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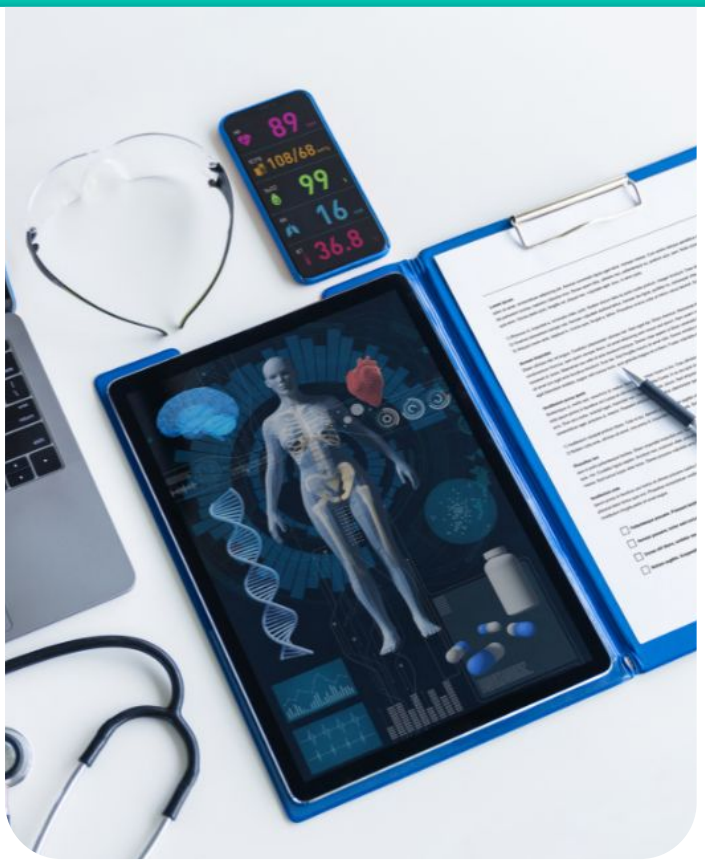
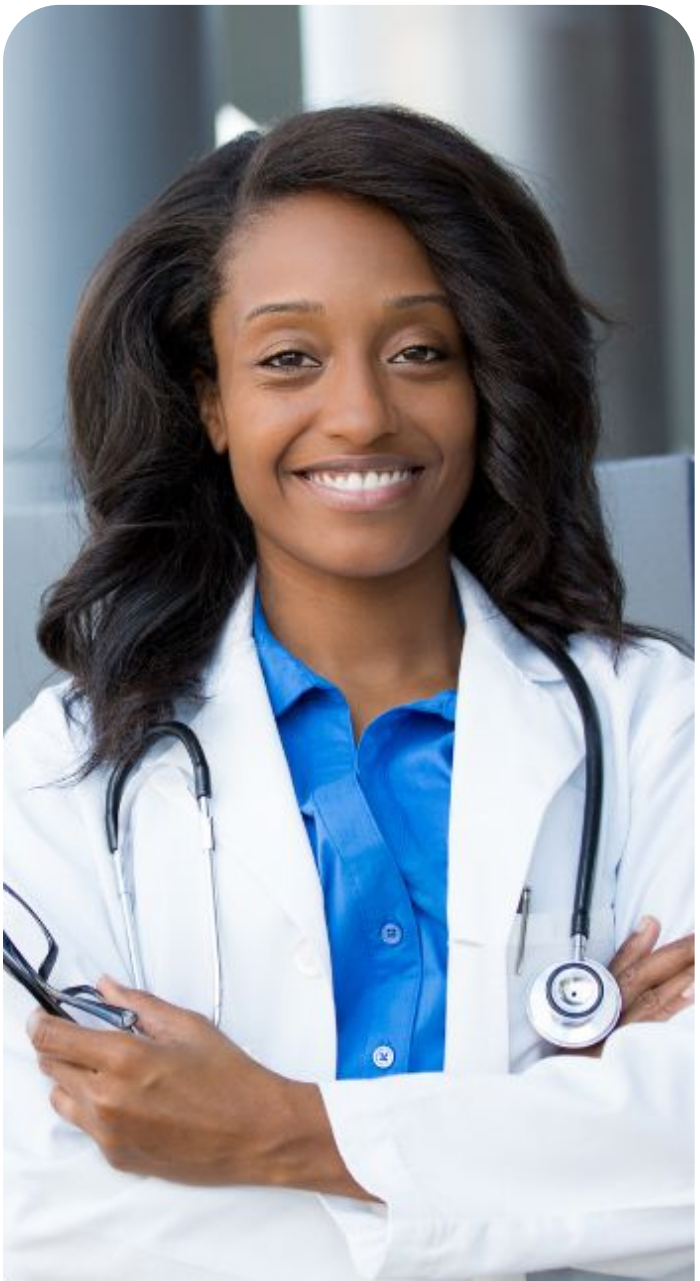


