MEDTECH INSIGHT
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EU Regulatory Roundup, July 2023: Weighing Up The Impact Of The MDR Amending Regulation

by Amanda Maxwell

July was a busy month for industry as the repercussions of the publication and enforcement on 20 March of the EU's amending regulation to the Medical Device Regulation start to be really understood.

Now, just over four months after the publication of the amending regulation to the MDR, which brought extended compliance timelines for legacy products, the real benefits and outstanding issues are really beginning to be understood.

Notably, during July, the European Commission published a survey showing the number of certificates granted by and applications made to EU notified bodies designated under the MDR and IVDR. It provided useful insight into how implementation of these regulations is progressing. It also offered information on the rate of certificates issued and applications made to notified bodies, as well as the scale of the challenges ahead.

In two separate interviews with three key EU medtech regulatory players, Medtech Insight probed more deeply into the implications of this new legislative tool, as well as the impact of the IVD implementing regulation, which was published in January 2022.

Among the most salient points to come out of these interviews with BSI's Graeme Tunbridge, TÜV SÜD's Andreas Stange and Qserve consultancy's Gert Bos were how there is now "*ample" time to file applications under the MDR* and there is now "clearer communications and expectations" from notified bodies towards their clients.

(For more details about the amending regulation to the MDR (Also see "*MDR Amending Regulation Officially Published And Already In Force*" - Medtech Insight, 20 Mar, 2023.))

This optimism contrasted starkly with the *concerns the same experts had expressed about the implementation of the IVDR*, despite the amending regulation that extends timelines for IVDs in the EU. Indeed, the speakers warned that too many perceived factors are being used by IVD manufacturers to unnecessarily delay progressing their applications under the IVDR.

(For more details about the amending regulation to the MDR (Also see "*EU IVDR Amending Regulation Published And Staggered Grace Periods Now Official*" - Medtech Insight, 26 Jan, 2022.))

Given the changes in the timing of demand for regulatory expertise, Medtech Insight also touched base with Elena Kyria, founder and CEO of *Elemed* recruitment consultancy, to see *how the job market is shaping up*. It transpires that it has been a bit bumpy for those in employment and job seekers too. This is not just because of the changing deadlines created by the amending regulations, but also reflects a trend across many industries and job roles in response to global financial uncertainties amid political instabilities. But there are now signs of an uptick.

New Key MDR Documents

Also on the subject of the impact of the amending regulation, *the European Commission issued a six-page factsheet* to help the regulatory authorities in non-EU/EEA countries better understand when and why some devices entering their markets beyond the date of application of the EU's MDR and IVDR are still compliant with former EU rules.

Moreover, it revised a critical Q&A document to help manufacturers better understand how to keep legacy products on the EU market. This is essential reading as a number of important changes were made. But comprehension is somewhat challenging due to a list of cross-reference indicating the changes. The piece published by Medtech Insight looks at what those changes are.

In light of the MDR timeline extensions, it was decided that it would *no longer be necessary for manufacturers to use the MDR's Article 97* to obtain permission from national competent authorities to continue marketing legacy products on the EU market.

AI

The topic of AI remained under the spotlight again in July with experts in software and AI medtech regulation from the UK's MHRA *outlining the questions* that device developers should seek to answer when preparing for the regulatory process.

Medtech Insight also looks at what *changes to the EU's generic AI Act would most benefit medtech*.

AI and UK

Also on the topic, a regulatory pathway AI and software as a medical device, among other pathways for emerging healthcare technology areas, was prescribed in the UK Medicines and

Healthcare products Regulatory Agency (MHRA) three-year corporate plan, released in July. The agency, although not EU of course, announced the establishment of an AI and Digital Regulation Service.

More broadly, it said it is targeting *formalized recognition pathways for UK device approvals by 31 May 2025,* and reiterated a policy of pursuing "risk-proportionate regulation" for Great Britain (Northern Ireland remaining subject to the MDR and IVDR). It was announced in July that consultation on international device recognition would start in October.

Not included in our July round up was news on 1 August from the UK government that the Department of Business and Trade would allow indefinite CE marking approval for UK businesses and products launched in the UK – beyond the original 2024 deadline. The BIVDA and the ABHI medtech industry associations were quick to stress that this would *not* apply to medtech products and that recent legislation setting out a revised *2025 deadline* for medtech still stands.

The ABHI noted that this is helpful news for companies that rely on CE marking of manufactured goods as spare parts for operation and maintenance of equipment. BIVDA suggested that it might also shine a light of possibility on future continued recognition of CE marked medical devices in Great Britain.

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- For June's news summary, see: *EU Regulatory Roundup, June 2023: Medtech Shifts Focus To AI, Data And Digital*