

Impending Changes to the European Union Medical Device Regulations





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WHAT HAS HAPPENED?

Ranging from simple hand plasters to sophisticated neuromodulators and in-vitro diagnostics, medical devices are crucial for our well-being and quality of life. Consumers rely on these devices every day and expect them to be safe and include the latest scientific and technological innovations.^[2]

Medical device regulations (MDR) in the European Union (EU) have been relatively unchanged since their inception in the 1990s. Driven by the need to toughen the regulatory landscape to ensure better patient safety and finer synchronisation with the technological progress and innovation in this area over the past 20 years, the EU Medical Device Commission proposed Medical Device Regulations to update the rules. These new medical device regulations were officially adopted 26 May 2017 in the EU and will come into force from 26 May 2020 for medical devices, and from 2022 for in-vitro diagnostics devices.^[2]

WHAT HAS LED TO THE CHANGES IN THE MDR?

[1][2]

EU regulations surrounding the use of medical devices have not been significantly changed since their commencement in the 1990s. In order to improve the safety and efficacy of medical devices in the EU and develop rules in accordance to modernisation in the sector, the changes aim to:

- Simplify the MDR to provide patients and healthcare practitioners with comprehensive up to date quality assurance standards pre and post treatment – device approval, traceability, patient data privacy, etc.
- Strengthen the regulatory directives in order to reassure patients and consumers of the highest product safety standards in light of a series of high-profile cases such as with breast implants and metal on metal hip implants.
- Encourage a more consistent approach to regulation both within the EU and compared to other regulators such as the Food and Drug Administration (FDA).
- Move towards harmonisation, with drug regulations for certain products such as drug-device combinations, tissue engineering, and nanoscience.
- Support more standardised, consistent, and less complex trading between EU member states.



SPOTLIGHT

Medical Device Industry

\$407bn

Expected size of the medical device market in 2020.

3.5%

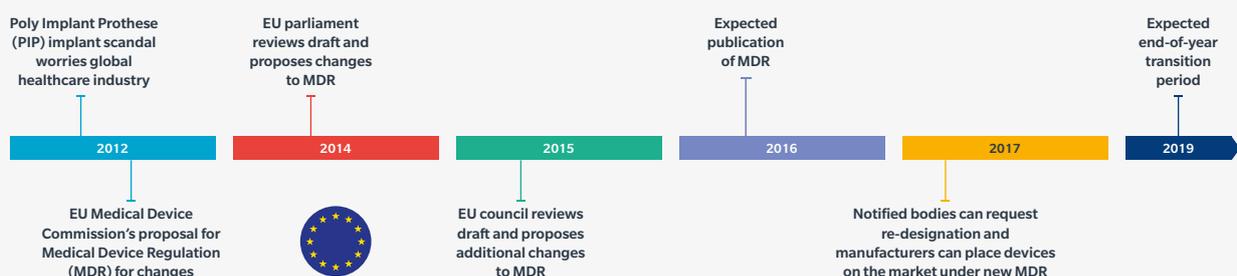
R&D expenditure annual global growth rate for MedTech through 2020.

33%

The EU accounts for one-third of the global medical device market.^[4]

FIGURE 1 Timeline for the Changes in the MDR

Source: LRQA^[4]



WHAT ARE THE KEY CHANGES?^{[1][2][3][5]}

The directive will radically change the way devices are approved and regulated in the EU. As illustrated in Figure 2, patient safety is at the core of these modifications – they are intended to lead to better transparency, traceability, harmonisation, and simplification for the patients/consumers. The changes include the following:

- A change in the definition of what constitutes a medical device, such as aesthetic products and in vitro devices. As a result, more in vitro diagnostic devices will be considered as medical devices and fall under stricter governance.
- The introduction of changes to the classification of certain products. There will be increased evidence requirements for higher risk products, for example drug-device combinations and tissue engineering products.
- Technological advancements such as medical software, apps, and cyber security systems will be placed under stricter regulatory and compliance reforms.
- The implementation of a new Unique Device Identification (UDI) system for each device, to allow easier traceability.
- The introduction of an “implant card” for patients having implanted medical devices in order to make the information about the device easily accessible to the patients, thereby improving traceability.
- Hospitals being obliged to give options and clear information to their patients about the device that is being implanted into their body, thereby promoting transparency for patients.
- Extended information obligations for manufacturers with respect to product labelling or instructions.
- The launch of the EU Database on Medical Devices (EUDAMED), which should contain the life-cycle of all the products available in the EU market.
- Uncompromising rules on quality management systems (QMS) and post-market surveillance (PMS) plans and stricter obligations around the confidentiality of patient data.
- Unannounced factory audits in order to compel manufacturers to be compliant with the regulations at all times.
- Enhanced functions for notified bodies (in the EU, a notified body is an entity that has been accredited by a member state to assess whether a product to be placed on the market meets certain preordained standards), but also greater scrutiny of their performance by local competent authorities and increased cooperation between member states.
- European Notified Bodies need to be re-designated under the new MDR and In Vito Diagnostic Regulation (IVDR); they may start applying for the designation from 26 November 2017.
- The regulations also acknowledge that medical device manufacturers (or their authorised representative in the EU for external companies) must have “sufficient financial coverage” in place to cover their potential liabilities from product litigation. They do not, however, specify what is meant by “sufficient”, other than that it should be proportionate to the risk profile of the device.

