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European Regulatory Roundup, March 2022: Unprecedented Hiatus In Implementation Announcements

by Amanda Maxwell

Unprecedented silence from the EU when it comes to news relating to the implementation of the Medical Device and IVD Regulations is disconcerting as compliance pressures mount.

The biggest news for March when it comes to the implementation of the Medical Device and IVD regulations is, in fact, the ongoing lack of news, prompting questions about whether this means the European Commission may be planning to take some decisive action that could result in an extension of timelines, for example, particularly for the MDR.

The French and German industry associations issued a *position paper* in mid-March calling for the grace period for MDR products to be extended by two years for class III and implantable devices and by four years for all other devices, if they are eligible and remain eligible.

The two associations are in no doubt that the lack of necessary structures and obstacles to companies proving the compliance of their products in a timely way is "already having catastrophic consequences on the availability of products in hospitals, among doctors and therefore for patients."

They say that beginning in the third quarter of 2022, when less than 18 months remain until the end of the grace period, companies will already be faced with decisions whether to pull their products from the market because from that point it will be doubtful that they will be compliant on time. This is not because of the company's lack of readiness, they argue, but rather the lack of readiness of the system and the bottlenecks at notified bodies.

There were also no more notified body designations in March; and only one is likely under the IVDR in the next few months, it transpired, with any remaining IVDR designations unlikely until

around October. Under the MDR, a few are in the pipeline and expected over the next few months.

Ongoing Relative Silence From Commission

While *one updated guidance on safety and clinical performance with two brief and minor changes was published* by the European Commission in March, there was otherwise an unprecedented and somewhat eerie silence. With the IVDR due to full apply in less than two months' time, the gap in document production seems unwarranted.

The hiatus in publishing guidance documents was certainly unexpected and a step in the wrong direction when it comes to implementation efforts. Indeed, there are *20 or so guidance documents still urgently needed by the medtech sector.*

For its part, the sources close to the European Commission told Medtech Insight in mid-March that the commission was *working towards the MDCG meeting due on March 21 and 22*. And the implication was that there would be more news, including on IVD guidance after that.

That news is still awaited.

Post-Market Surveillance

Another particularly popular piece in March was the *interview with leading devices expert Bassil Akra on the topic of post-market surveillance*. Akra explained the significant benefits of manufacturers investing more than the minimum in post-market efforts, why small manufacturers can perform PMS as well as large manufacturers, what the notified body responsibilities are, and the advantages of AI in this area. This article also features a link to listen into the whole interview.

Expert Panels

March saw the *coordination secretariat of the European Commission's medical device and IVD expert panels* handed over from the commission's Joint Research Centre (JRC) to the European Medicines Agency (EMA).

The move follows the adoption of *a new Regulation* at EU level to strengthen the EMA's role in overseeing various aspects of device management, as well as medicines, in the event of a health care crisis.

This was despite such developments being largely opposed by the EU medtech industry.

By mid-March, a picture started to emerge of how rapidly the expert panels are managing to review and produce opinions on the clinical evaluation carried out by manufacturers of high-risk

medical devices and IVDs. While the IVD panel is making rapid progress, and *had reviewed 15* by that time, *the medical device panels are finding it heavy going* and have been very critical of the three applications they had reviewed by mid-month.

UK

March was a busy month on the regulatory front for the UK.

In *UK MHRA's IVD Chief Warns About 'Wrong' Deviation From EU Medtech Regulations*, Mike Messenger, head of diagnostics at the UK regulator, the MHRA, reflected on the pros and cons of more or less regulation in the UK for IVDs when compared with the EU's IVD Regulation.

He believes that the IVD Directive was "quite out of date," as to the types of technologies considered to be high risk by the time the COVID-19 pandemic hit and "unfit for purpose". But too much up-regulation in the UK, or too much deviation from EU rules, could lead to problems too, unless it results in the UK becoming a more attractive place than the EU in which to launch products, he suggested.

Later in the month, Phil Brown, director of regulation and compliance at the Association of British HealthTech Industries (ABHI), spoke about how industry needed more certainty about the ongoing progress on UK medtech regulations in an interview that was published in two parts.

He explained how the ABHI is putting together a report intended to inform the ongoing discussions led by the regulator and the government on the new UK regulatory instrument. The report fills in the gaps in the MHRA consultation on the medtech regulation, Brown said. This MHRA consultation finished in December. Publication of the draft text is due imminently, Medtech Insight understands.

Brown also voiced concerns that staff losses at the MHRA are acting against the best interests of the UK medtech sector at this critical time.

The *second part of the interview series* focuses on two options when it comes to the future of the UK medical devices regulatory system: one is that, given its sophisticated health care system, the UK will need its own processes of regulatory approval, and enough qualified staff to take care of those needs. The other suggests the regulator should pursue merely a registration scheme for medtech products that it recognizes from international markets and admit them to the UK market after a process of domestic assurance.

The ABHI does not believe, however, that the UK regulatory should involve itself in setting its own, new, technical requirements for registration, Brown said. Nor should it adopt a "light touch", in his opinion, referring to the UK's mantra when it came to implementation of the medical device directives.

Italy

News that the *Italian authorities are going it alone when it comes to rules and sanctions around the advertising of medical devices* has led to a high level of concern.

Top 10 Lists

For the top 10 European medtech regulatory pieces published last month, see: *European Regulatory Roundup February 2022: Major Push Now On IVD Regulation Preparedness*

The following table shows the top 10 European regulatory pieces published in March:

Rank	Title
1	***Industry Asks Commission To Delay MDR Full Compliance Dates By At Least Two Years***
2	***Some 20 Key EU Guidance Documents Still Needed For MDR And IVDR Implementation***
3	***Medtech Companies Could Face Sanctions As Italy Enforces Own Advertising Rules Under MDR***
4	*EU Post-Market Surveillance: How Doing More Than Minimum Will Benefit Medtech Manufacturers*
5	***MDCG Meeting Updates Expected To Break Implementation Silence On EU IVDR***
6	***UK MHRA's IVD Chief Warns About 'Wrong' Deviation From EU Medtech Regulations***
7	***UKCA Marking Debate Moves To Next Level: All Eyes On The MHRA***
8	*European Commission Adds To Advice On High-Risk Device Safety And Performance Requirements*
9	***If You Build It, Will They Come? Vital That UK MHRA Creates Right Environment For Medtechs***
10	***EMA Takes Over Permanent Secretariat For Medical Device And IVD Expert Panels***