Houlihan Lokey | Caldwell

Au Revoir, Innovation? How the EU MDR Is Reshaping the MedTech Industry

Introduction

On 26 May 2017, the EU's Medical Device Regulation (MDR) came into force, replacing the Medical Device Directive (MDD) of 1993 with effect from 26 May 2021. The medtech industry has been in turmoil ever since.

Companies have been scrambling to comply with the new rules. Notified bodies have struggled to cope with the unprecedented workload. Leaders have voiced growing concerns over how the regulations are being implemented. Panic has spread over potential device shortages. Final dates for compliance have been pushed back—and then pushed back again. Dire predictions have been made about the future of innovation and investment in Europe.

Now the dust appears to be settling. Most companies look set to meet the revised deadlines and the backlog of product approval is slowly starting to ease. While it may be too early to describe the MDR as the new normal, there is no doubt that the regulations are here to stay.

How do boards and investors feel about recent events and about the future? What consequences will there be for Europe in the medium to long term? Will regulatory affairs play a more significant role in companies from now on? Who, if anyone, has benefited from the introduction of the MDR?

We have sought to answer these questions through extensive research and numerous interviews with leaders within the medtech industry in Europe and the United States. This paper weaves together their wide-ranging views and insights to chart the ongoing journey of the MDR and gauge its impact on the industry in the past, present, and future.

Background

The EU Medical Device Directive: Why, What, and When

Europe is one of the largest and most important markets for medical device manufacturers, with sales of approximately €150 billion in 2021.[i] Until recently, medical devices produced and distributed in the EU were mainly covered by the EU Medical Device Directive (MDD), the Active Implantable Medical Device Directive (AIMDD), and the IVD Directive (IVDD)(1). The MDD, first implemented in 1993, established a relatively light-touch regulatory environment compared to the FDA that enabled companies to launch new products quickly and easily and made the EU a magnet for innovators around the world.

That all changed in 2009 when concerns began surfacing about the abnormally high rupture rate of silicone gel breast implants produced by the French company Poly Implant Prothese (PIP). It was later discovered that PIP had been illegally switching the silicone they were using from mandated medical-grade to in-house industrial-grade production. Hundreds of thousands of women worldwide were affected, and the company's founder was imprisoned in 2013.[ii]

In the aftermath of the scandal, the EU sought to strengthen the rules governing the safety and monitoring of medical devices. This ultimately led to the MDD being replaced in 2021 by the EU Medical Device Regulation, otherwise known as MDR. The aim was to establish a more robust, transparent, sustainable, and predictable regulatory framework, bring legislation in line with technological advances and progress in medical science, and harmonise the review and approval process across all member states. Many of the industry leaders we spoke to expressed their support for this aim. As Roland Goette, Executive Vice President and President, EMEA at Beckton Dickinson says: "There were too many loopholes and inconsistencies. The system needed to be modernised and made safer."

What Changed?

The most obvious difference between the MDR and the MDD is reflected in their names: a "regulation" is a law enacted directly for all European member states, whereas the previous "directive" merely set minimum standards which each member state could choose to interpret and implement however it saw fit.[iii]

The MDR is also significantly more comprehensive and detailed than the MDD. It introduces new or revised responsibilities for many devices, including medicines with an integral device, medical devices containing an ancillary medicinal substance, and medical devices made from substances that are absorbed by the human

(1) In Vitro Diagnostic Regulation (IVDR) replaced the IVDD and entered into force on 26 May 2017 with 26 May 2022 as date of application.

> "The European Union's Medical Device Regulation increases safety and improves health outcomes for millions of people across the EU with the objective of higher benefits to European patients. Going further, we believe that the system can evolve to acknowledge technological innovation and harmonise the review and approval process across all EU member states. MDR has the key objective of enabling the Industry partners to bring their advanced medical devices to the EU market in a more transparent, sustainable, and predictable way."
>
> – Samih Al Mawass
>
> Divisional Vice President, EMEA, Abbott's Vascular Business

body.[iv] Classification changes were implemented to take into consideration of the changing medtech landscape and innovation (e.g. software) and to "up-classify" products with higher risk profiles (e.g. spinal disk and joint replacement devices). In addition, it establishes new requirements for clinical evaluation,[v] clinical investigation,[vi] and post-market surveillance.[vii] These rules apply to both new and existing products, meaning that companies need to recertify legacy devices and update labelling to align with the MDR.