MEDICAL DEVICE INSURER’S REACTIONS

“We welcome the enhancements, but that doesn’t mean that we will lower our due diligence guard.”

NEWLINE GROUP

“We will want to see that the regulations are being effectively embraced and implemented and that the client hasn’t just taken a tick-box approach.”

NEWLINE GROUP

¹ Deloitte. *Preparing for the future: The new European Union medical devices regulation*, available at <https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-eu-med-device-regulation.pdf>, accessed 2 October 2017.

² European Commission. *New EU rules to ensure safety of medical devices*, available at http://europa.eu/rapid/press-release_MEMO-17-848_en.htm, accessed 2 October 2017.

³ European Commission. *Communication From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions*, available at <https://www.bsigroup.com/meddev/LocalFiles/en-GB/Documents/BSI-md-mdd-ivdd-communication-2012-540-UK-EN.pdf>, accessed 2 October 2017.

⁴ LRQA. *The New Medical Device Regulation (MDR)*, available at <http://www.lrqausa.com/Images/133-103126medical-device-regulation-mdr-lrqa.png>, accessed 2 October 2017.

⁵ Emergo. *Entry into Force Milestone Reached for European Medical Device, IVD Regulations*, available on <https://www.emergogroup.com/blog/2017/05/entry-force-milestone-reached-european-medical-device-ivd-regulations>, accessed 2 November 2017.

WHO DOES THIS IMPACT?

The new regulations will impact every element of the supply chain, including all medical device raw material suppliers, component/parts manufacturers, device manufacturers, distributors, and retailers.

Each entity involved in the supply chain must be compliant with these regulations if they want to continue trading with the EU.

FIGURE 2 The Key Changes in the EU Medical Device Regulation and Their Impact
Source: Marsh



MEDICAL DEVICE INSURER'S REACTIONS

"A move towards harmonisation with systems used for regulating pharmaceutical products that was long overdue."

CHUBB

"We welcome the new Regulation as a huge step forward in the way that medical devices are approved and regulated in Europe. We look forward to seeing its impact on suppliers of medical devices as it is implemented over the next few years."

ALLIANZ

WHAT IS THE IMPACT ON THE MEDICAL DEVICE INDUSTRY?

The requirements imposed by the new regulations are going to be both costly and cumbersome, and it is important that medical device companies proactively work towards their implementation. These changes will have significant impact as it could influence the revenue stream and ability to trade products within the EU^[3].

The implementation of these rules requires resources and technical support; it could be particularly challenging for the small or medium-sized companies with limited funds to devote to the necessary time and resources toward implementation. As a result, this could lead to greater collaboration and an increase in mergers and acquisitions (M&A) activities in the sector.

It is expected that there will be some cost benefits associated with the changes, such as a simpler pan-European registration process, and there is potential for a dividend flowing from improvements in quality and risk management.

In theory, compliance with the new legislation across the industry is expected to lead to:

- Lower incident frequency of product failures.
- Improved quality management and product traceability.
- A reduction in the cost and frequency of product recalls.
- Reduced litigation costs resulting from product safety improvements.
- Improved terms and broader availability of insurance transfer solutions.

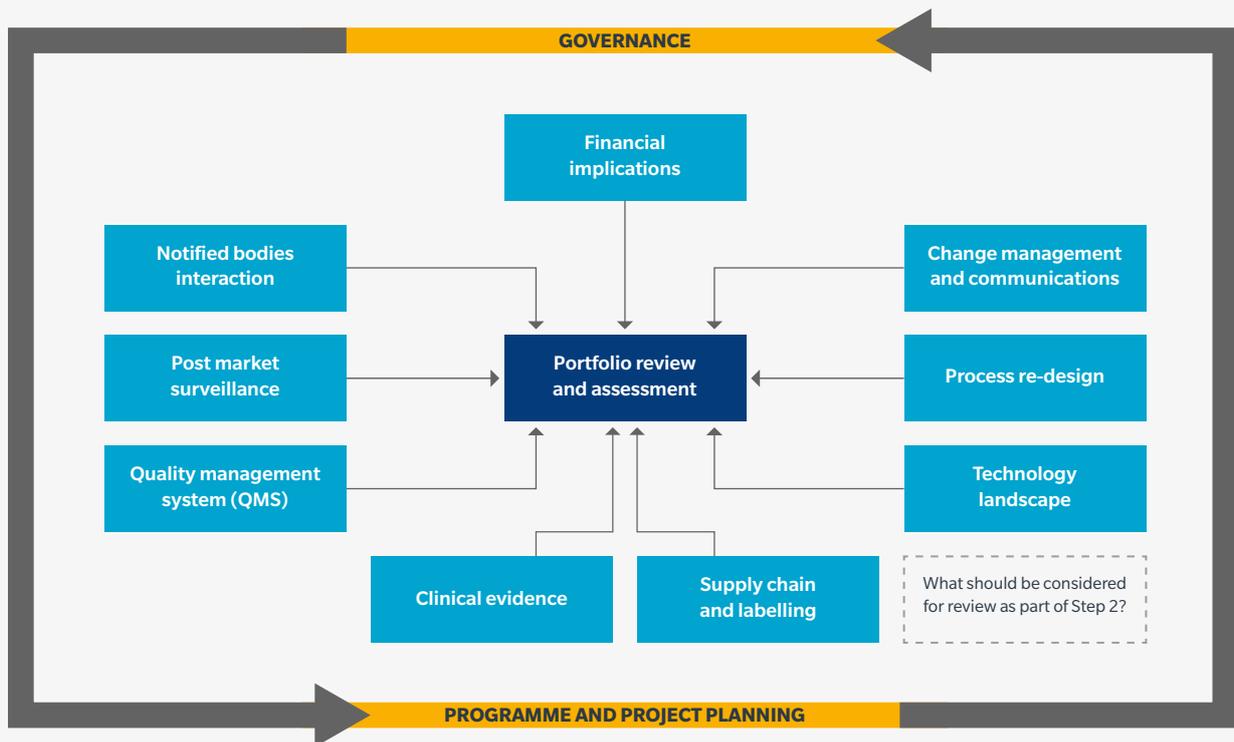
WHAT IS THE IMPACT OF THE DIRECTIVE ON COUNTRIES OUTSIDE THE EU?

