EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (POST-MARKET SURVEILLANCE REQUIREMENTS) (AMENDMENT) (GREAT BRITAIN) REGULATIONS 2024

2024 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency ("MHRA"), an executive agency of the Department of Health and Social Care ("DHSC") and is laid before Parliament by Command of His Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Declaration

2.1 Baroness Merron, Parliamentary Under-Secretary of State for Patient Safety, Women's Health and Mental Health at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

2.2 Dr Laura Squire, Chief Healthcare Quality and Access Officer at the Medicines and Healthcare products Regulatory Agency can confirm that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Dr Clare Thompson at the Medicines and Healthcare products Regulatory Agency Telephone: 020 3080 6000 or email: info@mhra.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 The main objective of this instrument is to introduce more stringent and clearer Post-market Surveillance (PMS) requirements that are risk proportionate with improved regulatory oversight. This will help to improve the ability of manufacturers and the MHRA to identify issues with medical devices on the Great Britain (GB) market and where necessary, take appropriate action to safeguard public health.

4.2 PMS is a set of activities conducted by manufacturers, to collect and evaluate experience gained from medical devices that have been placed on the market or put into service, and to identify the need to take any action. PMS is a crucial tool to ensure that medical devices continue to be safe and well-performing and to ensure actions are undertaken if the risk of continued use of the medical device outweighs the benefit. Evaluation of the information gathered through PMS and the consideration of user experience can also highlight opportunities to improve the medical device and drive innovation.

Where does the legislation extend to, and apply?

4.3 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is the United Kingdom, except for regulation 4 which extends to Scotland, England and Wales only.

4.4 The territorial application of this instrument (that is, where the instrument produces a practical effect) is Great Britain only. Since 26 May 2021, the EU Medical Devices Regulation (Regulation 2017/745) (EU MDR) has applied in Northern Ireland. Since 26 May 2022, the EU in vitro Diagnostic Medical Devices Regulation (Regulation 2017/746) (EU IVDR) has applied in Northern Ireland.

4.5 Qualifying Northern Ireland Goods that carry a valid CE marking may continue to be placed on the market in Great Britain on an indefinite basis. This arrangement is in accordance with the government's commitments to Northern Ireland's unfettered access to the market in the rest of the United Kingdom and is underpinned by the United Kingdom Internal Market Act 2020. Manufacturers based in Northern Ireland that supply medical devices to Great Britain will have to comply with the new PMS requirements.

5. Policy Context

What is being done and why?

5.1 The term "medical device" covers a wide range of products from everyday devices such as spectacle frames and contact lenses, to more complex devices such as total joint replacement systems, surgical mesh and automatic external defibrillators. It includes devices for diagnosis, for example SARS-CoV-2 lateral flow tests, pregnancy tests and blood glucose monitoring systems, as well as hospital equipment such as MRI machines. Software incorporated within these devices is also regulated and standalone software may be considered a medical device in its own right, for example clinical calculators and certain mobile medical applications.

5.2 These regulations introduce new PMS requirements to ensure that manufacturers continue to effectively monitor the safety and performance of their devices after they have been placed on the market or put into service in GB.

5.3 The regulations will increase the scope of medical devices that must comply with the PMS requirements in GB. This will include CE marked devices, which are currently allowed onto the GB market under transition provisions[1] within the UK MDR 2002 and, at the time of writing, are estimated to constitute 91% of the devices registered with the MHRA, based on the registration of new medical technology products[2]. 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 marked devices. For CE marked devices, regulation 44ZE(4), which requires a manufacturer to ensure the data gathered through the PMS system are used to update the technical documentation, does not apply as this instrument cannot mandate that manufacturers update technical documentation as set out in EU law.

5.4 The regulations will require manufacturers to maintain a PMS system for all devices placed on the market or put into service in GB. A PMS system includes the analysis of data relevant to the quality, performance and safety of the device throughout its

[1] Implementation of the Future Regulations - GOV.UK (www.gov.uk)
https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices/implementation-of-the-future-regulations

[2] Please refer to the Impact assessment for these regulations

lifetime, and a record of the manufacturer's conclusions based on that analysis. The purpose of a PMS system is to identify preventive and corrective actions, trends in incidents, options to improve the usability, performance and safety of the device, and any impact on PMS of other devices to safeguard public health.