Medical Devices - Changing Regulatory Landscape in the UK & EU



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15 April, 2025

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Table of Contents

Medical Devices - Changing Regulatory Landscape in the UK & EU

01 About the Author

02 Unlocking Market Access

03 Introduction

04 United Kingdom

- 4.1 New Regulations for Post-Market Surveillance (PMS)
- 4.2 New Regulations for Pre-Market Requirements (PMR)
- 4.3 Policy Development and Software/AI Guidance

05 European Union

06 Navigating Regulatory Convergence: EU and UK Reforms and Their Cross-Market Impact

07 Conclusion: The Path Forward for Manufacturers

08 References

01. About The Author

Fernanda Paro
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Fernanda is a Regulatory Compliance Specialist within the Global Regulatory Compliance Team, serving as the primary Subject Matter Expert (SME) for Medical Devices.

She specializes in monitoring and analyzing regulatory updates across various Latin American countries. Fernanda holds a Master's Degree in International Trade Law with a focus on Medical Devices, Data Protection, and Cybersecurity.

As a qualified lawyer registered in both Brazil and Portugal, she brings extensive expertise in navigating complex regulatory landscapes to ensure compliance and strategic alignment.

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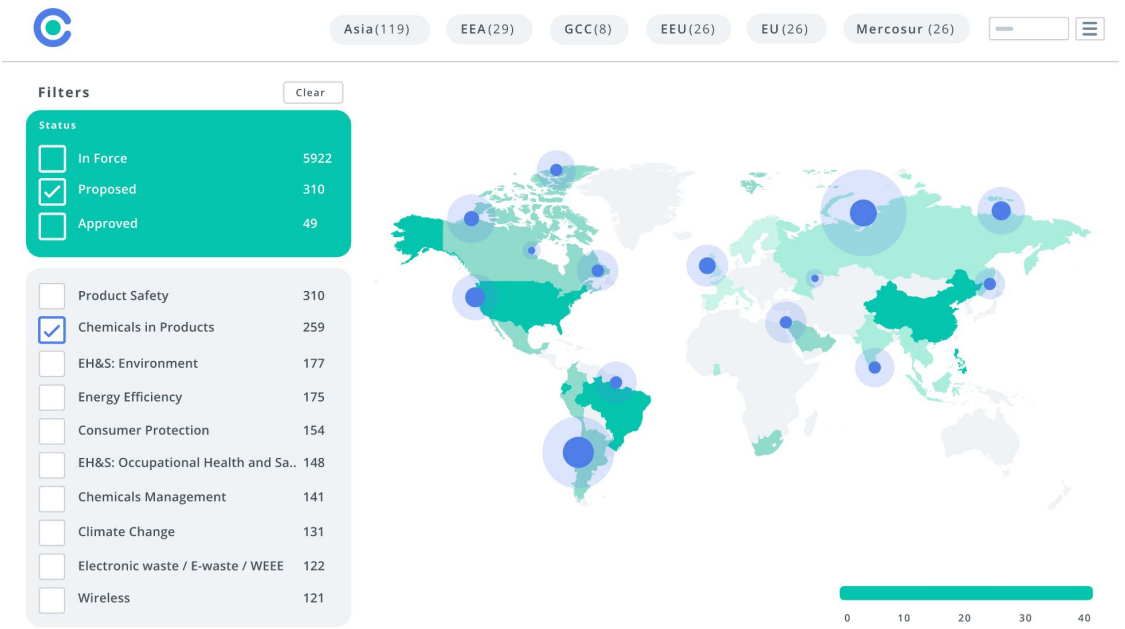

