EU MDR:

WHAT'S NEW AND WHAT'S CHALLENGING?

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Table of Contents

Introduction

The European Union's Medical Device Regulation (EU MDR), which came into effect on May 26, 2021, has not only brought about significant changes to safety requirements but has also presented the medical device industry with a host of new challenges.

The EU MDR replaces the previous Medical Device Directive (MDD) and aims to enhance patient safety, streamline regulatory processes, and ensure the availability of safe and effective medical devices throughout the European Union (EU).

The stringent safety requirements mandated by the EU MDR are aimed at improving patient safety and ensuring the reliability and efficacy of medical devices. However, these requirements have introduced a range of complexities and hurdles for manufacturers, notified bodies, and healthcare professionals.

This article will delve into the new safety requirements of the EU MDR and examine the challenges they pose to stakeholders in the medical device industry.

New Safety Requirements

EU MDR has implemented new and stringent pre-market safety requirements that demand greater scrutiny and additional safety and performance data for medical devices prior to their introduction into the European market.

While MDD had only 13 Essential Requirements (ERs), MDR has 23 General Safety and Performance Requirements (GSPRs). Refer to MDCG 2021-8 Annex 6 which includes a "Checklist of general safety and performance requirements, Standards, common specifications and scientific advice."

POST-MARKET SURVEILLANCE (PMS) REQUIREMENTS

The EU has implemented updated regulations for Post-Market Surveillance (PMS) requirements under the Medical Device Regulation (MDR). These new guidelines aim to enhance the monitoring and evaluation of medical devices in the market, ensuring their continued safety and performance.

MDR holds medical device manufacturers responsible for all PMS activities. These activities are performed for a PMS system based on the device's degree of risk.

Manufacturers must:

- PLAN
- ESTABLISH
- DOCUMENT
- IMPLEMENT
- MAINTAIN
- RECORD
- ANALYZE DATA

Reporting requirements can vary based on the device type and risk class. Class I devices require a PMS report, but devices in higher risk classes require a Periodic Safety Update Report (PSUR). A PSUR includes results and conclusions of PMS activities, findings from any post-market clinical activities, and sales data.

MDR requires certain serious incidents to be reported within 15 days. Under the MDD, those same incidents were to be reported within 30 days.

New Concept of the Purpose of Medical Devices

Products that may not have been traditionally considered medical devices, such as software applications, health monitoring devices, or cosmetic products with medical claims, now fall within the jurisdiction of the medical device category.

The reclassification of these products under the medical device umbrella underlines the EU MDR's commitment to aligning regulatory requirements with technological advancements and evolving healthcare practices. This provides a more robust framework for ensuring patient safety and product quality throughout the European market.

Under the EU MDR guidance, products that were never previously categorized as "medical devices" now fall under that medical device umbrella.

These products may include:

- Contact lenses, other products used in/on the eye
- Products introduced to the body via surgically invasive means
- Products used for facial or other subcutaneous fillings
- Equipment used for liposuction, lipolysis, or lipoplasty
- High-intensity radiation equipment used for tattoo and/or hair removal
- Equipment that stimulates the brain via electrical or magnetic current products intended for cleaning, disinfection, sterilization of medical devices

New Medical Device Classification

The EU MDR has brought about the reclassification of drugs into higher-risk classes. This reclassification aims to ensure a more comprehensive evaluation and monitoring of drug safety and effectiveness.

As a result, certain drugs that were previously classified under lower-risk categories are now being placed in higher-risk classes, subjecting them to stricter regulatory requirements and scrutiny.

All medical devices with a CE mark are required to meet new EU MDR guidelines. Devices that still carry a valid MDD certificate will remain valid for five years from the date of that certificate's issuance.

MDR reclassifies many devices into higher-risk categories, meaning those devices may be subject to an increased level of scrutiny in both pre-market and post-market regulation. Examples of reclassifications include:

Medical software:

- Under MDD: Class I
- Under MDR: Class II

Implantable devices

- Under MDD: Class IIb
- Under MDR: Class IIb implantable (Well-Established Technology (WET)) and Class IIb implantable (excluding WET)

Spinal disk replacement devices, devices that contact the spine, and extremity joint replacement devices:

- Under MDD: Class IIb
- Under MDR: Class III

Invasive surgical instruments (reusable)

- Under MDD: Class I
- Under MDR: Class Ir

Clinical Evaluation

These challenges include ensuring the availability of clinical data to support the safety and performance of medical devices throughout their lifecycle.

