How prepare for the new PMS requirements for Great Britain

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Learning Objectives

By the end of this session delegates will be able to:

01

Understand how the new regulation will impact any manufacturer placing medical devices on the market or putting them into service in Great Britain

02

Understand how to ensure the PSUR is compliant, when intending the document to meet both EU and Great Britain requirements

Poll

Which of the following statements best describes your current position?

- I have a plan for implementing the Great Britain PMS requirements
- I need more information to help me prepare
- I’m not sure how this affects me
- This is all new to me

Agenda

01
Introduction and overview of the PMS regulations

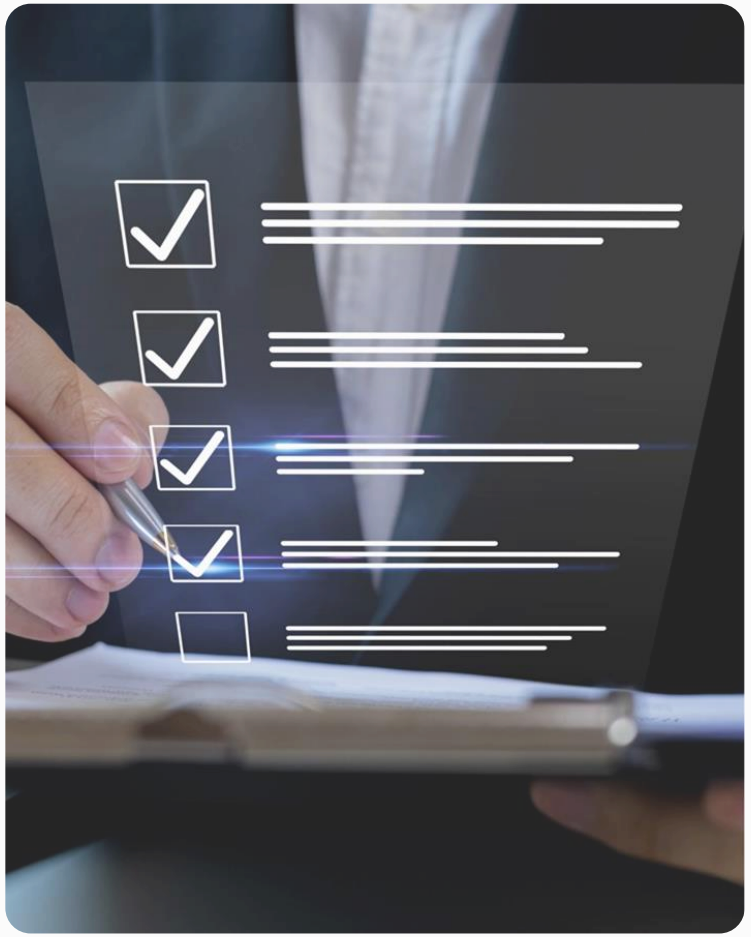
02
Timelines for implementation

03
PMS requirements relating to the QMS

04
Periodic safety update reports

05
A look to the future for the core UK MDR

06
Q&A session



Introduction

01

MHRA seeks to introduce regulatory reform in response to recommendations made by the Independent Medicines and Medical Devices Safety review (IMMDS review, 2018-2020)