5.5 The PMS system must be based on a PMS plan, which specifies the lifetime of the device, the shelf-life plus the period the manufacturer expects the device to perform as intended, and includes processes for the collection and assessment of information in relation to the device, suitable indicators and threshold values for use in the reassessment of risk analysis, processes to investigate complaints, analyse feedback, manage incidents and trends, and communicate effectively regarding the device, including with users and suppliers of the device.

5.6 The regulations set out greater detail on what must be included as part of a PMS system and a PMS plan. For example, manufacturers will need to ensure that their PMS system includes the analysis of relevant data throughout the lifetime of the device and captures PMS data on similar devices available within and outside of the UK. This requirement is intended to ensure that the MHRA captures a better picture of how devices are performing outside of the GB market. The regulations will require manufacturers to carry out preventive and corrective actions. The regulations will also include requirements around notification and monitoring of preventive and corrective actions. These requirements are consistent with international best practice and ensure an appropriate level of regulatory oversight to protect patient safety.

5.7 Field safety corrective actions (FSCA) are corrective actions taken by the manufacturer to prevent or reduce the risk of a serious incident in relation to a device which has already been placed on the market or put into service. The regulations will require manufacturers to produce a risk assessment of the proposed FSCA and submit an initial report on the proposed action to the MHRA (on behalf of the Secretary of State). They must also submit a proposed field safety notice, which must be issued when taking an FSCA. This notice can be submitted following the FSCA, if the manufacturer believes the FSCA needs to be taken urgently. The manufacturer must take all reasonable steps to ensure the field safety notice is sent to users of the device. After completing the FSCA, the manufacturer must submit a final report to the MHRA setting out the outcome of the action and including evidence to demonstrate its effectiveness.

5.8 Where a manufacturer of a device takes any FSCA outside GB for a device which is of the same model as a device that has been placed on the market or put into service in GB, they must submit a report to the MHRA This requirement does not apply if the manufacturer is taking the same FSCA in GB.

5.9 The detail surrounding the reporting of incidents is currently covered within guidance. The regulations will bring into force vigilance requirements with greater detail about the investigation and reporting of serious incidents including the timelines for notifying the MHRA. This will help to improve the quality of data the MHRA receives regarding serious incidents and ensure that safety issues are captured and acted upon sooner.

5.10 The regulations will introduce requirements for manufacturers of low-risk medical devices to maintain a PMS report (PMSR). The purpose of a PMSR is to summarise the results and conclusions of a manufacturers PMS data over a period to ensure the device continues to perform as intended. The PMSR must then be updated at least every three years and made available to the MHRA upon request.

5.11 Manufacturers of medium and high-risk medical devices will be required to produce a Periodic Safety Update Report (PSUR). A PSUR is similar to a PMSR but includes additional information. The regulations will require that manufacturers of medium-risk devices produce and update a PSUR every two years and for high-risk devices every year. The PSUR must be made available to the MHRA upon request. PSURs must be submitted to the conformity assessment body responsible for approving the device certification, the Approved Body (if there is one for the device) who will take the PSUR into account when carrying out its surveillance activities to assess whether the device continues to perform in accordance with its certification. The Approved Body must review the PSUR for the highest-risk devices and issue a report to be made available to the MHRA upon request. This requirement is aimed at improving regulatory oversight and coordination between manufacturers, Approved Bodies and the MHRA.

5.12 The regulations will introduce new requirements surrounding trend reporting. The regulations will require manufacturers to monitor the number of incidents, both serious and those which are not classified as serious incidents (i.e. do not require separate notification to the MHRA) over time. This will help to support manufacturers in recognising adverse safety trends or signals in their PMS data, including those which may become serious incidents or impact the benefit-risk ratio of a medical device, once placed onto the market or put into service.