Another key impact of the MDR is the introduction of two new regulatory systems:

- **EUDAMED**
  The EU Commission has created a database (EUDAMED) that will provide a living picture of the lifecycle of medical devices. This requires companies to provide additional data in areas including post-market surveillance and clinical performance.[viii]
- **UDI**
  Any company intending to provide or distribute medical devices in the EU will now need to comply with a new unique device identification (UDI) labelling system, which aims to increase the traceability of medical devices.[ix]

Timelines

The MDR entered into force in May 2017 and became applicable on 26 May 2021. However, the EU Commission recently extended the deadlines for medical device manufacturers to certify their products under the new MDR rules. Although the extensions allow additional time for products to comply with the MDR, manufacturers must in any event comply with the rules on registration and post-market vigilance. This is the second time the deadlines have been extended. The new delay, proposed by the EU Commission and adopted by the EU Council and the European Parliament in February 2023, extends the transition period to December 2027 (for Class III devices and Class IIb implantable devices) and December 2028 (for Class II and Class IIb non-implantable devices).[x]

The extension has been welcomed by the industry and is set to ensure patients do not lose access to the essential medical devices they need. In general, it is considered that further deadline extensions are now less likely.

Implications

Key Impacts of the MDR on MedTech Companies

The MDR has posed many questions for medtech companies, raising uncertainty levels across the industry—and, as several interviewees reminded us, uncertainty is always bad. However, some key impacts of the new regulation on manufacturers and users have now become clear.

Increased Time to Market

The new regulations have lengthened the time it takes to bring medical devices to market in the EU. This is partly due to the regulations themselves, which require many product developers to do more pre-launch work than in the past. The other critical factor is the notified bodies, which are currently unable to process applications at the speed companies would like. Wilfred van Zuilen, President, EMEA at Zimmer Biomet, explains: "They are not able to manage the huge demand that has been caused by the recertification process for legacy devices. Getting approval for medium-complex medical devices in Europe now takes around nine months, sometimes close to one year." The delays are being caused not just by lack of capacity, but also by lack of expertise, as staff at notified bodies without specialist knowledge are sometimes asking for irrelevant or unproduceable evidence. The process is also being slowed down because notified bodies are not providing companies with direction or guidance through the application process, as the new rules require them to remain independent.

Higher Costs

The MDR has proved costly for many medtech businesses. Companies are required to spend more to document the clinical effectiveness of new products, in line with the new requirements. Businesses have faced a significant one-off expense building the technical files and clinical evidence needed to recertify legacy devices. Some of our interviewees estimated the total cost to the industry to be somewhere in the region of $6 billion to $8 billion. This will ultimately be passed on to patients in the form of raised prices, increasing the cost of healthcare for all.

Rise of Regulatory Affairs

Many companies have grown their regulatory affairs (RA) capacity in response to the MDR, both by hiring additional team members and by partnering with external consultancies. While demand for RA specialists may have peaked, it is unlikely to ever return to pre-MDR lows. Larger compliance teams are the new normal, and medtech businesses need to continue developing strategies to attract and develop strong regulatory talent. At the same time, knowledge should not be limited to regulatory specialists. Several of the executives we interviewed stressed the need for leaders across their organisations to understand and take responsibility for compliance with the new rules. David Floyd, Chair of Corin Group, says: "When thinking about career development ladders, I would always encourage people in marketing and product development to consider a rotation in Regulatory."

