IMed Consultancy

THE PERFECT TIME TO PERFECT PMS

LEVERAGING MDR EXTENSIONS TO LAY VITAL COMPLIANCE GROUNDWORK

02

TABLE OF CONTENTS

IMed Consultancy

SUMMARY

03

Deadlines for Medical Devices Regulation (EU) 2017/745 (MDR) and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) implementation have been pushed back once more. Extensions under MDR are to the end of 2027 for high-risk devices and to the end of 2028 for medium and certain lower risk devices. Similarly, transition to full IVDR compliance has been rescheduled according to the classification of the device, with Class A and new devices requiring full compliance from May 2022 and a gradual deadline for devices already on the market that are Class D (May 2025), Class C (May 2026), Class B and Class A Sterile (May 2027).

This may induce some manufacturers to procrastinate with a number of MDR compliance activities by lulling them into a false sense of security.

In fact, a number of new or enhanced requirements under MDR are already enforceable, specifically those relating to Post Market Surveillance, a key pillar of the new Regulation that is closely connected to patient safety. The following have been a requirement since 26th May 2021 [1]:

- Post Market Surveillance (PMS)
- Periodic Safety Update Report (PSUR)
- Post-Market Clinical Follow up (PMCF)
- Person Responsible for Regulatory Compliance (PRRC)

Far from being a good moment for manufacturers to rest on their laurels, this is the perfect time to get key compliance processes such as Post Market Surveillance into shape.

This paper outlines the scope of the task, supporting manufacturers who are still getting to grips with developing a best-practice PMS strategy.

INTRODUCTION 04

In late 2022, European Union (EU) Health Commissioner Stella Kyriakides identified a need for “additional measures to address the structural problems” relating to the implementation of MDR and proposed delaying MDR enforcement by three to four years to prevent product shortages and give the market time to implement new measures [2]. The Commission has since formalised the Commissioner’s suggestion and has set out plans to extend the transition period for higher-risk devices until the end of 2027 and for medium and lower risk devices until the end of 2028 [3].

This is just the latest in a string of postponements of the enforcement of the MDR; pressures and delays caused by the industry's and healthcare’s unprecedented efforts to counter COVID-19 had previously pushed back the initial implementation date to May 2021 [4]. Even before COVID-19, however, capacity uncertainties posed a significant obstacle to the implementation of MDR.

Specifically, the lack of capacity of EU Notified Bodies (NBs) continues to plague the industry with many manufacturers still “orphaned” as they have not found a suitable NB to take them on or are at risk of becoming orphaned in the near future as NBs choose to retire from their roles [5]. At the time of writing, six new notified bodies have received MDR designation since June 2022, creating a pool of 36 organizations that need to process a staggering estimate of 23,000 certificates by May 2024, provided all existing devices remain on the market [6].

05

“The transition to the new rules has been slower than we anticipated. The pandemic, shortages of raw materials caused by Russian war against Ukraine and low notified body capacity has put a strain on market readiness,”-Stella Kyriakides, EU Health Commissioner

This latest delay acknowledges the risk of imposing a deadline that the market is not yet ready for. And more specifically there is a danger of pushing products out of the market which could lead to many existing and new medical devices and invitro diagnostic medical devices (IVDs) not undergoing timely conformity assessments under the MDR and IVDR regulations. Aside from the damage to the industry’s competitiveness in global markets, to employment and to the European economy in general, more importantly, impeding future availability of critical devices could mean patients lose access to potentially lifesaving, or life-changing medical devices and IVDs.

Although these transition arrangements have been welcomed by the industry, there is a risk that manufacturers may be lulled into a false sense of security by the ever-shifting deadlines. Not only is preparedness key to ensure competitivity but certain aspects of the MDR, such as the need for cyclical and proactive Post Market Surveillance (PMS), are already enforceable.

This paper aims to provide manufacturers with a clear overview of the breadth and scope of activities they would be wise to tackle during this transition period, in order to achieve PMS compliance, regardless of their CE Marking status.

PMS: WHY PROCRASTINATION WON'T CUT IT

06

PMS requirements under the MDR have been applicable since 26th May 2021 for all medical devices sold into the EU, regardless of a device's MDR CE Marking status. Certain PMS requirements are in fact also applicable to legacy devices on the market under the MDD or AIMDD. Such requirements cover the obligation to draft a complete PMCF plan in addition to a detailed PMS plan, plus cyclical PMS reports for Class I devices or PSUR reports for Class IIA, IIB and Class III devices. Class IIA devices require the PSUR to be updated at least every 2 years, whilst Class IIB and Class III devices require the PSUR to be updated at least annually.

