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EU Regulatory Roundup, November 2020: Plenty Of Advice And Guidance As Deadlines Approach

by Amanda Maxwell

Those marketing products covered under the EU's MDR and IVD Regulations have plenty of reading this month to help them prepare. More details have also emerged about the UK's regulatory future.

In November, our popular three-part interview with Amie Smirthwaite, senior director, global clinical practice at Maetrics consultancy, explored the fundamental differences in clinical evidence expectations under the Medical Device Regulation compared with the existing Medical Devices Directive (MDD).

The *first part* explored what defines "sufficient" clinical evidence and gave practical advice on how manufacturers should transition from the MDD to the MDR. The *second part* of the interview looked at the impact of risk class on clinical evidence, where the significant differences in expectations lie in the MDR when compared with the MDD, the changing role of notified bodies, and other factors that will impact clinical evidence requirements under the MDR. The *third part* looked at the most common pitfalls when trying to gather sufficient clinical evidence, and answered key questions, such as under what circumstances and with what device risk classes claims of "equivalency" can be used.

MDR Notified Body Pain Points

The most popular session at the virtual Medtech Summit was the Notified Body Panel Discussion: EU MDR Pain Points, where *delegates were told* that medtech companies need to do an in-depth check that their notified bodies will be able to still service them under the new MDR. Delegates were warned: Do not expect, because you have been working with a notified body for many years, that it will get the same designation scope under the MDR as under the MDD.

Other topics covered included potential auditing bottlenecks, capacity and staffing, what notified

bodies see as the biggest challenge for manufacturers in submitting their applications for conformity assessment and alignment in notified body operations.

EU IVD Classification Guidance Published

Also in November, the European Commission *published a key guidance document* on the classification of IVDs under the new IVD Regulation, which will be relevant to the entire IVD industry.

The long-awaited 48-page document gives industry critical clarifications on the seven IVD classification rules, as set out under Annex VIII of the IVDR. We reported on initial reactions from industry, which were mixed.

UK High On The Agenda

UK news is taking a more urgent tone as the end of the UK's transition out of the EU approaches. In early November, *the 50 days-to-go threshold was passed* with no EU-UK free trade deal on the horizon, let alone on the table. The month ended with no deal in sight.

Should a deal be concluded – and should there be some form of mutual recognition agreed for EU-UK device regulation—this will be factored into the evolving Medicines and Medical Devices (MMD) legislation that to date has reached the House of Lords Grand Committee stage.

In the meantime, the *Office for Life Sciences*, Medicines and Healthcare products Regulatory Agency (MHRA), the UK's approved bodies and the main UK medtech industry associations have all been putting in a shift to explain to the main provisions of the new UKCA marking and the CE marking grace period to users accessing the UK market after 31 December.

These themes were developed in the UK flavored articles that appeared among our top regulatory reads in November. They noted that while a lot of work remains to be done to ensure an ideally seamless transition to a standalone national system, much progress has been made.

More guidance for industry is awaited, but the MHRA has worked hard to catch up and get to a stage of readiness, which *Medtech Insight* reported on at the month end.

Convergence with EU regulation as far as possible remains the UK industry's wish, and confidence has increased that the UK has developed a workable system that will be able to factor in mutual recognition, possibly in MMD secondary legislation. But if that is out of reach of the UK's EU negotiators, UK industry will not be left without a regulatory platform.

Rank	Title
1	***Making The Leap From EU MDD To MDR Clinical Evidence (Part 1): Practical Advice***
2	***Long-Awaited EU IVD Classification Guidance Just Published: Initial Reactions***
3	***Notified Body Pain Points: The Challenges And Obstacles Industry Needs To Avoid***
4	***50 Days To Brexit – And No Extension, Govt Warns UK Medtechs***
5	*UK Updates Medtech Industry On National Regulatory System Progress*
6	***Making The Leap From EU MDD To MDR Clinical Evidence (Part 3): Critical Questions Answered***
7	***Key Changes In Commission's Latest Draft EU Standards Request To CEN/Cenelec***
8	***One-Stop Shop For Regulatory Service Providers: New Search Engine Launched***
9	***Deadlines Needed For Urgent EU MDR Vigilance And Postmarket Surveillance Guidance Documents***
10	***EU Regulatory Roundup, October 2020: Commission Holds Steadfast On MDR/IVDR Dates***