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European Regulatory Roundup, April 2022: A Meaty Month For News And Analysis

by Amanda Maxwell

April saw many more regulatory developments and documents compared to March, and also the promise of much to come over the near-term. With HTA and AI rules asking much more from the sector, these are demanding times for medtech.

After a month of unprecedented silence in March when it came to news related to the implementation of the EU's Medical Device and IVD Regulations, the pace picked up again in April.

The European Commission updated its *Ongoing Guidance Developments and Deliverables within the Medical Device Coordination Group (MDCG) subgroups*, and published this alongside an updated *Implementation Rolling Plan for the MDR and IVDR* plus *Joint Implementation and Preparedness Plan* for the IVDR. Together, these documents demonstrate how much work is on the EU's short-term—as well as mid-term—agenda, and are a useful refresher to understand what is still needed in terms of both regulations.

Towards the end of April, a *new 27-page guidance* was published on the borderline between medical devices and medicinal products. And when it comes to guidance in the immediate pipeline, two critical new guidance documents on periodic safety update reports (PSURs) and on the development of harmonized reporting forms for device incidents are due to be endorsed by the MDCG by the end June. These are in addition to a document on "hybrid audits" carried out by notified bodies in the context of both the MDR and the IVDR. Hybrid signifies the audits being performed both on site and remotely.

Medtech Insight also reviewed *the pattern of MDR and IVDR implementation activity* during the six months leading up to the end of March.

Notified Bodies

In other news related to implementation the *Slovenian Institute of Quality and Metrology (SIQ) was designated as the EU's 28th notified body under the MDR*; this was followed by *the designation of 3EC as the 7th notified body under the IVDR* at the start of May. There is now likely to be a lull in designations under the IVDR, probably until October.

With notified bodies bearing the brunt of managing the incomplete aspects of the new EU medtech regulatory system as demand increases, while also having to adapt to extra work that new structures and documents create, some are already turning down applications from medtech manufacturers.

BSI's *Graeme Tunbridge*, IMQ's *Daniele Bollati*, and TÜV SÜD's *Andreas Stange* explained how difficult it is for notified bodies to manage their workload at a time when the available talent pool is already employed, and when the learning curve ahead, including when it comes to the IVD Regulation, is steep for notified bodies and their auditors, and for manufacturers too.

One tool that they believe may help address some of the pressure is hybrid auditing. All three felt more clarity is needed in this area.

Eudamed

Many of the structures intended to underpin the EU's new regulations are missing still, and arguably the most critical and the most challenging of these is the Eudamed medical device database. But there is still no official news about its launch date.

During April, the commission *updated rules and guidance for two of its Eudamed medical device database modules*—the UDI/Devices module, and the notified bodies and certificates module. Richard Houlihan, CEO of EirMed, explained to Medtech Insight the importance and impact of the changes.

Also on the subject of Eudamed, the commission published *an updated version of the existing user guide* which was first released for the launch of the actor registration module in 2020 and Medtech Insight spoke to Katalin Maté, manager of regulations and industrial policy at industry association MedTech Europe to better understand the main changes in the document.

Delegated Act Powers Prolonged

Additionally, during April the commission acted to retain its powers to adopt delegated acts. None have been adopted so far. (Delegated acts supplement or amend basic laws, while implementing acts are intended to ensure uniform conditions for implementing the basic laws.) *This article* explains how and what can be expected over time.

HTA and AI

As if the medtech sector does not have enough on its plate with the MDR and IVDR, new EU artificial intelligence (AI) and health technology rules are going to introduce a whole new set up demands. The HTA Regulation has already been adopted. But *MedTech Europe's Oliver Bisazza explained in an interview* why it is critical for the industry to remain involved to ensure HTA considerations related to the access and purchasing realm do not enter the CE marking world.

The EU's AI Act, meanwhile, is still at the proposal stage. *In part one of a two-part interview* with Medtech Insight, Royal Philips' Koen Cobbaert addressed the thorny issue of misalignments between the EU's proposed and the MDR and the IVDR and explained challenges ahead. *In part two*, he focused on the impossible situation that medtech notified bodies could find themselves in due to the new AI Act and at the very important, but potentially compromised issue, of standards.

UK

In the UK, meanwhile, Medtech Insight reported on the MHRA's April 2022 board meeting held in public. With the 31 March deadline for the agency's release of its consultation response and finalized policy positions already missed and still outstanding, it seems that the UK may have overpromised when it comes to timescales for the new rules.

Agency CEO June Raine said: "We are aware of the concerns of industry about the risks of a truncated implementation period due to the pre-election restriction on government announcements [a 2023 UK general election has recently been mooted] and continue to work to ensure that there is a realistic time-frame to enable system readiness before any new rules take effect in full."

Although referenced several times during the board meeting, devices work does not feature in Raine's current top ten agency headline activities.

EU vs US

When it comes to which market medical device manufacturers are choosing as their launch market, a recent study has highlighted how most are choosing the US first, upending a decades-long tradition of companies going to Europe first for a CE mark. This is because there was a perception that the pathway to market was simpler and more predictable. But that situation has now been reversed, mainly, the report says, due to the MDR and IVDR and to challenges associated with Brexit.

It will be interesting to speak to Serge Bernasconi, of MedTech Europe, later this month to see what his views are on this topic.

- For last month's round-up of our top 10 European regulatory pieces, see: *European Regulatory Roundup, March 2022: Unprecedented Hiatus In Implementation Announcements*

Rank	Title
1	***Against The Odds: Notified Bodies Pinpoint The Real Obstacles And Ways To Move Past Them***
2	***How European Commission Has Updated Rules And Guidance For Two Eudamed Modules***
3	***All Guns Blazing: Commission Brings Sector Up To Speed With Its MDR/IVDR Implementation Plans***
4	***European Regulatory Roundup, March 2022: Unprecedented Hiatus In Implementation Announcements***
5	***Device Makers Are Bucking Decades-Long Trend Of Launching Products In EU: Here's Why***
6	***EU Regulatory Output In 2022 To Support MDR And IVDR***
7	***EU's 28th Notified Body Under The MDR Is Based In Slovenia***
8	***Changes Featured In Upgraded Eudamed Economic Operator User Guide***
9	***UK MHRA Notes Concern Over Medtech's Mid-2023 Deadline – But Still No Draft Law Progress***
10	***The EU HTA Regulation: How It Threatens Device Launches And Where The Solutions Lie***