the European Court of Justice; European Pharmacopoeia standards; and common specifications.

- The commission's Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) also *finalized* its revised phthalates benefit-risk assessment guidelines – which must be updated at least every five years under the MDR – on 17 June.

In additional environmental news, the European Chemicals Agency's committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) *is evaluating sector by sector the proposed REACH restriction on per- and polyfluoroalkyl substances (PFAS)*. A meeting has not yet been scheduled for the review of PFAS in medical devices. But concerns have been voiced by the medtech industry that the EU's European proposed restriction on PFAS could eliminate medical devices required for minimally invasive surgeries, among many others.

More Documents To View

July was a busy month for new further EU documents which included the following:

Template for notified body confirmation letter of the status of a formal application, written agreement, and appropriate surveillance with a manufacturer in the framework of Reg EU

2024/1860 which allows an extended transitional period for certain legacy devices under the MDR and IVDR (in addition to *the gradual roll-out of the Eudamed medical device database* and new obligations to disclose which devices they are discontinuing).

- A guidance document from the Notified Body Coordination Group, NBCG-Med 2024-1 on the *application of hybrid audits to quality management system assessments* under the MDR/IVDR – operational elements.

- The third update of MDCG 2020-16 (Rev.3) - *Guidance on Classification Rules for In Vitro Diagnostic Medical Devices* under the IVDR.

- The first revision of MDCG 2021-5 (Rev. 1) Guidance on standardisation for medical devices.

- A *presentation on the "state of play of MDR/IVDR implementation" and recording of the "Information session on MDR/IVDR for international regulators"* held on 4 July.

Medtech Insight's Most Popular Pieces In July

These were the most popular articles among Medtech Insight' subscribers in July:

Rank	Title
1	***AI Act Is Officially Published: Implementation Challenges Ahead For Medtech***
2	***Does The AI Act Apply To My Medtech Product And What Do I Need To Know?***
3	***EU Guidelines On Justifying Phthalates In Medical Devices Applicable To Growing List Of Regulated Substances***
4	***MDCG 2021-5 Rev. 1: EU's Standardization Guidance Brought Up To Date***
5	***EU's Historic PFAS Restriction Looms Over Medical Devices Sector***
6	***Why And How Last-Option, Essential Devices Must Now Be Identified As A Matter Of Urgency***
7	***EU Must Widen Debate Around Medtech Regulations Beyond Liese's Proposal***

8	***How The EU Must Address Regulatory Hurdles Deterring Medtech Investors***
9	***MedTech Europe Appeals To Re-elected Von Der Leyen To Address MDR/IVDR Problems***
10	***Two High-Profile Members Of Newly Elected European Parliament Have Valuable Medtech Expertise***

- For a round-up of exciting news that occurred in May and June, see *EU Regulatory Roundup, May And June 2024: Sweeping New Proposals Take Medtech By Surprise*