Medicines & Healthcare products Regulatory Agency

ANNEX A- Detailed response to WTO comments for The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Draft Regulations 2023

1. Background

1.1. The government intends to introduce updated regulations for medical devices that prioritise patient safety, while still giving patients access to the safe medical devices they need and ensuring the United Kingdom (UK) remains an attractive market for medical technology innovators. The government is taking a risk proportionate, phased approach to the implementation of the future regulatory framework, which supports system readiness and minimises the risk of supply disruption for patients.

1.2. The government intends to introduce legislation in 2024 that will bring into force strengthened Post-Market Surveillance (PMS) requirements in Great Britain (GB) ahead of the wider future regulatory regime. This reflects the government's priority of improving patient safety as part of the future medical device regulations. The government intends for the PMS statutory instrument (SI) to be laid in the first part of 2024 and it is expected to apply towards the end of 2024.

1.3. The draft PMS SI was published to the World Trade Organization (WTO) website in July 2023. WTO members have raised that certain topics relating to the wider regime were not covered in these regulations (for further information see section 4). The government is considering further consultation in these areas. For further information regarding upcoming regulatory activities please view our Regulatory Roadmap[1] published 09 January 2024.

2. Purpose

2.1. The purpose of the PMS SI is to introduce clearer and more stringent PMS requirements for medical devices in GB that improve patient safety. Under the current Medical Devices Regulations (MDR) 2002, manufacturers are required to maintain a PMS system; however, the detail surrounding how they conduct their PMS and vigilance obligations is covered in guidance not in legislation. This has led to inconsistencies in the way manufacturers perform their PMS activities which impacts the quality of adverse incident data reported to the MHRA and puts patients at risk.

3. Commencement and application

3.1. The PMS SI will apply to devices that have been put into service by the manufacturer, or placed on the market, on or after the date on which the

[1] https://www.gov.uk/government/news/regulatory-roadmap-points-the-way-ahead-for-new-measures-to-support-safe-access-to-medical-technology-including-ai-and-diagnostics

Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 come into force. The requirement for data collection with regard to PMS will apply from the date of commencement for these regulations.

3.2. The PMS SI will increase the scope of devices that must comply with the PMS requirements. This will include CE marked devices, which are currently allowed onto the GB market under transition provisions[2] within the UK MDR 2002. Extending the scope of the regulations to these devices will maintain parity between the requirements for manufacturers to report to the MHRA for both CE and UKCA market devices. However, while manufacturers of CE marked devices will be required to comply with GB requirements, this instrument cannot mandate that manufacturers update technical documentation as set out in EU law nor stipulate the activities of EU Notified Bodies. Despite this, we consider that patient safety will not be compromised as equivalent standards are present in EU legislation and are a key component of the quality management of medical devices.

3.3. Comprehensive guidance will be published before the PMS SI comes into force to support manufacturers to understand their obligations and facilitate smooth implementation of these regulations.

4. Topics covered by future amendments to the UK MDR 2002

4.1. The Government intends to introduce a framework for international recognition, enabling swifter access for devices already approved by comparable regulators as well as for those who have Medical Device Single Audit Program (MDSAP) certificates. The MHRA will continue to review the PMS requirements for these devices as part of this regulatory update to ensure they are fit for purpose and maintain an appropriate level of safety.

4.2. Further amendments to the MDR 2002 will provide for improved connectivity and transparency across the device lifecycle, strengthening relationships and communications between the Secretary of State, manufacturers, UK responsible persons (UKRP), importers/distributers, and Approved Bodies to enhance traceability, patient safety and accessibility of information.

4.3. The PMS SI does not fully address the topic of performance evaluation and post-market follow up (PMPF) for In Vitro Diagnostic medical devices (IVDs) at this stage as these regulations are reliant upon subsequent changes to the to the future regulatory regime. For now, it is expected the manufacturer will use their judgement to determine the best type of PMPF dependent upon the device, its circumstances and history.

[2] Implementation of the Future Regulations - GOV.UK (www.gov.uk)

4.4. The government recognises the issues around compliance with regulation upon acquisition or liquidation of a manufacturer. MHRA will consider further consultation on this topic.