Fewer Products

The time and cost involved in bringing existing products into an MDR-compliant world have forced many businesses to make tough choices about legacy devices, especially orphan devices and niche devices. We are now seeing technologies leave EU markets, as

> "When you're developing new products, you have to ensure that the MDR is part of your thinking. It can't be an afterthought. It has to be built into your internal product development process."
>
> – David Perez
>
> Chair of Advanced Instruments and Laborie

companies decide it is not worth investing in post-market surveillance for products where volumes and profits are small. The end result of this widespread portfolio rationalisation is that European patients and clinicians will have fewer choices.

Potential Decline of Smaller Companies

Many of the industry leaders we spoke to express the view that small companies are being impacted disproportionately by the new rules. This is a problem because small companies are where new ideas and products tend to come from. While innovative startups may not have to recertify legacy devices, as their established counterparts do, they are facing some potentially existential challenges because of the MDR. These include:

- **Unmanageable Costs**
  Small, cash-strapped companies cannot always afford the additional expenses needed to meet the new regulatory requirements.
- **Reduced Investment**
  Startups rely on a steady stream of investment, but the unpredictability surrounding the MDR is causing some investors to think twice.
- **Fatal Delays**
  Notified bodies tend to prioritise existing customers, meaning that it can take longer for early-stage businesses to get products approved. The delay affects these small companies doubly hard because they cannot afford to burn through cash during a protracted approval process.

End of the Free Riders

One way in which the MDR is good for innovation is that it is now harder for poor-quality manufacturers to enter the market by copying existing products. Under the previous system, companies could certify copycat products by claiming they were equivalent to the original device. The new regulations require them to prove their copies produce the same results and are equally safe and effective. This helps to protect the original innovators and will benefit patients by reducing the number of substandard products on the market.

Innovators Quit Europe for the United States

Europe was once seen as a natural choice for medtech startups due to relatively relaxed rules surrounding medical devices and the speed with which companies could get new products into the market. The MDR has made the

process lengthier and more onerous. As a result, we are seeing a shift in focus to the United States, with innovations arriving much later in Europe, if at all.

This shift in focus across the Atlantic is potentially the most significant of all the MDR's impacts. We cover it in more detail in the following section.

Location

Europe's Changing Status vs. the United States and the Rest of the World

Which market is best for launching medtech products? Until recently, the answer was Europe. The pre-MDR regime made it a hugely attractive market for producers of new technology, providing them with a fast track to clinical evidence that they could then use to gain approvals in the United States and around the world. Post-MDR, that incentive is gone, and the pendulum has swung back significantly in favor of the United States.

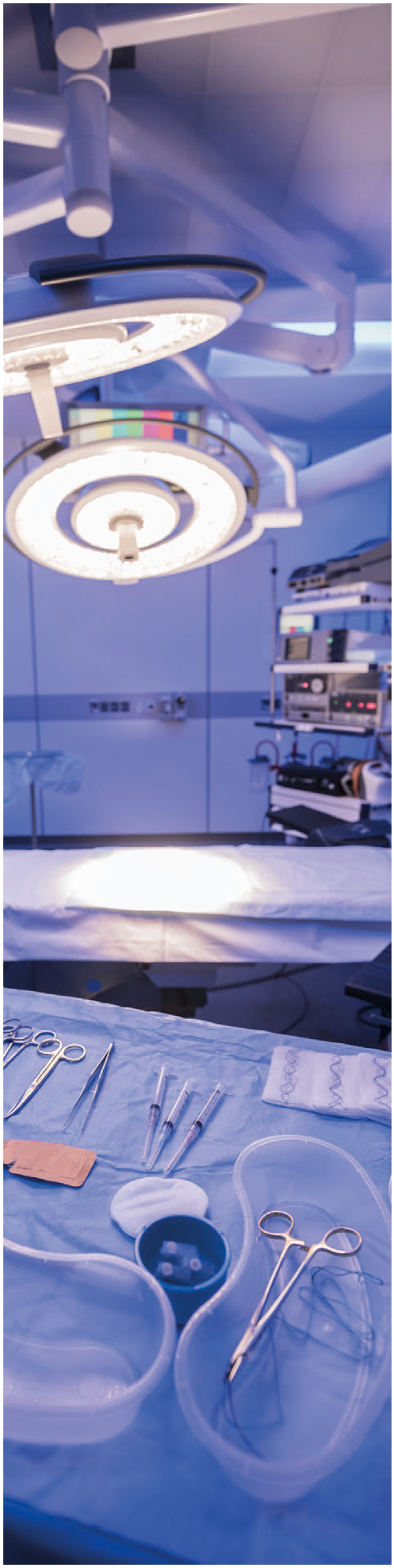
Large organisations will never turn their back on the EU altogether. It remains a significant market due to its size and potential for growth. Europe is home to some of the world's most comprehensive and long-standing public healthcare systems, which are receiving significant post-COVID-19 investment from the EU and member states.