Irrespective of political landscapes and geographical locations, it is presumed that medical device companies will implement the new regulations if they want to continue trading with the EU. It is critical that companies be compliant with the new regulations if they want to keep selling products in the EU.

WHAT DO THE MEDICAL DEVICE PRODUCT LIABILITY INSURERS THINK?

Whether this will follow through in practice remains to be seen. Marsh has consulted with a range of leading insurance capacity providers to the medical device sector and, while there was no absolute consensus, the following themes emerged:

FIGURE 3 Key Focus Areas That Medical Device Companies Should Consider During Review and Assessment^[1]
Source: Deloitte^[1]



- Enhanced regulation in Europe is seen as being long overdue and, in many ways, viewed as simply catching up with FDA systems in US. Nevertheless, its introduction is a welcome move.
- Stricter regulation is seen as particularly essential for new higher risk devices in areas such as tissue engineering and nanomaterials.
- Insurers will seek evidence of material safety improvements springing from the practical implementation of the regulations, rather than as a compliance exercise.
- It is hoped that the new regulations will be more difficult to deliberately breach; it is, at this stage, unclear if these regulations would have been robust enough to have prevented scandals such as the use of industrial grade silicon in PIP breast implants.
- Each company's risk profile will continue to be judged on its own merits, with premium levels set accordingly.
- The introduction of a new device identification system has been universally welcomed. It is too early to say, however, whether this will result in greater appetite for offering product recall insurance, as insurers in this space have experienced significant losses in the past.
- Clearer regulation on maintaining confidential data has also been welcomed. However, this, in combination with the new EU General Data Protection Regulation (GDPR), adds new obligations and, consequently, potential additional risks for manufacturers.
- Insurers remain concerned about the vulnerability of many medical devices to cyber-attack, but the extent the new regulations will address this issue remains unclear.
- If improvements lead to a constant reduction in adverse incidents and insurance claims across the medical device sector, it is likely that the sector will become more appealing, attracting more insurance capacity, creating competition, and reducing premium costs.
- Marsh is continuing dialogue with insurers that do not currently offer cover for higher risk implantable devices. We do not expect there to be an immediate increase in insurance capacity available for these devices, but, in general, the insurance industry has been positive and welcoming towards the change.
- Have you performed a vulnerability (revenue impact) assessment for non-compliance across your supply chain?
- Businesses should explore whether their business interruption policies can be extended to include "non-damage triggers" such as regulatory breach for themselves or their major suppliers.
- The potential for management to be held personally responsible if the company fails to comply with the new regulations. Companies should check that their directors and officers policies will respond to litigation from stakeholders alleging breaches of their governance duties.
- The potential that as Brexit terms become clearer, the UK chooses a different regulatory pathway.
- Businesses should ensure that adequate product liability and clinical trials liability are in place and meet the "sufficient financial coverage" requirements.

WHAT ACTIONS SHOULD INSURANCE BUYERS TAKE NOW?

As the requirements of the legislation become clearer and regulators implement the new rules, manufacturers should be aware of how these may increase risk profiles and consider the ways these will be managed and financed.

Such considerations include:

- How can you assure compliance and preparedness to the new regulation across your supply chain? Have you built provisions in your supply agreements to account for these developments and failure to comply?

Medical device companies will need to meet the requirements of the regulations to continue trading within the EU markets. Companies should contact their life science insurance adviser and scrutinise their risk management plans now with respect to the new EU medical device regulations and consider how the changes will affect the risks they face and the industry specific insurance cover they need to have in place.

MEDICAL DEVICE INSURER'S REACTIONS

"Unique Device Identification as a standard practice is hugely reassuring to insurer's from a traceability and accountability perspective."

HDI

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