4.5. For further detail on upcoming regulatory changes please see the government response to the 2021 consultation[3].

5. Specific topics raised by WTO members

5.1. *The PMS SI is overly prescriptive:* The PMS SI lists specific details for certain regulatory requirements to provide manufacturers with clarity on their obligations and the data they need to collect. Listing the detail of the mandatory reporting requirements for serious incidents within legislation will ensure a consistent level of stricter safety standards across medical device manufacturers, providing significant improvements to patient safety aligned with our notified objective. WTO respondents have raised that listing the detail in this way is overly prescriptive, however, MHRA considers this crucial to providing the fundamental improvements to PMS that are needed. Moreover, a consistent standard of regulation may improve competition in the MedTech sector across the UK.

5.2. *Under-reporting of incidents to manufacturers is not addressed:* The PMS SI will place obligations on manufacturers around incident reporting and require that they monitor and address trends in incident data resulting in a more pro-active approach to protecting patient safety. The government appreciates that complementary information from different sources is important to build a more comprehensive picture of potential issues or adverse events associated with a medical device and will continue to engage with stakeholders to determine the most effective means to improve under-reporting of incident data across the system.

5.3. *Requirements for real world evidence are lacking:* WTO members highlighted that the term “real-world evidence” is not defined nor used within the PMS SI. For certain devices, real-world evidence plays a vital role in the process of PMS providing valuable insight into the long-term performance, durability of a device as well as potential issues that may arise with prolonged use or in specific subgroups of patients. The term PMS is used to describe activities carried out by manufacturers to proactively collect and review **experience gained from devices that are in use**, it is expected that real-world evidence will be generated through the collection and analysis of real-world data through PMS. Guidance accompanying this SI will highlight that processes to gather information must ensure comprehensive real-world data, i.e. data collected on device safety and performance outside of a controlled clinical trial, is obtained.

[3] Consultation on the future regulation of medical devices in the United Kingdom - GOV.UK (www.gov.uk)

5.4. *The 3-day reporting deadline is unreasonable:* The PMS SI will introduce a 3-day reporting deadline that will require a manufacturer, UKRP or Approved Body to respond to a request for documentation from the Secretary of State within 3 working days. The purpose of this requirement is to ensure that when it is necessary, the MHRA is provided access to essential documentation, which should be readily available to the manufacturer, in a timely manner to safeguard patient health. The MHRA considers it necessary that this short timescale for engagement be enforceable to uphold patient safety based on previous insufficient engagement with some manufacturers. The MHRA has always intended to use discretion following dialogue with manufacturers to provide longer timelines when appropriate. Updates to guidance will clarify this point and a discretionary clause has now been included within the PMS SI (**regulation 44ZR**), which makes clear this flexibility for the MHRA to assess the appropriate timeframe on a case-by-case basis. A definition for "working days" has also been added to the PMS SI for further clarity.

5.5. *There is no mention of PARD updates:* The MHRA has no plans to update the Public Access Registration Database (PARD) as a result of the measures introduced under the PMS SI at this time. However, we will keep this under review.

6. Regulation 44ZC - Interpretation

6.1. WTO respondents have raised that divergence in established terms from EU regulations could create unnecessary complexity and additional burden for both manufacturers and Approved Bodies. GB and EU medical device regulations are distinct, the MHRA have taken into account global definitions provided by the International Medical Device Regulators Forum (IMDRF) and international standards to ensure that they are non-discriminatory and do not create unnecessary obstacles to trade while providing improvements to patient safety aligned with our notified objective. Where a definition diverges more significantly, the MHRA considers this necessary to either improve clarity, maintain global alignment or introduce new requirements to safeguard public health and ensure devices placed on the GB market are subject to appropriate surveillance. Further information is provided for some of these comments below.

6.2. A definition of "**Approved body**" is not provided for in these regulations as can be found within The Medical Devices Regulations 2002, Section A45 and will not be updated.

6.3. The definition of "**Incident**" within the PMS SI includes those that arise from a side effect if it has a negative impact on the health of an individual, patient management, or public health. As such, should a "**serious incident"** relating to a side-effect occur, i.e. a death, serious deterioration pf any person's state of health or serious public health threat; it is reportable to the MHRA. The MHRA considers this is in the best interest for public health as it will improve both the under-reporting of device-related incidents and the MHRA's data collection relating to serious incidents providing significant improvements to

patient safety. The MHRA consulted on these changes in 2021 and the response to this amendment was positive.