However, early-stage companies are already migrating to the United States in significant numbers. The best engineers and entrepreneurs are certain to follow. For some businesses, Europe is now third behind APAC as an ideal location for a product launch. Ultimately, it is Europe's patients and health practitioners who will miss out by having limited or delayed access to industry innovation.

How the New MDR System Compares With the FDA

- **Less Timely**
  While companies seeking FDA approval are guaranteed a decision within 90 days,[xi] companies in Europe are being told by notified bodies that they will have to wait anywhere between nine and 15 months.
- **Less Predictable**
  In our discussions with certain investors, they said the EU market has become less attractive relative to the United States because the length and outcome of the MDR approval process are much harder to predict.
- **Less Consistent**
  The application of the MDR varies across notified bodies and between member states,[xii] whereas the FDA is a centralised organisation with uniform standards.

> "I could name you 20 early-stage companies that have moved to the US or decided not even to launch in Europe."
>
> – Michel Lussier
>
> Experienced MedTech and BioTech Entrepreneur



- **Less Mature**
  As the MDR is still in its infancy, the system is not yet as fine-tuned and well-adapted as the FDA approval process.
- **Fewer Repercussions**
  The consequences for companies breaching the MDR are not as serious as they are for those breaching FDA regulations.[xiii] Several leaders we spoke to saw this as a drawback, as it allows bad actors to get away with wrongdoing. As Erik Jan Worst, CEO at OPHTEC, says: "I like the fact that the FDA has a very clear controlling function. If you violate the rules, it's a federal offense."
- **More Iterative**
  One advantage of the MDR is that companies can improve their products iteratively, whereas companies that fail to get FDA approval are forced back to square one. As the MDR process stabilises and matures, this could make Europe a more attractive proposition for launching innovative technologies.

Outliers

What Does This Mean for Switzerland and the United Kingdom?

Switzerland is not part of the EU, and since 2020, neither is the United Kingdom. Up to this point, medical devices have been able to move freely between both countries and EU member states, but the frictionless movement ends with the MDD. Switzerland has yet to pass a mutual recognition agreement for the MDR, meaning that Swiss manufacturers will from now on be treated like other non-EU entities. The United Kingdom (Northern Ireland excepted) has not adopted the regulations, as it came into effect after the country's exit from the EU but announced that it is looking at international approval routes, including recognising conformity assessments or approvals from international regulatory partners.[xiv] Both countries are now seeking closer alignment with the US, with the Swiss Parliament reaching a decision on 28 November 2022, to adapt national laws to accept medical devices with FDA approval.[xv]

Several executives we spoke to were concerned by the prospect of EU divergence because having multiple systems adds complexity, time, cost, and risk of compliance. "As somebody running multiple countries," explains David Johnson, Chair of the Board at Advanced Medical Balloons, "The last thing I would want to see a decade from now is a Europe with 15 different systems." There is also skepticism about whether closer alignment with the FDA will provide patients with early access to meaningful innovation, as it is intended to do. Several of our interviewees pointed out that medtech businesses may be slow to enter Switzerland and the United Kingdom, even if their FDA-approved products are allowed, as both markets are very small relative to the United States and the EU. Then there is the

labelling issue: US products being exported to the United Kingdom or Switzerland will need to be adapted to meet each country's labelling requirements, adding complexity for manufacturers. In addition, there are some concerns about the United Kingdom's unpredictability, with businesses and investors maintaining a wait-and-see approach to the post-Brexit UK market.