5.13 The regulations also make provision for the MHRA to notify manufacturers of incident reports and trends identified in the information the MHRA receives. They also require the manufacturer to submit reports explaining any action the manufacturer will be taking in response. As the competent authority for Northern Ireland, the MHRA remains apprised of safety information across the UK.

5.14 Where appropriate the new PMS regulations align with international requirements to help support the availability on, and favourability of, the GB market and reduce additional burden on manufacturers supplying medical devices across multiple jurisdictions.

What was the previous policy, how is this different?

5.15 Under the current Medical Device Regulations 2002 ("MDR 2002") there are limited provisions relating to PMS and these are high-level. Manufacturers are required to maintain a PMS system, however, the details surrounding how they conduct their PMS and their vigilance obligations are covered in guidance and not the current legislation.

5.16 This has resulted in inconsistencies in the way manufacturers placing on the market, or putting into service, devices in GB perform their PMS activities. This also negatively impacts the quality of adverse incident data reported to the MHRA.

5.17 The Independent Medicines and Medical Devices Safety (IMMDS) Review highlighted the need for better capture of adverse incident data to minimise the risk to patient safety. By introducing clearer and more stringent PMS requirements this instrument will improve the safeguarding of public health and patient safety.

6. Legislative and Legal Context

How has the law changed?

6.1 This instrument amends the MDR 2002, which regulate medical devices on the GB market, to insert new PMS requirements. The MDR 2002 were made under section

2(2) of the European Communities Act 1972 (amongst other powers) to implement Directives 90/385/EEC, 93/42/EEC and 98/79/EC.

6.2 Regulation 4 of this instrument inserts a new part, Part 4A, into the MDR 2002. Part 4A (regulations 44ZC to 44ZR) contains new PMS requirements, for medical devices and accessories to medical devices placed on the market or put into service in GB.

6.3 Schedule 2A to the MDR 2002 makes modifications to the annexes to Directives 90/385/EEC, 93/42/EEC and 98/79/EC, which included the existing PMS requirements. Regulation 5 of this instrument amends Schedule 2A to remove the PMS requirements that are replaced by Part 4A. A saving provision is set out in regulation 6 for devices placed on the market or put into service before new Part 4A applies.

Why was this approach taken to change the law?

6.4 To ensure that the new PMS requirements will be legally binding and a consistent approach will be taken to these important patient safety measures by all manufacturers, it is necessary to set them out in legislation. The instrument is made under section 15 of the Medicines and Medical Devices Act 2021 ("MMDA"), which only allows provision to be made by amending or supplementing the MDR 2002. By amending the MDR 2002 and inserting a new Part 4A, these new post-market requirements sit within the same set of regulations as the pre-market requirements for placing a device on the GB market. By amending the MDR 2002 to include these new requirements, they continue to be the main set of regulations for manufacturers of devices for the GB market.

7. Consultation

Summary of consultation outcome and methodology

7.1 The MMDA requires that, before making regulations under section 15, a public consultation must be carried out in accordance with section 45(1) of the MMDA. A public consultation was carried out from 16 September 2021 to 25 November 2021 and proposals relating to PMS were included in chapter 8. There were 891 consultation responses: 413 from individuals and 451 from organisations. Responders from organisations included manufacturers of medical devices, healthcare institutions, trade associations and small/medium enterprises.

7.2 The responses were generally supportive of the proposals to introduce strengthened PMS requirements for medical devices, with 8 of the 15 proposals receiving support from at least 80% of respondents and all 15 proposals supported by at least 55% of respondents. A summary of the consultation responses and the Government's response was published on 26 June 2022[3].

7.3 The MHRA has engaged with officials in the Devolved Governments on the development of this instrument.

8. Applicable Guidance

8.1 Guidance on gov.uk will be updated when the instrument comes into force to reflect its content, as we recognise this will be critical for proper implementation and interpretation of this instrument.

[3] Consultation on the future regulation of medical devices in the United Kingdom - GOV.UK (www.gov.uk) https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website.