6.4. The definition of the term "**lifespan of a device**" has now been removed from the PMS SI. After consideration, the MHRA intends to consult further on the use of this term to ensure that the obligations it generates are practical, in the best interest of patient safety, support regulatory compliance and do not create unjustified barriers to trade.

6.5. The "**PMS period**" is the period during which a manufacturer must conduct their PMS activities. It begins from the day on which the first device of a device model is put into service by the manufacturer or placed on the market, whichever is sooner. Following removal of the term "**lifespan of a device**", the end of this obligation has now been aligned to the "**lifetime of a device**" such that the PMS period ends with the end of the lifetime of the last device of that model that is put into service by the manufacturer or placed on the market, whichever is later. The "lifetime of a device" refers to the period that manufacturers claim to have evidence to support that their device will perform as intended, while the "lifespan of the device" extends to a further period of reasonably foreseeable use based upon real world usage experience. The MHRA considers requiring manufacturers to conduct PMS throughout the lifespan of a device provides significant improvements for patient safety, particularly for implantable devices and large capital equipment in hospitals that undergoes regular preventive maintenance. However, not all devices can, nor should, be used beyond their lifetime and the MHRA considers it is not in the best interest of patient safety to encourage this across all device classifications. As such, further consultation will consider whether this obligation can be applied in a risk-based manner to achieve its intended benefit. The MHRA will also consider how this can be achieved without creating unnecessary regulatory burden for the manufacturers of low-risk devices or introducing new patient safety risks both around supply and the inappropriate use of medical devices beyond the point they are considered safe.

6.6. The definition of "**required risk analysis**" features in the PMS SI and WTO respondents have raised that this would be better termed as the "benefit-risk determination". The "required risk analysis" refers to the risk analysis that a manufacturer must perform as part of the essential requirements a device must meet. This states "devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons". To meet this requirement manufacturers are expected to systematically use the available information to identify hazards and estimate risk, performing a risk analysis before conducting a benefit-risk determination. MHRA consider the use of this definition is appropriate.

6.7. WTO respondents have raised that the terms “same type of device”, “similar device” or “device model” are confusing. A definition for “**similar device**” has now been included within the PMS SI and these terms have been applied more consistently to improve clarity for manufacturers on their obligations and when data is requested. In this SI “similar device” means a device which has the same or a similar intended purpose and is based on the same or similar technology.

7. Regulation 44ZF – Post-market Surveillance plan

7.1. Regulation 44ZF requires the manufacturer to include information within their PMS plan on processes for the collection and assessment of information about user experience in relation to safety and performance, including through patient and public engagement (PPE) where appropriate. WTO respondents have raised that the requirement for PPE is a divergence from EU regulations. The MHRA considers that PPE is a crucial aspect of healthcare research and for certain devices can provide valuable insights from patients’ real-world experience that can help identify improvements that could have meaningful outcomes for patient safety and public health. This may not be relevant for all devices and flexibility is provided within the regulations to undertake PPE “where appropriate”.

7.2. WTO members raised concerns on the requirements for statistical methods. MHRA consider these types of analysis are not unique to medical device monitoring and information on how to perform these analyses is widely available. It is considered overly burdensome to dictate requirements in this area and could lead to the use of inappropriate techniques given the breadth of devices on the market. The manufacturer must use their professional judgement or seek specialist expertise in determining the appropriate choice of technique to fit their device or circumstances.

8. Regulation 44ZG – Preventive and Corrective actions

8.1. This regulation details the reporting requirements for corrective and preventive actions. WTO members have raised that reporting these actions to Approved Bodies is overly burdensome. However, the MHRA considers firstly that this is important to improve the protection of patient safety, and secondly that there is flexibility in how to achieve this as corrective and preventive actions can be summarised within the post market surveillance report (PMSR) and periodic summary update report (PSUR). These reports can provide a vehicle for a manufacturer to update their Approved Body as needed without introducing additional regulatory burden. Comprehensive guidance on this topic will clarify this.

