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Readying your product portfolio for the new European Medical Devices Regulation (MDR)

What is the impact of the new regulation?

Introduction

Following the breast implant scandal and the breaking hip replacement incidents, the EU decided to completely revise and align its regulations on medical and in-vitro devices.

In April 2017, the EU parliament accepted the new directive which is set to become binding by 2020 for medical devices and by 2022 for in-vitro devices. The directive shows a tendency to align the regulation on medical and in-vitro devices closer to the regulation on pharmaceutical products. Some products that were as yet unregulated up to now will have to comply with the new stricter regulation.

The main difference between the new Medical Devices Regulation (MDR) and the one for pharmaceutical products is that the former will not be overseen by a central authority.
The MDR follows a decentralised approach, linking the National Competent Authorities (NCAs), the Notified Bodies (NBs) (acting as certification authorities granting the Conformité Européene (CE) label) and the manufacturers through a new database (Eudamed).

Eudamed requires different sets of medical data to be fed into it.

The data has to be collected from sources out of the manufacturing process, but also through clinical trials and comparison of the device to other treatments. There is also a new role to be established: the Person Responsible for Regulatory Compliance (PRRC). The PRRC must personally sign to guarantee the compliance of the manufacturer or importer and must physically sit within the EEA.

The new regulations will lead to a significant increase in costs and efforts to manufacture and market medical devices. Considering the life cycle of products, the market situation, and the penetration of markets, we expect that fundamental decisions on investments into products, divestments, or retirements of products will have to be made.

What are the MDR requirements?

In order to be compliant with the new MDR, companies will need to:

- Include new products under the medical device category (e.g. cosmetics)
- Incorporate Clinical Trials into the R&D process
- Introduce the role of a Person Responsible for Regulatory Compliance (PRRC) located on EEA ground
- Implement Unique Devices Identifiers (UDIs) linked to both the production chain and the technical documentation
- Comply with unexpected audits by the Notified Bodies
- Communicate and action requests from the National Competent Authorities (NCAs) through the Eudamed system

New products falling under EU MDR

Several product families are now coming under the regulation:

- Non-medical products used as medical devices
- Cosmetics used for medical purposes
- Tools or accessories used for medical purposes

As part of the regulation, these products must now be classified according to the EU MDR classification scheme. All existing procedures defined for medical devices must also be applied – including the collection of data, the supervision by a PRRC, and clinical studies for the use of the medical devices.

The regulation introduces a completely new dimension for these products and manufacturers will have to decide if the current positioning and commercialisation of the product as a medical device is still viable.

Clinical trials

For all medical devices, clinical trials must now be completed to ensure the benefit of the device to patients and prove the medicinal safety of the device use. Data from the clinical trials has to be compiled into post market clinical follow-up reports, which have to be delivered to the NCAs. Products have to be compared to identical devices (same methods of application of devices) and similar devices (non-identical products aiming to cure or support patients for a specific medical condition).

The planning and execution of the clinical trials fall under the regulation for clinical trials in the EU. Those trials are expensive and require long-term planning, revision of results, processing of safety information, and publication to the authorities. The extent to which the clinical trials are required will depend on the classification of the medical devices. Costs for clinical trials must be assessed against the commercial value of the product to decide if manufacturing the product is still viable.

Person Responsible for Regulatory Compliance and Safety Communication

All manufacturers selling within the EEA must have a PRRC. The role includes the supervision of the manufacturing and safety procedures. The PPRC is personally responsible for the product meeting the compliance requirements.

The processes around the role of a PRRC have to be defined, including the data sources for

the management and reporting of safety concerns to NCAs. Identified safety concerns must be communicated through electronic Instructions for Use (eIFUs) allowing the Health Care Professionals (HCPs) to receive the information within a period of at most two weeks. This means that the safety instructions have to be defined and translated into all applicable languages to be published at the same time.

Unique Device Identifiers (UDI)

All medical devices must bear a UDI, which is composed of a Device ID and a Product ID. They have to be applied to the medical device and link back to both the production chain and the technical documentation.

Depending on the nature of the medical device, the definition and application of the UDI onto the medical device can be costly and requires a considerable upfront investment, including the set-up of new production steps to be able to apply UDIs to the devices.

Notified Bodies (NBs) and audits

With the new regulation, the NBs (which act as the outsourced review boards for the compliance of the medical devices and grant the CE label) have to perform unexpected audits of the manufacturers' facilities to ensure compliance.