Investment

Shift in Attractiveness of Businesses Due to the Changing Regime

Investors we spoke to have mixed views about the MDR.

Some welcome stronger regulations. Marc Lambrechts, Investment Director at Capricorn Partners, says: "For us, regulation is a quality check, which proves that it's a good product. It makes it harder for competitors to come along and just copy the value proposition, but for keeping the sector competitive in Europe, the EU and regulatory bodies will have to speed up and increase transparency."

Others believe the MDR makes EU businesses less attractive investment propositions and predict that the focus for IPO activity could move permanently across the Atlantic. Simon Cartmell OBE, an experienced chair and board member, says: "I think there's a danger that we'll see a withering of the vine in Europe, not only because companies are looking more to the FDA as a result of MDR, but also because of funding challenges, especially now [that] the IPO market is not open and won't be open for medical device companies for some time."

We are also likely to see a shift in the timing of M&A activities as a result of the new regime. Small companies struggling to meet MDR requirements will be forced to sell earlier—and for much less value—to large or midsized organisations that have the infrastructure and skill sets to get products through the process. At the same time, there will be buyers who are only interested in companies with EU approval, who will need to delay purchasing until MDR compliance is achieved.

Either way, medtech startups need to remain vigilant, as any company acquiring in the future will be looking at MDR-readiness as part of their due diligence. The need for top-quality compliance systems and regulatory experts is here to stay.

> As patients, we will pay more to be treated, but we will have more trust in the devices being used on us because they will be more scrutinised. There will be more clinical data and more transparency. In this sense, the market will be better.
>
> – Enrico Perfler
> CEO at 1MED

Leadership

Changing Demands and Focus Areas for MedTech Leaders

We have identified several key areas of skill and experience that have become more important for CEOs and other senior executives since the introduction of the MDR. These include:

- **Regulatory Know-How**
  Medtech CEOs and business leaders need to be MDR-knowledgeable, whether they are running smaller, early-stage companies or large, multinational organisations. It is also now desirable to have somebody at the board level who understands regulatory pathways and timelines.
- **Adaptability and Agility**
  The full implications of the MDR are yet to play out. The situation remains fluid and is changing fast. This makes it more critical than ever to have leaders who can understand complexity, cope with ambiguity, and rapidly adapt to new facts on the ground.
- **Focus on Profitability**
  The current economic climate is pushing leaders to focus on margin. The MDR is exacerbating this trend. Shar Matin, CEO at Cordis, says: "Being able to see and play the marketplace differently, driving higher profitability versus simply taking market share—this is going to become a core competency for European leaders in the future."
- **US Experience**
  Post-MDR, companies will refocus their operations with commercial infrastructure being increasingly built in the United States rather than in Europe for smaller companies. The United States will also become the primary launch site for innovation. This means that there is an increasing demand for leaders and board members with US experience for European companies.

Winners

Beneficiaries of the New Regulatory Environment

We have covered the many negative impacts of the MDR. It is important not to forget the positives. Some of the industry players who have benefitted most from the new regulation include:

- **Regulatory Specialists and Consultancies**
  Demand for their services is at an all-time high, as medtech organisations build and buy the expertise they need.
- **Large, Successful Companies**
  The MDR gives established businesses the edge over smaller competitors and could even become a point of differentiation

for those with well-established regulatory teams.

- **Early Adopters and Adapters**
  Understanding and embracing the new regulation will give an organisation a competitive advantage, whatever its size. This includes conscientious manufacturers, who will gain market share as noncompliant players exit the market.
- **Startups in the Software Space**
  The new system has been developed with modern technologies in mind. Software development companies are likely to benefit from the iterative nature of the process, which suits them better than the stage-gated approach of the FDA and the previous MDD.

Finally, we must remember that the main purpose of the MDR is to ensure the safety and effectiveness of medical devices in the European market. In this respect, it is a clear improvement on the previous system—and patients across the EU will benefit from the change. Sarah Cowlishaw, Life Sciences Partner at Covington & Burling LLP, speaks for many of our interviewees when she says, "This is obviously intended to improve patient safety and ensure that the devices used on patients will have had more robust clinical standards applied to them. If the MDR does what it's intended to do, then the winners will be patients."