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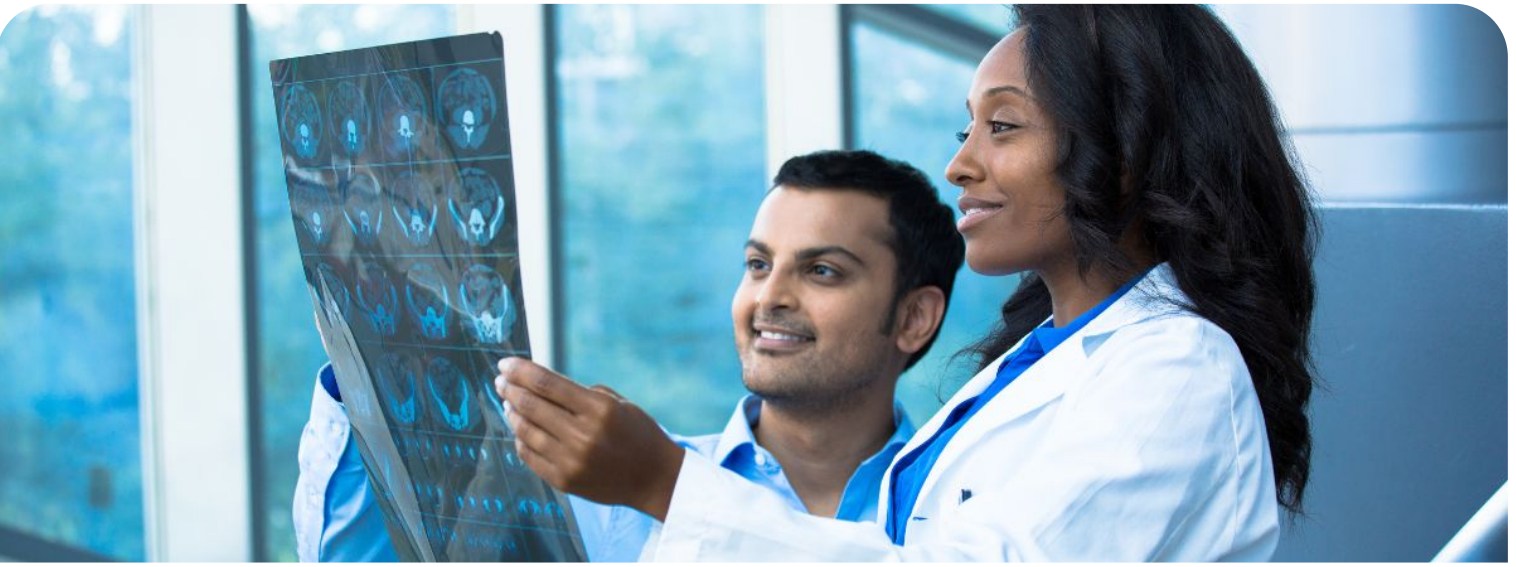
03. Introduction

The medical device industry faces a complex regulatory landscape in the UK and EU, characterized by evolving requirements and diverging standards.

While the EU continues to refine its Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR), the UK is forging its path post-Brexit, implementing reforms under the Medicines and Healthcare Products Regulatory Agency (MHRA).

This whitepaper provides an overview of these changes, focusing on the key developments in both regions and the challenge they pose for manufacturers seeking to access both markets.

Furthermore, this analysis explores the concept of regulatory convergence and examines how initiatives aimed at harmonization and international recognition can help mitigate the impact of differing requirements.



04. United Kingdom

In 2025, the UK's MHRA is set to implement major reforms and new regulations/ guidelines designed to improve patient safety, expand market access, and foster innovation in the medical technology sector.

These changes and updates cover a wide range of areas, including digital mental health technologies, artificial intelligence (AI), Unique Device Identification (UDI), In-vitro diagnostics (IVDs), and more.

One area of divergence between the EU and the UK that has drawn attention is labeling. To address this and facilitate a smooth transition, the UK government has revised the UK Medical Device Regulations (2002), allowing devices with CE (Conformité Européene) marking to transition to the new UK framework until June 2028 or June 2030, depending on the specific conditions met.

Also, the MHRA is actively exploring the possibility of approving devices that have already received authorization from major regulatory bodies such as the U.S. FDA, Health Canada, and the Therapeutic Goods Administration (TGA) of Australia.

Furthermore, the MHRA's 2024 roadmap outlines its comprehensive plans for 2025 reforms, which include four primary updates:

- New regulations for post-market surveillance (PMS);
- New pre-market requirements;
- Policy development; and
- Additional guidance on AI and software for digital health products.

4.1. New Regulations for Post-Market Surveillance (PMS)

A key element of the MHRA's 2025 reforms is a comprehensive overhaul of post-market surveillance (PMS) requirements. Set to take effect on 16 June 2025, these updated regulations aim to strengthen the oversight of medical devices once they are on the market in Great Britain.