Under the new regulation, the NCAs must control the NBs more tightly. Some of the former NBs will not be eligible to continue their business anymore, which might require the re-approval of the CE Label by a new NB. This re-approval will have to be paid for and might also require amendments to the existing technical documentation on the medical devices.

National Competent Authorities (NCAs)

Through the Eudamed database (which has not yet been implemented), the NCAs must be able to communicate with the manufacturers and directly request information on the devices. All device manufacturing organisations will have to be able to deal with any request from the NCAs. Enquiries will have to be answered and information exchanged with a specific NCA as well as being made available to all other NCAs, which in turn might trigger additional requests for information.

How to get ready?

The new regulation will impact the entire organisation, not only R&D or compliance. Hence, the entire business model and long term financial implications on the manufacturing of the device must be assessed. The outcome of the assessment will highlight the necessary steps companies need to plan and execute before 2020.

To absorb the extra costs, companies can implement one or more of the following measures:

Protect revenue:

- Introduce revenue generation initiatives and sales channel optimisations to increase profits
- Implement the new regulation early to increase the positioning (i.e. pricing) of the product in the market
- Launch a new product
- Search for a partner or put the company up for sale if not able to absorb the additional costs and achieve a better value from the sale transaction before the new directive becomes binding in 2020

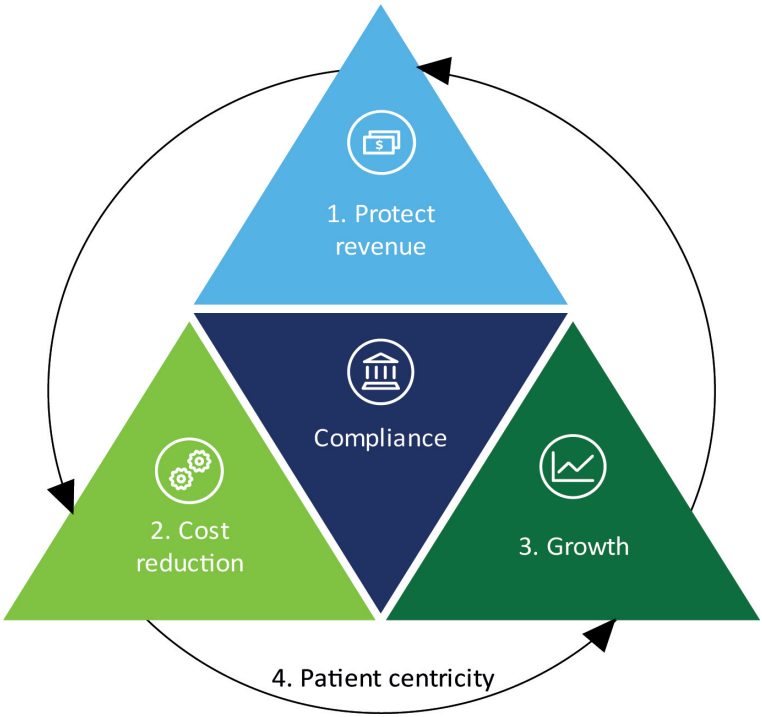
Reduce costs:

- Retire a selection of products that are at the end of their life cycle, are/will soon be under increased pressure on the markets, or do not have sufficient market potential to justify the additional spending needed to maintain compliance of the devices
- Find an outsourcing company that will help to adhere to the new regulation and maintain business continuity
- Optimise working capital (a one-time effect) to free up cash
- Divest part of the portfolio by selling it off to another manufacturer with a similar product range to meet economies of scale

Follow the growth path:

- Acquire companies offering identical products to achieve strategic advantages, economies of scale and other revenue and cost synergies
- Expand into new markets or withdraw from markets where the new regulation turns out to be too costly and focus on less regulated markets.

The manufacturers could take multiple paths based on the outcome of the assessment:



Become patient centric

- Transform into a patient-centric organisation by integrating patient focus across the value chain, hiring a Chief Patient Officer to drive patient engagement, etc.
- Prioritise the patient and reduce exposure to medical device manufacturing (if feasible within the value chain)
- Build on rapid advances in digital technology to introduce web-based or smartphone apps that connect with wireless medical devices or wearable devices to differentiate from the competition and support patients in achieving better outcomes.

Depending on the classifications of the medical devices, the existing market presence, the strategy in the different national markets and in the EU in general, a mix of the above measures might be the optima for the business.

Organisations need to start re-shaping now to continue to optimally supply medical devices to the markets in the EEA. There is no one-size-fits-all solution – we can help you find the best solution for your company to face the challenges lying ahead.

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