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European Regulatory Roundup, June 2022: Solutions Needed As MDR/IVDR Frustrations Grow

by Amanda Maxwell

June was characterized by an intense debate focused on shortfalls in the implementation of the EU MDR and IVDR, on who is to blame and how solutions can be found, as well as by news of some regulatory progress, at last, in the UK.

In May, a *notified body survey* highlighted how products may need removing from the EU market, in exactly two years, because of lack of notified body capacity.

In May 2024, 13,104 legacy product certificates are due to expire; but the survey by notified body association, TEAM-NB, shows that its 30 notified body members have the capacity to issue only around 6,300 certificates a year under both the MDR and the IVD Regulation.

In response, in mid-June, the Competent Authorities for Medical Devices (CAMD) group and the Biomedicine Alliance In Europe *issued statements* reflecting their concerns about the lack of implementation readiness. And the CAMD called for the Medical Device Coordination Group (MDCG) to be tasked as a matter of urgency with seeking solutions to ensure a smooth MDR implementation.

But the *MDCG hit back* on 13 June, pointing the finger of blame for delays in compliance at companies and warning them that they would suffer if they did not get themselves prepared immediately.

The document left some reeling and others angry. In a late June *interview with Medtech Insight,* Bassil Akra, CEO of the consultancy Akra Team, called the MDCG's comments "unreasonable." The responsibility for the delays, he said, lies in many areas, most of which are beyond manufacturers' control.

The nature of the MDCG document was unusual, indeed a departure from the usual guidance documents. Many share the view that the MDCG document should not be taken at face value; what it is actually trying to do, several medtech regulatory experts told Medtech Insight, is put pressure on companies to ensure they are prepared, without delay, but also offer reassurance that there will be some concessions for those who do take action now.

There is no indication of exactly what those concessions will be and nor does the MDCG have the authority to promise them.

But on 14 June, when EU commissioner for health and food safety, *Stella Kyriakides, addressed the Employment, Social Policy, Health and Consumer Affairs (EPSCO) European Council meeting*, she said hybrid notified body audits and coordinated market surveillance are among the measures that the European Commission has identified as possible actions to alleviate the current burden on notified bodies and improve the speed of compliance with the MDR and IVDR.

But she made it clear that the commission would not countenance a further delay.

She added that the commission has initiated work by the MDCG to agree on a list of actions to enhance notified body capacity and the preparedness of economic operators.

Other measures are under consideration, the commissioner said, including that the certification of certain devices, such as orphan devices and of some legacy devices, will be accompanied by targeted conditions to alleviate the strain on the market.

Notified Bodies

Apart from the public debate on the challenges the EU medtech regulatory sector is facing, June was a landmark in terms of notified body designations; the 30th certification and testing organization, *Berlin Cert in Germany*, was designated under the MDR during the month. (There are still just seven notified bodies designated under the IVDR.)

European Commission *figures published in early June* also indicate that there is one more designation in the immediate pipeline under the MDR, but none for several months at least under the IVD Regulation.

New Guidances

When it comes to new guidance documents, the European Commission *issued an update* on Ongoing Guidance Development and Deliverables by the various sub-groups of the MDCG, demonstrating when key guidances are due to be published in the next six months. It reveals that a flood of new guidance documents will be published under the MDR and IVDR in the third and fourth quarters this year.

Two implementing regulations, one on reference laboratory tasks and criteria, and one on their fees, were published during the month, signaling the *go-ahead for appointment of European Union reference laboratories for IVDs*.

UK

26 June saw the release, finally, of the UK government's official response to the Medicines and Healthcare products Regulatory Agency's (MHRA's) 2021 consultation on its post-Brexit medical devices regulatory framework. This is an *implementation plan for reform of the system*.

While the UK still plans for the new regulation to come into force in 2023, there are measures enabling products which already have valid conformity markings, issued in the UK or the EU, to remain on the market after the UK Regulation comes into force for a period of up to three years for devices and five years for diagnostics.

The 155-page response shows the agency has factored in the feedback and observations made by almost 900 respondents to the MHRA's 10-week consultation that closed last November.

Also in June, the MHRA voiced its "excitement" of the UK's MHRA acceptance as a full member of the International Medical Device Regulators Forum (IMDRF), where it had acquired observer status soon after the Brexit transition period ended. This is seen as a step cementing the UK's commitment to the global approach to regulation.

This is a busy time for the MHRA which is going through a *period of transformation* and has been having some teething troubles, including staffing issues.

- For May's round-up of European regulatory news, see: *European Regulatory Roundup, May 2022: IVDR Applies And MDR Critics Clamor Loudly For Action*

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