Significant updates include clearer, risk-proportionate PMS requirements designed to enhance the traceability of device safety incidents and ensure timely actions to prevent patient harm. Manufacturers will also be required to provide more detailed data throughout a device's lifecycle, including shorter reporting timeframes for serious incidents.

Additionally, the new guidance on Field Safety Notices improves how manufacturers communicate corrective actions, ensuring that patients and healthcare professionals are informed quickly.

These changes are intended to establish a strong foundation for patient safety and pave the way for future regulatory reforms.

4.2. New Regulations for Pre-Market Requirements

The goal of pre-market regulations is to create more patient-centric and balanced requirements for medical devices that keep pace with technological advancements while fostering stronger international collaboration and practices.

The upcoming pre-market regulations will introduce several changes, including:

- Implantable medical devices will be up-classified, resulting in more stringent requirements.
- Manufacturers will also be required to provide implant cards, allowing patients to identify the devices that have been implanted in them.
- Devices will be mandated to include a unique device identifier (UDI), and several types of devices will see changes in classification. Specifically, certain software will be up-classified as medical devices and in-vitro diagnostic (IVD) classifications will be aligned with those of the International Medical Device Regulators Forum.
- Strengthening the requirements for technical documentation, and introduce a framework for international recognition. This will enable quicker market access for devices already approved by comparable regulators.
- New requirements will be implemented for custom-made devices, and manufacturers will face updated regulations on the claims they can make about their devices, ensuring that these claims align with the statement of intended purpose.

Additionally, the essential requirements for placing medical devices on the GB market will be brought into closer alignment with those of the EU, which will include cybersecurity requirements for software as medical devices, such as artificial intelligence. Overall, these pre-market regulations aim to enhance international collaboration, establish more patient-centered and proportionate requirements for medical devices, and ensure the regulations are responsive to technological advances.

As per MHRA the results from consultations on these proposed changes shall be published in spring 2025. The new rules are expected to come into force later.

4.3. Policy Development and Software/AI Guidance

As digital health technologies, including AI and software as medical devices, continue to evolve, the MHRA is committed to creating a policy framework that ensures safety while encouraging innovation.

The roadmap includes guidance on:

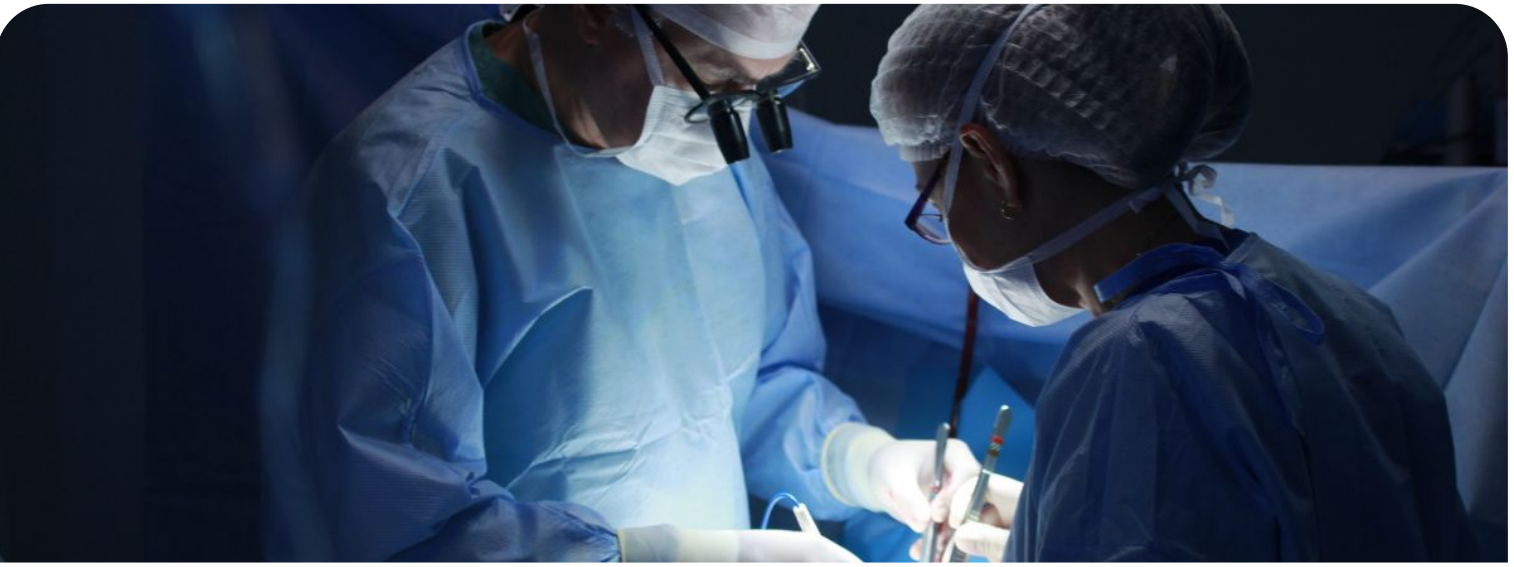
- **Exceptional Use Authorizations:** These provisions allow medical devices that are not yet UK Conformity Assessed (UKCA) to be sold if they are necessary to protect patient health and no alternative exists.
- **Good Machine Learning Practice (GMLP):** In collaboration with the U.S. and Canada, the MHRA issued guidance on machine learning best practices in medical devices.
- **AI and Digital Mental Health Guidance:** This guidance provides updates on AI development, deployment, and cybersecurity for software-based medical devices. The agency has also partnered with the Wellcome Trust project to improve regulations for digital mental health products, ensuring they are both safe and effective.