For IVDs that are Class C and Class D, PSURs are required to be submitted to the NB at least annually (IVDR Article 81), [7] while PMS reports will be required for Class A and Class B IVDS which are to be made available to Competent Authorities and NBs upon request and updated as needed (IVDR Article 80) [8], with best practice suggesting they are reassessed and updated every 12 months. At time of writing, all these proactive PMS measures have been a requirement for IVDs since May 2022.

The MDR lays special emphasis on gathering clinical and safety-related data after completion of the CE certification process, approval and market access, where proactive post market surveillance is given special focus. It is no longer sufficient to only address issues further to a complaint, but regular, careful assessments relating to the device's feasibility need to be made. The objective here is to prevent problems rather than address them once they have become manifest.

07

"'Post-market surveillance' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions"- EU MDR Art.2 (60)

PATIENT SAFETY

08

While PMS has always been intended to be proactive, under the MDR there is a stronger focus shift to proactivity with PMS being a cardinal element of the MDR. The objective of carrying out extensive, ongoing monitoring is to ensure that device safety issues are identified early on, reducing or completely eliminating any impact on patient safety. When potential issues are identified early on, it is possible to intervene in a number of ways to ensure that patients are not put at risk and can benefit from the positive outcomes they expected.

While patient safety is a key driver for the MDR, manufacturers can also reap a number of commercial benefits from adhering to a rigorous PMS system. Manufacturers that thoroughly canvass the market for data and act upon the intelligence it yields will benefit from greater customer confidence, improved brand awareness, a reduction in complaints they must deal with, as well as administrative and compensation savings relating to managing these complaints. In addition to this, thorough PMS is also a requirement for placing devices in other international markets, so efforts to comply with the MDR can also prove useful for export strategies outside the European market.

09

The onus of the activities covered by PMS should not be underestimated, however, and for this reason manufacturers would do well to devote this grace period to focus on perfecting their PMS strategy. The main activities manufacturers will need to ensure they are carrying out in an ongoing fashion to ensure that their PMS truly satisfies patient safety needs can be summarised as follows:

1. Engaging with patients and users
2. Reviewing current publications in literature and trade channels (media, forums etc)
3. Monitoring social media
4. Monitoring competitor product safety performance
5. Continually reassessing risk management data

5 STEPS TO SHAPING UP SURVEILLANCE

10

This paper draws on IMed Consultancy's extensive experience supporting medical device manufacturers as they face regulatory change and complexities and ensure their products are not only compliant, but highly competitive on international markets. Here, we delve into five major areas for PMS that need to be regularly monitored by specialist teams with a suitable skills set to identify any issues that may be lurking ahead, before they become a problem, or worse, a medical issue for patients.

1

Engaging with users and, where relevant, with patients. This two-way conversation will help manufacturers assess any potential issues with their product that can only be identified through use- such as discomfort or particular side-effects in specific groups of patients. It may also serve the important role of uncovering off-label use of devices. Manufacturers need to be fully aware of any off-label use to ensure they are in no way complicit with it; specifically, a manufacturer that is aware of off-label use can ensure that marketing and sales are not promoting or inferring an off-label intended use, even if it has become standard practice.

Manufacturers are duty-bound to inform users if they discover off-label use of a device, a scenario that may involve Health Care Professionals (HCPs) for example, but that needs to be clarified immediately and, if relevant, counterbalanced with training and education on the intended use of the device.

Finally, knowing about an off-label use may eventually prove to be an advantage, as it may offer the company the opportunity to make new claims about their device, provided they gather enough clinical, safety and performance data to enable conformity assessment and approval of the change.

2 Surveillance of published literature involving the manufacturer's product and similar products provides a source of knowledge on the product's use, performance, and safety. This is vital clinical evidence that can highlight risks or provide stronger proof of a product's clinical benefit. Wider than literature, relevant trade publications that cover the market of application of the device as well as broader nursing, medical or healthcare titles are also a good source of intelligence. While the former provide an excellent source of "on the field" views by practitioners and even patients, the latter may cover broader issues relating to off-label use or common interactions with other devices or drugs.

3 Monitoring social media channels is key to providing insight both from patients and users who may share experiences over social media. Social media monitoring is also critical to ensuring that marketing and communications departments are aligned with company compliance policy and not seeming to endorse off-label use of devices: a simple "Great Idea!" or "Good for you", relating to a use of the device that is not approved, could be seen as promotion of off-label use and result in legal as well as reputational damage.