Meeting these requirements can be demanding for manufacturers, as it involves collecting, analyzing, and reporting large volumes of clinical data while complying with stringent regulatory standards. Ultimately, the implementation of EU MDR has forced a significant shift in the approach to clinical data collection and management, posing additional challenges for stakeholders in terms of resources, expertise, and timelines. When equivalence is not demonstrated as per (Annex XIV, Part A) the following steps need to be taken:

Plan to obtain new data:

CLASS I AND CLASS IIA

Surveys
National registries (TVT, SCAAR, NCDR)
Small product registry
Large registry and/or randomized controlled trials

CLASS IIB AND/OR IMPLANTS

Surveys
Hospital database
National registries (TVT, SCAAR, NCDR)
Small product registry
Large registry and/or randomized controlled trials

CLASS III AND IMPLANT DEVICES

Surveys
Hospital database
Investigator-sponsored study
National registries (TVT, SCAAR, NCDR)
Small product registry
Large registry and/or randomized controlled trials
Agreement to access technical documentation for the equivalent device in order to fulfill EU MDR ANNEX II and III requirements (chapter vi, article 61, section 5)

Use Hierarchy of Evidence:

- Results of high-quality clinical investigations covering all device variants, indications, patient populations, duration of treatment effect, etc.
- Results of high-quality clinical investigations with some gaps
- Outcomes from high-quality clinical data collection systems such as registries
- Outcomes from studies with potential methodological flaws but where data can still be quantified and acceptability justified

Vigilance & Post-Market Surveillance

The EU MDR requires Post-Market Clinical Follow-up Studies (PMCFs) to gather long-term data on device performance and patient outcomes.

Manufacturers face several challenges concerning PMCFs, as they involve collecting, analyzing, and reporting large volumes of clinical data while complying with stringent regulatory standards. Furthermore, the implementation of EU MDR has forced a shift in the approach to clinical data collection and management, posing the following challenges for stakeholder in terms of resources, expertise, and timelines:

Data Collection

CHALLENGE

PMCF studies require real-world clinical data from large patient sizes over an extended period. Obtaining sufficient data can be challenging, especially for products with a low patient population or rare conditions.

SOLUTION

This challenge can be alleviated by patient registries. These registries would systematically collect, store, and analyze information about patients with a particular condition or use of a specific treatment. By enrolling patients who meet specific criteria, such as having a rare condition or using a particular medication, valuable data can be collected over time.

Study Design

CHALLENGE

Designing PMCF studies that meet the regulatory requirements and address specific safety and performance concerns can be complex. There is a need for well-defined study protocols, appropriate endpoints, and control groups, which may pose challenges in terms of resources, expertise, and time.

SOLUTION

This challenge can be alleviated by early planning, expert involvement, literature review, patient input, protocols and SOPs, and pilot studies criteria, such as having a rare condition or using a particular medication, valuable data can be collected over time.

Data Quality

CHALLENGE

Ensuring the quality and reliability of the collected data is crucial for drawing meaningful conclusions. Challenges may arise in terms of data accuracy, completeness, and consistency, as data is often obtained from various sources and may require harmonization.

SOLUTION

This challenge can be alleviated by having clear data collection protocols, training and education, data validation and quality control, data traceability, data monitoring and auditing, data governance, and collaboration and data sharing.

Vigilance & Post-Market Surveillance Cont.

Post-market Surveillance Resources

CHALLENGE

Implementing effective PMCF studies requires dedicated resources, including skilled personnel, infrastructure, and financial support. Manufacturers need to allocate sufficient resources to plan, execute, and manage PMCF studies effectively.

SOLUTION

This challenge can be alleviated by resource planning, dedicated teams, collaboration and outsourcing, prioritization and risk-based approach, and proactive monitoring.

Regulatory Compliance

CHALLENGE

Compliance with the EU MDR's regulatory requirements for PMCF studies can be challenging, as manufacturers must navigate complex guidelines and ensure adherence to reporting obligations, data analysis, and continuous monitoring of product safety and performance.

SOLUTION

This challenge can be alleviated by performing internal gap analysis, having a dedicated regulatory team, document management, periodic audits and reviews, monitoring regulatory updates, and proactive communication with Notified Bodies.

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Outside of work, Monil enjoys staying active, whether it be by going to the gym, playing basketball, or spending time with his dog. He joined Azzur Group in 2021.

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EU MDR General safety and performance requirements

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Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices

Summary of safety and clinical performance

Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD

Guidance on classification of medical devices

Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC

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