The MHRA is also addressing the growing importance of AI and digital technologies in healthcare.

Thus, the agency updated the Guidance on Software and Artificial Intelligence (AI) as a medical device, which is a vital component of health and social care. In the UK, many of these products are regulated either as medical devices or as in vitro diagnostic medical devices (IVDs).

In addition, through its AI Airlock Programme, the agency is seeking to tackle the unique regulatory challenges posed by AI in medical devices. The initiative aims to streamline submission processes, reduce costs for the industry, and enhance patient access to innovative healthcare solutions.

Finally, it is good to highlight that besides these regulatory changes, the UK government is also working with health and safety regulators to modernize existing frameworks. The Health and Safety Executive (HSE) will review older regulations, such as the Pressure Systems Safety Regulations 2000, to ensure they reflect current technological advances and reduce unnecessary burdens on the industry.



05. European Union

The landscape of medical device regulations in the European Union is undergoing significant change as the European Parliament and the European Commission work to address a variety of challenges that have emerged with the implementation of the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR).

Both regulatory frameworks were introduced to ensure patient safety, but the complexity of their requirements, coupled with challenges faced by manufacturers, particularly small and medium-sized enterprises (SMEs), has resulted in substantial criticism and calls for change.

In October 2024, the European Parliament voted in favor of a resolution emphasizing the urgent need for revisions to the MDR and IVDR. Regulation (EU) 2024/2849, published on 29 January 2025, came in response to growing concerns about certification delays and high compliance costs, market access barriers and device shortages, lack of Fast-Track approval pathways (mainly for innovative medical technologies), and inconsistent Notified Body (NB) Processes (variation in procedures and timelines across NBs led to lack of transparency).

In response to these issues, the European Parliament has called for the European Commission to propose legislative amendments to the MDR and IVDR by the end of Q1 2025. These revisions aim to address the most pressing challenges faced by the industry, streamline the regulatory process, and improve transparency. Several key actions are being proposed, including the harmonization of procedures across the EU, an introduction of Fast-Track Approval Pathways, support for Small and Medium-Sized Enterprises, and strengthened Digital and E-Health Regulations.

In the meantime, concomitant relevant developments are set to occur within the regulatory landscape:

- **Expansion of the Well-Established Technologies (WET) List:** The European Commission plans to adopt a delegated regulation in the third quarter of 2025 to expand the list of well-established technologies exempt from certain legal requirements under the MDR. It intends to help reduce administrative burdens while maintaining health and safety standards.

- **Electronic Instructions for Use (eIFUs):** A new regulation expected for the second quarter of 2025 aims to allow for electronic instructions for all medical devices intended exclusively for professional use. This will streamline access to device information for healthcare professionals.
- **Increased Notified Body Requirements:** On 7 February 2025, the EU updated the "MDCG 2019-6 rev.5-Questions and answers: Requirements relating to notified bodies" aiming to improve consistency and reliability in the conformity assessment process.

In addition to the MDR and IVDR, another major milestone was achieved in the first quarter of 2025. The European Commission published the European Health Data Space (EHDS) Regulation which has been applicable since 26 March 2025, but includes future applicability dates for certain parts.

The Regulation facilitates the exchange of health data across EU Member States, improving the efficiency of healthcare systems and supporting the development of digital health technologies. By March 2029, the EHDS aims to make key categories of health data, such as medical images and lab results, available for use across the EU, paving the way for more efficient and data-driven healthcare solutions.