4 Keeping up to date with competitor device performance is not only good commercial practice, it also supports the ongoing assessment of 'clinical benefit' and 'state of the art' (SOTA), both of which are important new elements of the regulations. This allows manufacturers to feed the data into ongoing clinical evaluation and consequently, demonstrate a level of compliance with the new regulations. Should complaints or potential issues be discovered with a device that is similar, or performing the same function as the manufacturer's device, this allows the manufacturer to intervene in a timely fashion. In this instance, manufacturers should ensure that either there are objective differences between their own and the competitor device that account for the lack of complaints, or to rectify any issue before it landslides and presents a risk to patient safety.

5 Reassessing the risk data for each device should be a cyclical process and not a one-off activity; in fact, far too many manufacturers prepare the risk management documents for the launch of their products accurately but fail to keep updating them with new statistics and data ongoing. Best practice suggests that this activity should be carried out continually as new information comes to light, and irrespective of interim data, at least every year to ensure that, for example, if fail rates have worsened because an issue has been uncovered, the product's entire risk profile is reassessed to evaluate whether it remains acceptable or not.

ORPHANED MANUFACTURERS

13

Although orphaned manufacturers are still able to place their CE marked devices on the EU market thanks to Competent Authorities, the intention of the derogation is that manufacturers should find a Notified Body within a year. Such manufacturers are in a difficult position and need to make up for this disadvantage by finding a NB as soon as possible, but also continue to lay key groundwork prior to the MDR implementation date.

In addition to this pressure, Competent Authorities can struggle with capacity should a manufacturer request a change of use, making devices from orphaned manufacturers even more vulnerable on the market and in desperate need of NB support to ensure their devices are properly regulated and remain competitive. Now is the perfect time to leverage this latest delay to move forward with compliance strategy before the feared implementation date bottleneck.

In addition to the obligation to carry out regular PMS, the regulations specifically states that a written procedure for PMS is drafted, stored and utilised by the company [9]. This procedure, as part of the Quality Management System, adequately defines how the manufacturer will proceed with their PMS, citing channels and range of sources as well as designated human resources to carry out the task. Of course, this document also needs periodic updating and reviewing to take into account new channels and requirements.

14

“For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer’s quality management system referred to in Article 10(9).”- EU MDR Art.83 (1)

It is important that manufacturers do not underestimate the onus required to maintain yearly PMS in terms of both channels that need to be monitored and man-hours. These cyclical processes typically require significant investments in time and highly specialised staff.

PLANNING AND PROCESS

15

Routine tasks tend to be easily pushed aside by busy staff as they struggle to shift focus away from daily firefighting activities. Not having a specific deadline to work towards can be a deterrent to devoting sufficient time and resource to what is a cardinal element for safeguarding patient safety, as well as company and industry reputation. PMS activity is specifically designed to help detect and flag potential issues before they landslide into problems for users and patients, therefore failing to keep up to date with the PMS data sources now available is inexcusable.

Of course, building compliance towards the MDR is also crucial because manufacturers maintaining devices on the market under the transitional provisions are unable to make any significant changes in design or intended purpose of that device (MDR Article 120(3)). Accordingly, MDR-compliant competitors will be at an advantage, while compliance laggards may not be able to keep up with 'state of the art' changes in clinical practice and product feature expectations. This places an increased risk on both device and business.

Enlisting the support of specialist consultants who are experts in satisfying post-market obligations, should provide ample reassurance that manufacturers are meeting their obligations, are compliant and at the same time, ease the considerable pressures on busy teams. It is essential that these truly extensive and complete monitoring activities are carried out routinely and consistently. Now is the perfect time to make headway in establishing solid systems and processes to protect the device from potential non-conformities and safeguard users and patients.

REFERENCES

16

[1] European Commission, Press Corner, Questions and Answers: Commission proposes an extension of the transitional periods for the application of the Medical Devices Regulation

[2] European Commission, Press Corner, Opening Remarks by Commissioner Stella Kyriakides at the EPSCO Council-Implementation of the Medical Devices Regulation, 9th December 2022

[3] MedTechDive, European Commission formalizes plan to extend MDR transition out to 2027, 2028, 9th January 2023

[4] Financier World Wide, COVID-19: application of EU Medical Devices Regulation postponed by one year, until 26 May 2021 ,1st June 2020

[5] MedTechDive, Swiss notified body to exit sector, heightening EU capacity fears, 9th June 2019

[6] European Commission, Notified bodies survey on certifications and applications, 26th October 2022

[7] REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

[8] REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

[9] REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

CONTACTS

hello@imedconsultancy.com

tel:+44-01295724286

www.imedconsultancy.com

IMed Consultancy