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European Regulatory Roundup, July 2022: Threat Of Ongoing Hurdles Masks Progress

by Amanda Maxwell

The first seven months of 2022 have seen significant progress on documents, tools and new structures needed for the MDR and IVDR implementation. But with major hurdles ahead, in July it was still the problems and not the successes taking centre stage

A significant amount of progress has been made in finalizing documents and processes needed for the implementation of the Medical Device Regulation (MDR) and IVD Regulation (IVDR), as the *European Commission's latest update to its rolling plan*, issued in July, showed.

But despite this headway, the outcome of a recent extensive survey by MedTech Europe "clearly indicates an urgent need for immediate action" by decision-makers to help keep needed medical devices available in Europe.

In the *analysis of its survey results*, MedTech Europe warns that unless swift action is taken, the clinical benefits of new and improved device designs will be more likely to become available to patients in other markets ahead of the EU, requiring patients in Europe to wait until the MDR system is ready.

Indeed, MDR hurdles are deterring some 50% of companies from prioritizing the EU as their launch market, the survey found, and 33% of respondents' medical devices are currently planned for discontinuation.

The outcomes highlight the lack of responsiveness from notified bodies, unpredictable certification time and non-harmonized interpretations of the same requirements of the MDR, not only among notified bodies as a group but also within them individually.

The urgency of addressing the EU's regulatory problems was also emphasized by industry association, COCIR, during July. In its paper, the body proposes *a series of detailed solutions* that

it believes would prevent anticipated bottlenecks at notified bodies. Included among its proposals are to: expand the use of remote audits to all products generally, without the need for specific justifications; and allow notified bodies more flexibility in defining the appropriate technical documentation sampling (e.g. lower the number of technical files based on risk class and not groups).

Another July reader favorite on the topic of avoiding a scenario where uncertified devices have to be unnecessarily removed from the market was a Medtech Insight *interview with Bassil Akra*, CEO of consultancy firm Akra, published at the end of June.

Akra slammed *suggestions by the Medical Device Coordination Group* that manufacturers were to blame for product certification delays.

He wants regulators to acknowledge that notified bodies are receiving a huge number of applications and have not been able to accept them all because of the magnitude of work involved in dealing with them in the context of new regulations.

Moreover, he said, some manufacturers have not been able to even apply to a notified body yet because their notified body has not been designated and/or others offering services in their area have no capacity.

Notified Bodies

The *Spanish Agency for Medicines and Healthcare Products' Medical Devices Certification Division* was the only new notified body designation in July. This is the first and likely only Spanish notified body under the MDR.

This brings the total number of EU MDR notified bodies to 31, while those designated in the context of the IVDR remain at seven.

Analysis was published during the month highlighting the challenges that manufacturers face in *finding a notified body active in their particular product area*. It emerged that only two of the 31 notified bodies designated under the MDR are authorized to carry out conformity assessments under all MDR product codes. Four out of the seven designated under the IVDR have full authorization under that regulation.

IVDs

The *Implementing Regulation on common specifications for Class D IVDs* was finally adopted in July, six weeks after the IVDR took effect.

Class D is the highest risk category under the new IVDR, and legacy IVD Class D must be in full compliance with the new rules by 26 May 2025. Common specifications are like standards but

more technically detailed. In this case, they focus particularly on IVD performance characteristics.

New products had to meet the requirements by 26 May this year, and these missing common specifications have been causing challenges and confusion among manufacturers and notified bodies.

Also in the areas of diagnostics, *the European Medicines Agency issued in July final guidance* outlining the procedure that IVDR-designated notified bodies must follow when seeking a scientific opinion on the suitability of a companion diagnostic (CDx) with the concerned medicinal product.

Eudamed

Delays and uncertainty over the launch of the updated version of the Eudamed medical device database, an MDR and IVDR cornerstone, have caused medtech stakeholders much frustration. In July, however, there was more certainty *when the commission published an updated timeline*.

The commission expects to declare all six modules of the updated Eudamed medical device database to be sufficiently ready to allow the launch of the full system in the second quarter of 2024.

This will then be followed by two critical deadlines:

- Six months after the publication of the notice, i.e., Q4 2024, the requirements of Eudamed will become mandatory for the following modules: actor registration; vigilance; clinical investigation and performance studies; and market surveillance.

- 24 months after the publication of the notice, i.e., Q2 2026, Eudamed will become mandatory for the following modules: UDI/device registration; notified bodies and certificates.

Also in July, new EU guidance was published to help IVD manufacturers understand in detail what they should do pending the full launch of the database.

The 34-page document, *MDCG 2022-12 Guidance on harmonized administrative practices and alternative technical solutions until Eudamed is fully functional*, features a 30-page table offering alternative solutions to the provisions that were foreseen in the implementation of the IVDR had the database been ready in time for the full application of IVDR on 26 May 2022.

This is not the first text of its kind that has been made available. In May 2021, the month that the MDR fully applied, *a similar document was published* in the context of the MDR.

UK

In the UK, meanwhile, there have been fears that the *stormy political waters following Boris Johnson's resignation* as prime minister could impact the timing of the publication of the new, post-Brexit UK medtech regulations. But with new prime minister due to be in place by 5 September, and unlikely to deviate much from the plans of their predecessor, the hiatus is likely to be short.

In the meantime, it has emerged that device manufacturers will have a clearer picture of the post-Brexit system of medtech regulation in the UK once a number of focus groups, to be appointed by the Medicines and Healthcare products regulatory Agency (MHRA), can focus on *developing key aspects of guidance* that will accompany the new regulations. This step follows publication of the response to the UK consultation on the future shape on the new regulations.

Top Ten List

Below is the list of the top 10 most popular EU and UK regulatory reads in July 2022.For last month's round-up see: *European Regulatory Roundup, June 2022: Solutions Needed As MDR/IVDR Frustrations Grow*

Rank	Title
1	***Extensive EU Medtech Regulatory Survey Reveals Scale Of MDR Hurdles And Where Problems Lie***
2	***European Regulatory Roundup, June 2022: Solutions Needed As MDR/IVDR Frustrations Grow***
3	***European Commission Expects Eudamed To Be Fully Ready By Q2 2024***
4	*MHRA Offers Medtechs Extra Transition Time For UK Regulatory System Compliance*
5	*The Good And The Bad News When It Comes To EU Notified Bodies' Designation Capacity*
6	*Akra: Time To Acknowledge EU's Real Implementation Problems And Stop Scapegoating*
7	***Here At Last: EU's Implementing Regulation On Common Specifications For Class D IVDs***
8	***How Stormy UK Politics Could Intrude On Medtech Regulatory Readiness***
9	***Spanish AEMPS Latest To Gain Notified Body Designation Under EU Medical Device Regulation***
10	***Notified Body Process For Consulting EMA On Companion Diagnostics***