Conclusions

The Future of the MDR and How Companies and Regulators Can Make It Work

So, are we really bidding goodbye to medtech innovation in Europe, as the title of this paper speculatively suggests? Or would it be more accurate to say, "See you again soon"?

We have heard many leaders voice frustration and concern with the way in which the MDR has been implemented. We know larger companies are being impacted by increased time to market and costs and that early-stage companies are switching their focus away from Europe and choosing to launch new products in the United States instead. We can see that EU patients and practitioners are in danger of losing access to the latest healthcare innovations.

But many of those we have spoken to for this paper agree that it would be short-sighted of any medtech company to consider exiting the European market because of the MDR. The current period of confusion and uncertainty is only temporary. Over time, the system's bugs and bottlenecks will be resolved.

Regulators and notified bodies have an important role to play in making the new regime work more effectively. Actions that could be taken to mitigate the impact of the MDR include:

> "If you look a little bit ahead to when the MDR is up and running, when the notified bodies know how to work with it properly and when they've made the improvements and alterations they need, then I think it will ultimately be better for companies. It's more suited to the iterative needs of innovation and the needs of new technology."
>
> – Yves Prevoo
> CEO and Founder of Easee

> "The more we can have a collaborative working relationship between regulatory bodies and manufacturers, the more we will be able to solve problems and create a fast, safe, efficient, and high-quality process."
>
> – Rob Walton
> President and CEO, EMEA, at GE Healthcare

> It's important that policy and regulatory developments increase access and improve patient outcomes. Using real-world evidence and data insight is critical to help drive and speed up innovation, combined with close global regulatory alignment to encourage a common approach.
>
> – Gavin Wood
>
> Company Group Chairman EMEA, Johnson & Johnson MedTech

- **Creating streamlined pathways for innovative products**
- **Separating general Class I products from those that have been up-classified and need notified body involvement for the first time to avoid delays in the system**
- **Encouraging greater collaboration between manufacturers and notified bodies**
- **Introducing higher reimbursements to offset the increased costs of compliance**
- **Look for alignment where possible with other major emerging regulatory trends such as sustainability and AI**

Companies also need to play their part by fully embracing the reality of the new environment. Compliance should be built into internal product development processes. Leaders must be agile and adaptable, as they steer their businesses through a regulatory environment that is still in a state of change.

In the long run, we believe the MDR could prove to be a positive development for the EU and, even, for the world. Allow time for the system to be tested, altered, adapted, and improved, and it has the potential to become a model of regulatory best practice.

It is even possible that, once the transition period is over, we will see other regulators learning from and adopting the most successful aspects of the MDR. It is a move that medtech businesses everywhere would welcome. For many executives and investors, global harmonisation is the holy grail, making it easier to deliver healthcare innovation and bring critical medical devices to the patients who need them. By requiring companies to provide transparent, consistent, and valuable clinical data on their products, the MDR could prove to be an important early step toward that ultimate goal.

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About Houlihan Lokey

Houlihan Lokey (NYSE:HLI) is a global investment bank with expertise in mergers and acquisitions, capital markets, financial restructuring, and financial and valuation advisory. The firm serves corporations, institutions, and governments worldwide with offices in the Americas, Europe, the Middle East, and the Asia-Pacific region. Independent advice and intellectual rigor are hallmarks of the firm's commitment to client success across its advisory services. Houlihan Lokey is the No. 1 investment bank for global M&A transactions under $1 billion, the No. 1 M&A advisor for the past eight consecutive years in the U.S., the No. 1 global restructuring advisor for the past nine consecutive years, and the No. 1 global M&A fairness opinion advisor over the past 25 years, all based on number of transactions and according to data provided by Refinitiv.

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Numerous interviews with senior executives in Europe and the United States. Statements and opinions expressed herein are solely those of the interviewees and may not coincide with those of Houlihan Lokey.

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