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Is EU Medtech Regulatory Reform On The Horizon? Seven Expert Perspectives Entering 2024

2024 Crystal-Gazing With Industry Leaders

by Amanda Maxwell

Ongoing threats to the availability of medical devices, obstacles to innovation, delayed structures and documents.... The medtech sector has plenty of reason to call for change in 2024.

Calls for radical change in the implementation of the Medical Device Regulation and the IVD Regulation in the EU grew increasingly strident in 2023 as industry and notified bodies alike struggled with gaps and challenges in the current regulatory system.

While there may have been improvements in manufacturers submitting their applications to notified bodies, there has still been insufficient progress in the certification of products under the EU's rules.

Most are blaming poor implementation of the EU medtech regulatory structure. What sort of changes will the sector be calling for in 2024?

To kick off the new year, *Medtech Insight* asked seven experts, well known to the sector, two questions:

1. **What are the most challenging uncertainties facing your role, organization or industry as we head into 2024?**

2. **In your view, are the MDR and IVDR sufficiently robust, appropriate and flexible to cope with how technology is changing? Or what regulatory action is needed in the EU now?**

These were their responses:

Oliver Bisazza
CEO
Medtech Europe

In 2024, the medical technology industry will have to adapt to new legislative landscapes in the digital, sustainability, and legal domains.

Our focus centres on supporting our industry dealing with the impact of emerging AI rules, the European Health Data Space, and stringent packaging regulations. Navigating the intricate implementation of IVDR and MDR will remain our key priority.

Our paramount objective is to ensure accessibility to safe technologies for patients and bolster healthcare systems. Facilitating timely access to medical technology innovations is critical to EU's implementation of the new pieces of legislation. Moreover, uncertainties stemming from the 2024 EU elections may prompt strategic shifts to address evolving political priorities. Our

commitment to safeguarding patient interests and advancing healthcare resilience guides us through these dynamic challenges.

MedTech Europe is asking for reforms to make the IVDR and MDR sustainable, robust, and supportive of innovation (*see our paper*). Our vision identifies system deficiencies leading to shortages, blocks to innovation, and a spiralling burden on our industry today.

Authorities and all actors must manage and improve on these issues today to keep devices available to the patients who need them. Yet the focus should be on more than just the necessary shorter-term measures. We need to discuss and fix the system's structural deficiencies to restore efficiency, support innovation, and improve governance.

Innovation, from groundbreaking advancements to iterative improvements, is pivotal in addressing health crises, championing sustainability, and meeting societal expectations. Enabling a regulatory environment that embraces innovation, while maintaining unwavering safety standards, is critical to empowering individuals and alleviating healthcare system burdens and ensuring a resilient and progressive medical technology landscape.

Read more about how MedTech Europe is driving discussions in the sector to create a new governance structure and a new regulatory vision.

Sabina L. Hoekstra-van den Bosch
Global Director Regulatory Strategy
TÜV SÜD Medical Health Services

Heading into 2024, significant uncertainties confront notified bodies. The implementation of the MDR and IVDR has introduced a challenging regulatory landscape. Additionally, economic considerations are influencing a shift from initially stringent requirements.

The abrupt shift to full new certification poses challenges and bottlenecks. Notified bodies are grappling with the need for swift adaptation to regulatory changes, shifting timelines, and evolving interpretations by authorities.

This dynamic environment creates a high and not fully predictable workload, expected to persist throughout 2024.

On top of this, the delay in the European Database on Medical Devices (Eudamed) and the non-readiness of other regulatory infrastructure exacerbates the situation, adding extra tasks for notified bodies. Harmonizing interpretations among EU member states remains a persistent challenge, introducing uncertainties for manufacturers and notified bodies.

With a well-implemented regulatory infrastructure, the MDR and IVDR can offer a robust, yet flexible framework. While improvements in clinical substantiation and transparency are noteworthy, ensuring consistent

implementation across the EU and adjusting for orphan devices, scientific advice, and efficient interaction with other regulatory systems (e.g., pharmaceuticals and AI) would be beneficial enhancements.

Additionally, further progress could be made by aligning with global regulatory standards and restructuring the framework for a more process-oriented, digitally adaptable structure.

This would involve separating technical requirements from legal texts, allowing for agility in accommodating rapid developments without necessitating frequent changes to the legal framework. Such modifications would promote a globally harmonized approach and facilitate the evolving landscape of medical technology.

Read more about how notified bodies are coping with the challenges they are facing in managing their unpredictable workloads.

Lionel Tussau
Lead Healthcare

Bayard Consulting

Working for a solution provider, the uncertainties about the future of Eudamed and their impact on industry's readiness are the most burning ones for me. Will Eudamed be accelerated as strongly requested by most member states in the last European Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) meeting? Or will it be delayed for many years as per the latest European Commission official roadmap, or even discontinued as some companies may start to believe?

From a broader perspective and talking to the Industry, I am concerned by the adverse impact of the medtech regulations on both innovation and re-certification process we see in Europe versus other countries like the US. This may decrease the number of new devices on the European market. I am also concerned about the potentially conflicting vertical (MDR, IVDR) and horizontal European regulations (e.g. on AI and sustainability).

I believe the MDR and IVDR's obvious weaknesses should be assessed in depth by the authorities and stakeholders together. This should focus on remedying negative impacts on patient safety arising from potential device shortages in Europe in the coming years, as well as from delayed transparency from improved vigilance and post-market surveillance (which require a mandatory and functional Eudamed).

The next step will then be to take regulatory and business actions accordingly, to remedy the flaws in the current regulations and their implementation. The challenges are well-known – the reasons must be made clear to be efficiently addressed.