9. Regulation 44ZH – Initial reporting of serious incidents

9.1. WTO members have raised that the requirement to provide information on similar incidents at the initial reporting stage is unnecessary and unusual to see at this stage. Following review, the MHRA has removed this from

regulation 44ZH of the PMS SI. Instead, this requirement has been introduced to regulation 44ZI at the final reporting stage. The MHRA considers that this aligns best with current practice and removes a potential barrier to the prompt reporting of serious incidents at this initial stage, thus providing patient safety benefits.

10. Regulation 44ZJ – Field safety corrective actions and field safety notices

10.1. Field safety notices (FSN) are essential communications for device users regarding safety concerns. Current practice is for manufacturers to submit these to the MHRA and they are published on the MHRA website. WTO respondents have raised objections to publishing FSN on the manufacturer's website, highlighting concerns around data sensitivity and divergence from international practice. The purpose of this regulation is to provide patients and device users with greater visibility of safety notices and transparency on issues relating to the devices they may use. The requirement to publish an FSN on the manufacturer's website alongside promotional information may ensure a balanced overview for patients and the public. Following consideration, MHRA has concluded it may be inappropriate to stipulate the means by which this objective is achieved in the legislation, as other technologies may be better placed to do so in future. As a regulatory body, the MHRA is committed to improving transparency to enhance patient safety and protect public health. Guidance will encourage this activity as best practice, and the MHRA will consider further consultation as to how this requirement can be incorporated into existing legislation in a more future-proof manner.

11. Regulation 44ZK - Field safety corrective actions outside Great Britain

11.1. This regulation will require manufacturers to inform the MHRA of field safety corrective actions (FSCA) taken outside of GB if it relates to a device of the same model as a device placed on the GB market and the same FSCA is not being taken within GB. WTO members have raised that this regulation is overly burdensome and does not provide additional benefit to patient safety. The MHRA considers this a necessary and practical amendment which will avoid future confusion and decrease the burden of queries raised by MHRA to which industry would need to respond. Further clarification will be provided in guidance.

12. Regulation 44ZM – Periodic Safety Update Report

12.1. WTO respondents raised several queries around procedures and format of the periodic safety update report (PSUR) which is required for medium-high risk medical devices. The MHRA has conducted extensive stakeholder engagement to support the development of comprehensive guidance in this area to facilitate the smooth implementation of these requirements. The MHRA will clarify in guidance that the manufacturer should prepare the PSUR according to a standardised format to enable a consistent

method for reporting across manufacturers. Detailed advice will be made available on format, presentation of data and grouping of devices.

12.2. The MHRA appreciates that the preparation of multiple PSURs for different regulatory jurisdictions may be overly burdensome for manufacturers. However, the high degree of alignment of the post-market surveillance measures within the SI to international regulations should reduce this burden. The manufacturer must submit the PSUR and each updated PSUR to the Approved Body for the device (if there is one). Where manufacturers are not required to submit their PSUR to an Approved Body, for example when instead this report must be provided to an EU notified body, these documents must be made available to the MHRA within three working days of a request.

12.3. WTO respondents have indicated that the requirements for CE marked medical devices, which are currently permitted to be placed on the GB market, are confusing. For clarity, this SI cannot mandate that manufacturers update technical documentation as set out in EU law nor stipulate the activities of EU Notified Bodies. For example, regulation 44ZE (4) (requiring a manufacturer to ensure the data gathered through the PMS system is used to update the technical documentation) does not apply to CE marked devices. This will be further highlighted in guidance and the explanatory memorandum for the PMS SI.

13. Regulation 44ZO – Reports received by the Secretary of State

13.1. These regulations detail the Secretary of State's obligation to record reports of incidents involving devices and the obligation to notify a manufacturer of a reported incident for their consideration. A manufacturer is expected to provide a justification as to whether this should be considered a serious incident or not. However, should the Secretary of State disagree, the manufacturer must proceed accordingly. WTO respondents have raised that there is no provision for a manufacturer to challenge the MHRA on this decision. The MHRA is the regulatory authority acting on behalf of the Secretary of State, with the aim of keeping patients and public safe. The MHRA works with manufacturers on risk mitigations. Information provided by the manufacturer during an investigation will be taken into account before a final decision is taken. The MHRA does not consider it appropriate to introduce an appeals process in legislation for manufacturers as any decision will be made upon sound reason and legal direction.