The calls for new rules have been ringing out for almost a decade. And finally, they are here: on April 5, 2017, the EU Parliament adopted the European Medical Device Regulation (MDR). The MDR was published in the Official Journal of the European Union one month later and came into force on May 25. Its adoption ended years of uncertainty arising from the previous Medical Device Directive (MDD) from the 1990s, which had hardly been updated since. Scientific, technological and consumer protection developments had long overtaken it.
More Bite for Regulatory Bodies

What important changes and improvements does the new MDR bring for companies and consumers? Here are just a few examples of the new direction this legislation is providing:

1. Consumer and patient protection
   - High-risk devices shall undergo more rigorous evaluation before being introduced to the market, with expert panels provided at EU level.
   - The MDR also covers aesthetic devices – unlike before – if such devices are similar to medical devices in terms of their function and risk profile.
   - Patients throughout the EU shall be entitled to implant cards.
   - A financial instrument ensures that patients are compensated in the event of damage suffered as a result of a device.
   - The stipulations concerning handling of clinical data have been tightened, and authorization procedures are being harmonized across Europe.

2. Regulations for manufacturers and suppliers
   - Manufacturers, importers, and retailers of medical devices have been assigned clearer rights and responsibilities than before.
   - Manufacturers must install and maintain risk and quality management systems (and processes).
   - The possibilities of tracing the origin of medical devices along the supply chain have been improved, allowing companies to respond quickly and effectively to safety issues.
   - “Grandfathering” rules have been adapted. According to the new rules, previously approved devices must be recertified under the new requirements.
   - The requirements for clinical testing have been tightened in order to optimize medical device certification. References to comparable devices is no longer permitted for implants and devices in high-risk classes.

3. Oversight
   - The national regulatory bodies shall be better coordinated. The European Commission will provide scientific, technical, and logistical support for this.
   - The national authorities shall monitor independent assessment bodies more strenuously.
   - The criteria for selecting and supervising notified bodies have been tightened.
   - Post-market surveillance of devices has been improved. Assessment bodies are being given extended rights to in-depth inspection and sampling at manufacturers’ premises.
4. Transparency

- EUDAMED, the European Databank on Medical Devices, is being extended. Its comprehensive information shall be - depending on confidence level - available to authorities, notified bodies, manufacturers, and even the wider public.

Identifying Opportunities

Thus the MDR sets out clear premises and creates a more certain framework of implementation than the old MDD. While some medical device manufacturers may now see a labyrinth of new, even more complex rules ahead and soaring initial costs, a selection of companies has been monitoring the development of this regulation for some time now and know what to expect. Companies with long-term vision are seeking to identify the opportunities this new framework offers - and they will not be disappointed.

For example, several rule changes aim to improve patient safety and reliable device performance. Some manufacturers can use these stipulations to strengthen their quality and safety reputation and in so doing improve brand image. At the same time, the new requirements provide companies the opportunity to comb through their portfolios and “overhaul” certain devices, eliminate others, or add new devices as required.

The competitive business landscape must also be continuously observed. Depending on available resources, be these of a financial or operational nature, one or the other competitor will have to make dramatic changes to meet the new requirements. This may provide opportunities to extend a company’s own market share, potentially through acquisitions.

The Flip Side of the Coin

The new rules open up a number of opportunities for manufacturers to improve market position. However, it cannot be denied that the Regulation does place a great deal of stress on companies in the industry. Even the stipulated installation of the machine-readable unique device identification (UDI) will result in significant effort. But that is, in many ways, just the tip of the iceberg.

In actual fact, the MDR is introducing extensive changes, which in their entirety and complexity will affect nearly all areas of a manufacturer. For example, the increased requirements for clinical testing not only affect R&D; in many cases they will also lead to a potentially increase of time between the laboratory testing and product market launch - which is likely to have a noticeable impact on revenue growth, investment planning, and procurement of capital.

In very concrete terms, depending on the product range and the extent of the required changes, the cost of implementing the new MDR may make up five to eight percent of revenue. This is partly determined by the number of required clinical studies and how IT infrastructure needs to be converted or extended for the purposes of significantly expanded documentation. Furthermore, the conversion of technical documents such as patient leaflets, instructions for use, or implant cards to new formats and the introduction of new languages and content must not be underestimated. Changes to the strategies of the notified bodies may extend time to market further: likely fewer notified bodies will be certified to approve (high-risk) devices, and certain notified bodies will possibly leave the medical device field entirely.

Likewise, the supply chain will not remain immune to change. Even suppliers to medical device manufacturers will be subject to audits in future, in order to ensure their compliance with the EU MDR. Suppliers to medical device manufacturers have already determined that compliance with the MDR can offer them a competitive edge and have aligned themselves accordingly. They are also affected by the requirement to be able to trace the origin of their components back to the last upstream supplier.

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1 Based on EY’s experiences with our clients
Manufacturers’ MDR working groups will not be able to shoulder all of the responsibility of adapting to the new rules alone. For this reason, EY is seeking a broad approach that incorporates all functional areas. More than regulatory experts are needed in this regard. Finance, corporate strategy, product developers, quality management, and marketing experts will also need to contribute.

After all, the new Regulation will deeply affect all areas of business, with consequences for operational processes, revenue and profits, as well as for financial leeway or opportunities for M&A transactions. MDR teams must also make the importance of this regulation clear to their executive boards and leadership - not least to ensure that the required resources and budget for managing these challenges are provided.

Calling Out Important Matters in Advance

Before manufacturers develop their MDR compliance strategy, they should ask several essential questions. Just a few examples of these include: What proportion of our product range is affected, and what proportion of our revenue is potentially at risk? Do we need to revise our portfolio? How high are the costs of compliance in total, by device, business unit, or in comparison to industry standards and benchmarks? Are processes and capacities sufficient for managing the foreseeable volume of questions and potential challenges raised by notified bodies?

What is certain is that the medical device industry is under tremendous pressure. For some companies, implementing MDR may prove to be a test of their survival. It is conceivable that some companies are not up to the task - not just in terms of their finances, but also in terms of staffing - and may have to shut down operations. For others, the new requirements may mean that they will need to let go of individual products, product lines, or even entire units, potentially divesting, which may create an animated M&A landscape. Without doubt, the new MDR will trigger a transformation of an entire industry.

Adapting to the new rules is no walk in the park. Individual companies will find it laborintensive, costly, and most of all, disruptive to their usual workflows and habits. However, companies that do find the task challenging should not forget the actual aim of the “MDR project”: to make the EU a safer place for users of medical devices. That is the driving force behind the reform. And not least, it is about reinforcing and further strengthening trust in the entire industry.