9.2 The IMMDS Review reported on how the healthcare system in England responds to patient reports of side effects from a range of treatments, including medical devices such as pelvic mesh. It assessed the processes followed by regulators when patients report a problem, concluding that the system failed to listen to patients or to put patients at the centre of their care. The Government's response noted that more needed to be done to "develop a more responsive system for reporting adverse incidents, and to strengthen the evidence to support timely and robust decisions that protect patient safety."[4]

9.3 The lack of regulatory provision for PMS generates the risk of information failure. The failure to undertake sufficiently rigorous PMS leads to the risk that consumers may use unsafe medical devices, to the detriment of their health. Additionally, harmful medical device incidents may generate costs beyond those directly impacted by the incident. As such, there is a strong rationale for government intervention to limit these market failures.

9.4 The net present social value of this policy is negative. However, by standardising PMS requirements across manufacturers, the impact on patients is positive. Disadvantaged groups are more likely to be negatively affected by inconsistencies in provision or service; by bringing all manufacturers within new PMS regulations, this possibility is greatly reduced.

9.5 The introduction of these regulations is part of a response to the IMMDS Review to ensure that incidents such as those surrounding pelvic mesh, which disproportionately affected women, do not happen again: with increased reporting obligations on manufacturers, trends can be identified more easily.

9.6 The former Secretary of State for Health and Social Care, the Rt Hon Steve Barclay MP, had emphasised the Government's commitment to implementing "the small number of remaining commitments"[5] from the IMMDS Review. Recommendation 6 specifically refers to improvements required to adverse event reporting, which the proposed regulations seek to achieve. These regulations provide the MHRA with more information, facilitating greater traceability of incidents and trends, and allowing the MHRA to provide more evidence and information as and when it is necessary.

Impact on businesses, charities and voluntary bodies

9.7 These measures are expected to produce benefits to society from reduced medical device incidents. They will produce costs to the medical device industry from increased PMS requirements.

9.8 Benefits to society from reduced medical device incidents over the next ten years are indicatively estimated to be between £5.6m and £57m in total, with a best estimate of

[4] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1005847/IMMDS_Review_-_Government_response_-_220721.pdf - accessed 27 July 2023

[5] Independent Medicines and Medical Devices Safety Review: update report on government implementation - GOV.UK (www.gov.uk) - accessed 29 August 2024 https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-update-report-on-government-implementation

£31m. Further non-monetised (non - quantified) benefits may arise from greater consumer demand due to improved safety measures.

9.9 Across the whole industry, manufacturers who supply medical devices to GB may face total costs between approximately £240m and £380m over the next ten years, with a best estimate of £310m. This includes the transition costs of setting up a new PMS system and the cost of maintaining the new system. Some of these costs may be passed on to consumers of medical devices, but the impact of this is uncertain.

9.10 Deducting the costs to business from the total benefits from reduced incidents, the total net present social cost of these measures over the next ten years is expected to be between approximately £180m and £370m, with a best estimate of £280m.

9.11 Small and micro-sized enterprises are estimated to incur 15% - 25% of the costs to business. Given that one objective of these measures is to ensure a consistent level of stricter safety standards across medical device suppliers, the decision was made not to exempt SMEs. Ensuring a consistent standard of regulation may improve competition in the MedTech sector, and an arbitrary exemption for SMEs may deter business growth.

9.12 All values are in 2019 prices, with 2020 present values. All values presented are rounded to two significant figures.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring this legislation is captured in the MDR 2002, which this instrument amends. Regulation 67 states that the Secretary of State must carry out a review of the MDR 2002 and publish a report setting out the conclusions of that review before the end of 31 December 2025.

10.2 In addition, section 46 of the MMDA requires the Secretary of State to lay a report before Parliament every two years on the operation of regulations made under section 15 (and other powers under the Act).

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 This instrument is made under section 15(1) of the MMDA. It amends the MDR 2002 which were made under section 2(2) of the European Communities Act 1972 (amongst other powers). This instrument is subject to the draft affirmative procedure. The procedural and publication requirements applicable to this instrument have been followed.

12. European Convention on Human Rights

12.1 Baroness Merron, Parliamentary Under-Secretary of State for Patient Safety, Women's Health and Mental Health has made the following statement regarding Human Rights:

"In my view the provisions of the Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 are compatible with the Convention rights."

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").