The EU Commission has also developed the HealthData@EU Central Platform to comply with the forthcoming European Health Data Space Regulation. This digital system consolidates the Dataset Catalogue and enables the submission and evaluation of Data Access and Data Request applications by authorized Health Data Access Bodies.

Other recent developments taking effect in early 2025 and requiring attention are the following:

- Regulation (EU) 2024/1860, which came into force on 10 January 2025, mandates that medical device manufacturers must report any planned discontinuations or predicted supply interruptions at least six months in advance. Manufacturers will be required to notify economic operators, healthcare institutions, and professionals who receive their devices directly.
- EU's Directive on Liability for Defective Products (PLD) comes into force in December 2026 and imposes stricter accountability standards on manufacturers because it has changed legal compliance requirements for producers of products marketed in the EU. Thus, manufacturers must adapt their internal processes to meet the legal requirements in 2025 to avoid liability for damage caused by product defects, including software- and AI-supported medical devices.
- EU's Health Technology Assessment (HTA) framework, introduced in January 2025, aims to enhance collaboration among EU member states and streamline the process by which new medical technologies are assessed and introduced to the market.

The EU's medical device regulations have faced substantial challenges since their implementation, particularly with the MDR and IVDR and those related to innovative technologies. However, the ongoing dialogue between the European Parliament, the European Commission, and industry stakeholders points to meaningful changes shortly. By addressing the regulatory bottlenecks, streamlining approval processes, and supporting SMEs, the EU can foster innovation while ensuring the safety and efficacy of medical devices and in vitro diagnostic technologies.

06. Navigating Regulatory Convergence: EU and UK Reforms and Their Cross-Market Impact

Both the EU and the UK are undergoing various regulatory changes and new implementations, many of which impact both markets.

Staying informed about the latest legislation and guidelines in each region is crucial, but it is equally important to understand how these regulations interact and influence one another. As the EU and UK continue to refine their frameworks, the cross-border implications of these regulatory developments can significantly affect compliance, market access, and innovation in both jurisdictions.

A good example is the fact that the MHRA's 2025 reforms align with ongoing efforts in the European Union to regulate AI and digital health technologies more effectively. Collaboration between UK regulators and the EU is essential to ensure that new AI and digital health products are safe, effective, and accessible.

In terms of collaboration and alignment, the UK's IMDRF membership demonstrates its commitment to global medical device regulation harmonization. It actively participates in standardizing regulations and co-leads a working group on AI and Machine Learning-enabled medical devices, focusing on international consistency in this evolving sector.

In addition, as mentioned above, the UK has introduced the UKCA marking system as a replacement for the EU's CE marking, signifying a shift in regulatory compliance for products marketed within Great Britain. Thus, businesses operating across both the EU and UK markets face the challenge of ensuring dual compliance. This means that products intended for both regions must meet the distinct requirements of each marking system, potentially leading to increased administrative and regulatory burdens. As the transition progresses, staying informed on the evolving guidelines for both UKCA and CE marking will be crucial for maintaining market access and compliance.

Manufacturers must also consider the differences in post-market surveillance between the UK and the EU. Definitions of terms and PMS requirements vary, and non-compliance could be an issue.

07. Conclusion: The Path Forward for Manufacturers

As regulatory changes continue to reshape the medical device industry, manufacturers must take proactive steps to ensure they are prepared for the future and monitor regulatory developments closely, particularly those related to PMS, product liability, the new HTA framework, and others mentioned above.

By staying informed and adapting to these changes, manufacturers will be well-positioned to maintain market access, protect patient safety, and stay competitive in an increasingly complex and regulated landscape.

As the European Commission and MHRS move towards revising and creating several contents, it will be essential for manufacturers to:

- Stay updated on the latest legislative developments and adapt their compliance strategies accordingly;
- Participate in consultations and pilot schemes to shape the future of medical device regulation;
- Establish strong relationships with notified bodies and ensure clarity on assessment timelines; and
- Monitor upcoming regulatory changes, such as the expansion of the WET list and the implementation of the EHDS, to ensure they remain compliant and competitive.

The next few years will bring significant changes to the regulatory framework for medical devices in the EU and UK. By preparing for these revisions and adapting to the evolving landscape, manufacturers can continue to innovate and bring essential medical technologies to market while ensuring patient safety and regulatory compliance.

Compliance & Risks monitors for such updates regularly. Want to see how you can stay ahead of your medical device compliance obligations? Start a conversation now!

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