ENSURING PATIENT SAFETY AMIDST MEDICAL DEVICE REGULATION DELAYS WITH PMS

Here, Timothy Bubb, Technical Director at IMed Consultancy, discusses the five steps to setting up an effective post-market surveillance process.

In late 2022, EU Health Commissioner Stella Kyriakides identified a need for "additional measures to address the structural problems" relating to the implementation of the Medical Device Regulation (MDR) and proposed delaying MDR enforcement by three to four years to prevent product shortages and give the market time to implement new measures.[1] The Commission has since formalised the Kyriakides' suggestion and implemented regulation changes 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.[2]

Whilst this delay recognises the risk of setting a conformity deadline before the market and assessment systems are fully prepared, it does not resolve the threat for many existing and new medical devices of not being able to enter – or of being forced out of – the EU market.

A Challenging Scenario for Drug/Device Combination Products

This is therefore a particularly tough situation for many players in the flourishing drug delivery devices market, driven by an increasing level of chronic diseases, groundbreaking innovation and technological advancements in manufacturing. Indeed, as many new drugs require innovative delivery devices, there is a growing need for safe, advanced drug delivery devices to complement the approval of new drugs and the fast-growing advanced therapeutic medicinal products area.

With the aim of increasing patient autonomy, many drug/device combination products, such as prefilled syringes and implantable infusion pump systems, are designed to be used directly by patients to increase convenience through self administration – and, in some cases, even complete automation of drug therapy delivery. This makes monitoring device usage and performance to ensure patient safety all the more important.

MDR Requirements Related to Patient Safety

Therefore, even in the midst of these delays, ensuring patient safety is paramount for manufacturers. Fortunately, this can be facilitated by clearly identifying and aligning with the new or enhanced requirements under the MDR that are closely related to patient safety and already enforceable. For example:

- Post-market surveillance (PMS)
- Periodic safety update report
- Post-market clinical follow-up
- Person Responsible for Regulatory Compliance (PRRC) – unless selling only legacy devices.

As PMS requirements under the MDR have been applicable since May 26, 2021 for all medical devices sold into the EU, regardless of a device's MDR CE-marking status, now is the time to address those requirements.

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SETTING UP AN EFFECTIVE PMS PROCESS

With the objective of striving to prevent problems rather than seeking to resolve them once they occur, the MDR gives special focus to proactive post-market surveillance. By placing special emphasis on gathering clinical and safety-related data after completion of the CE certification process, approval and market access, it

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clearly highlights the importance of putting in place and maintaining regular, careful assessments relating to the device's performance.

Step 1: Connecting with Users and Patients

Thanks to modern technology, manufacturers can assess any potential issues with their product by connecting with patients and users of medical devices in a two-way conversation. For example, certain patient groups may experience specific side effects or discomfort. Additionally, this conversation may assist in identifying how devices are used outside of their intended use – a particularly important aspect as manufacturers must be fully aware of this to ensure they are not complicit in any off-label use. If off-label use of a device is discovered, manufacturers must notify users and take steps to remedy it. This is a scenario that could involve healthcare professionals and necessitate education and training on the device's intended use.

Finding off-label use does not always have to be bad – in fact, if the manufacturer collects sufficient clinical, safety and performance data to enable a conformity assessment and approval, it may provide an interesting insight that enables the formulation of new claims regarding the device and novel market segments in which to sell it.

Step 2: Monitoring Social Media Channels

Linked to step 1, this activity is crucial for obtaining information directly from patients and social media users who talk about their real-world experiences. Monitoring social media also plays an essential role in ensuring that marketing and communications departments adhere to the company's compliance and messaging, particularly regarding off-label use. Comments written in the wrong context – such as "So glad to hear that!" – could easily be interpreted as support for off-label use, causing legal and reputational harm.

Step 3: Tracking Competitor Device Performance

This is good business practice and also helps evaluate "clinical benefit" and "state of the art", which are important new elements of the regulations. Competitors' performance can be tracked to show appropriate surveillance, in compliance with the new regulations, and provide fresh data for ongoing clinical evaluation. If complaints or potential issues are found with a device that is similar or performs the same function, there is the opportunity to fix common problems before they spread and put patient safety at risk.

Step 4: Surveying Published Literature

Medical device manufacturers must regularly analyse published work that is relevant to their device market or to similar products. This is to gather information regarding the device's use, performance and safety profile. Key clinical evidence can be found in scientific and medical literature that may highlight potential risks or even provide more convincing evidence of a product's clinical benefits. Specialist trade publications that cover the target application market of the device, together with more general nursing, medical or healthcare titles, are also good sources of intelligence as they offer practical, real-life opinions from users and patients, and provide general insights regarding off-label use.

Step 5: Periodically Re-Evaluating the Risk Data for Each Device

When launching products, manufacturers prepare very precise risk management documents. But many fail to update them regularly with new statistics and data. Ideally, this activity should be done on a regular basis because repeated use in the real world uncovers new information. Best practice suggests that a review and update of risk management data should be done at least once a year – and more frequently for higher-risk and novel devices.

GETTING PMS PROCESSES IN PLACE

These five steps for effective PMS need to be regularly monitored by specialist teams with suitable skills to identify any issues before they become a problem or cause preventable patient harm. Therefore, although transition arrangements may be delaying the urgency for MDR certification, now is the perfect time to make headway in establishing solid systems and processes to protect devices from potential non-conformities, safeguard users and patients, and help generate the required safety and performance data needed for successful MDR approval of existing medical device product portfolios.

An immediate, plug-in solution aimed at easing the considerable pressures on busy teams is to enlist the support of specialist consultants who are experts in satisfying post-market obligations and can provide ample reassurance that manufacturers are meeting their obligations and are compliant.

ABOUT THE COMPANY

Founded in 2012, IMed Consultancy offers a wide range of regulatory and compliance services to the medical technology industry, supporting medical device manufacturers through all stages of the product lifecycle from concept and design consultancy through to PMS activities. IMed Consultancy's team of skilled and experienced medical regulatory professionals offers an outstanding yet flexible service covering regulatory affairs, UK Responsible Person (UKRP) and EU Authorised Representative (EUAR) services, PRRC, and quality assurance in medical devices, including Class III active and implantables, companion diagnostics, software as a medical device (SaMD) and *in vitro* diagnostics (IVDs). With extensive hands-on problem-solving expertise, IMed Consultancy's remit is truly global, ensuring that client devices are successfully launched and maintained in total compliance in the UK, EU, US and internationally.

REFERENCES

1. *"Opening Remarks by Commissioner Stella Kyriakides at the EPSCO Council-Implementation of the Medical Devices Regulation". Speech, European Commission, Dec 9, 2022.*
2. *"Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices". Official Journal of the EU, Mar 15, 2023.*

ABOUT THE AUTHOR

Timothy Bubb has more than 10 years' experience in quality assurance and regulatory affairs roles, with breadth and depth of knowledge across regulatory, engineering, clinical, design and development, and quality assurance disciplines. He has a passion for empowering innovation in medical devices and brings insight and pragmatism to projects bringing complex lifesaving and life-enhancing products to market.