Finally, European horizontal regulations covering medical devices need to be made consistent with the MDR and IVDR.

Read more about proposals to delay the Eudamed timelines and why the topic is high on the EU agenda at present.

Tom Melvin
Associate Professor of Medical Device Regulatory Affairs
Trinity College, Dublin

From a public health perspective, we are in a better place now when compared with 2022 when we faced the real possibility of the loss of significant numbers of medical devices, some of which would likely have been essential.

The main uncertainty that we face at present rests with the future governance of our system. The term of office of the current European Commissioners ends during 2024, which will be an opportunity to renew the strategic vision for how the regulatory system should work. Getting this right will be vitally important for our regulatory system.

The vision for the first Directives in the late 1980s was clear – a reduction in technical barriers to trade for electromedical equipment. Although clear, this created a series of blind spots, for example relating to the rules for clinical evidence, that we never managed to tackle comprehensively in Europe.

We have now been implementing the 'new' regulations for six years, and we face another six years of transitional rules. If we want to build a more proactive mandate for device regulation, we need to develop a compelling vision for the future of the regulatory system, one that goes beyond work programmes and implementation activity, and focusses on the important questions facing our system.

Read more about how Melvin highlighted the MDR's threat to essential medical devices in 2022.

Gert Bos
Executive Director
and Partner
Qserve
&
CEO
Qserve China

Key challenges certainly include the uncertainties that lie ahead of us. These may be as complex as the potential effects of AI on specific products and on general regulatory science, as well as for things that should not frighten us like running clinical studies.

Whilst social media is filled with the hustle and bustle on AI, there is no such vibe on clinical trials.

We see companies asking for support with designing and running their clinical studies. For innovative devices this has been ongoing for a while, as there is no escape for those. But for legacy devices we see a drift from post-market clinical follow-up (PMCF) surveys to enquiries about registries and post-market clinical studies. To many, that is a challenge, as they are inexperienced in that field.

In my view, the legislative framework underpinning the MDR and IVDR is well laid out to cope with innovation and technological advancements. However, there is room to add further details in additional legislation to support specific elements of change in medical technology.

Where challenges will be bigger is in cross-sectoral legislative developments. The AI Act, and environmental laws underpinning the "green deal", for example, are rocking the foundations of the MDR and IVDR, as they start from a different concept, with different definitions, even of who is named as what type of stakeholder.

Another critical element that will get more attention in 2024 is debate on broadening of a central agency scope to further support the structural implementation of the EU MDR and IVDR.

Read more about cross-sectoral legislative developments and possible solutions to manage them and about the AI Act and how it is expected to impact medtech.

Sue Spencer
Head of IVDs
Qserve Group

I've worked in the regulated space for 30 years and this year has been the most unpredictable.

The extension to the MDR transitional periods caused IVD manufacturers to press pause on their transitional efforts on the assumption that an extension would be given to the IVD sector. Whilst this may have been predictable to some extent, the magnitude of the slowdown caught everyone by surprise.

At one point notified body applications were down by 50% with a knock-on impact to all supporting services.

It is a difficult situation, delays in infrastructure and capacity in the system have hampered the transition to the IVDR; however, extensions cause industry to pause their efforts and do not move the sector closer to compliance.

The next transition deadline will be for Class D devices in May 2025. Manufacturers who have not already submitted applications will be late.

Many of these Class D devices are Covid tests and some companies have been hoping Covid may be down-classified to a Class C and holding back on making their applications.

Class D devices have also suffered due to the late designation of the reference laboratories who will not be fully operational until 2024.

Some are proposing a delay to the transition of Class D devices. The challenge is how to provide flexibility but keep the industry moving towards compliance and not punish the earlier adopters who invested and have made the transitions on time as they may not do this again in the future.

There has been a lot of discussion about structured dialogue with notified bodies. This will be a great addition; companies entering the US market really benefit from pre-submission discussions with FDA and it would be very beneficial for novel devices to have similar discussions in Europe.

It is also difficult to present emerging technology issues to competent authorities as a group. The reactivation of the IVD Technical Group and projects such as the COMBINE project* on clinical trial applications will hopefully provide more forums for discussion in 2024.

It is important to remember that all IVDR stakeholders are still on a learning curve, and we need to continue to evolve mechanisms for dialogue to address and resolve issues in a timely manner.

* The COMBINE project aims to tackle the complex regulatory interplay between the Clinical Trials Regulation, the IVDR and the MDR. In the long-term, 'COMBINE' seeks to clarify and align the interface between clinical trials of investigational medicinal products, IVD performance studies and clinical investigations of medical devices.

Read more about proposals to smooth the certification pathway for high-risk IVDs and to down-classify Covid tests.

Bassil Akra
CEO
Akra Team

Being part of the initial discussion on the EU's MDR and IVDR, I fear that the trust of the various impacted stakeholders in the system timelines and their implementation enforcement has become lost.

Even the legislator, who should be guiding us with clear commitments, is regularly delaying essential tasks such as the Eudamed timelines.

The biggest challenge is motivating resources, and management, to keep going since the new transitional timelines are final.

I think both legislations provide a baseline which can be shaped in the right way where guided by key experts and stakeholders.

The only problem that I was, and I am still seeing, is the unharmonized implementation at the various member states.

The EU system now needs: someone responsible for assurance of the healthcare system continuity; someone responsible for harmonization of the interpretation at EU level; a method to ensure early dialog between manufacturers, authorities and certifiers; and, finally, a responsible authority (at EU level) to do a special release of innovative devices or devices for

vulnerable populations.

Read more about how Akra anticipates EU legislators will react to calls for regulatory reform.