02

Initial public consultation launched in 2021, other consultations are ongoing

03

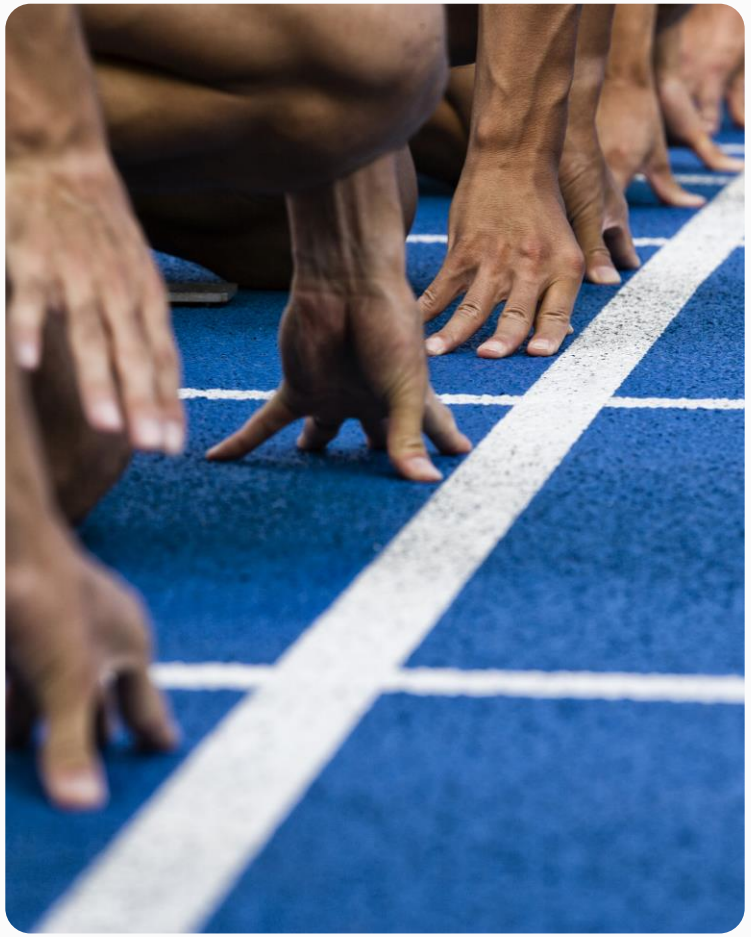
Post-market Surveillance Regulations are the first stage of strengthening regulatory requirements and aim to improve patient safety in Great Britain

04

Applies to all devices placed on the GB market or put into service, regardless of whether this is under the UKCA or CE scheme

05

Broadly mirrors the EU MDR/IVDR, some differences



Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 SI 2024/1368

Part 4A PMS

- Interpretation (definitions) (44ZC)
- Scope (44ZD)
- PMS System (44ZE)
- PMS Plan (44ZF)
- Preven
- Report
- FSCA a
- Post-m
- Periodi
- Trend R
- Reports received by Secretary of State (44ZO)
- Analysis of information received under Part 4A (44ZP)
- Retention of PMS documentation (44ZQ)
- Requests for PMS documentation (44ZR)

CE-marked devices must also comply!

Custom made devices are exempt from:

- FSCAs outside of Great Britain
- Post-market Surveillance Report
- Periodic Safety Update Report
- Trend Reporting

Complete exemption for:

- Devices for Clinical Investigation
- Devices for Performance Evaluation
- Device subject to an Exceptional Use Authorisation

Stakeholder responsibilities

Manufacturer

- PMS System and Plan
- CAPA
- Periodic reporting: PMSR, PSUR
- Serious Incident & FSCA reporting and investigation
- Trend reporting
- Co-operate with and provide information to MHRA upon request
- Retain PMS documentation

Approved Body

- Check manufacturers' compliance in surveillance audits
- Review CAPA notifications
- Review of PSURs, issue report when required
- Assess PMS Plans at initial application
- Provide information to MHRA upon request

UK Responsible Person

- Receive PSUR review reports
- Retain PMS documentation
- Co-operate with and provide information to MHRA upon request

MHRA

- Receive reports of Serious Incidents, FSCA and trends and monitor manufacturer's investigations
- Initiate separate investigations when necessary
- Identify trends, patterns and signals in information received & inform manufacturers
- Receive reports of incidents from healthcare professionals and the public and forward to manufacturers

Key new requirements

- **Preventive and Corrective Actions**: Notify UKRP, AB and MHRA and monitor
- **Serious Incident Reports**: 2 days, 10 days, **15 days**, defined content for initial and final
- **PMSR or PSUR**: Risk class dependent, updated regularly, defined content
- **Trend Reporting**: **all incidents** with significant increase in severity or frequency

Timelines for implementation

16 Dec 2024

- Regulation is passed into law by the UK government
- Impact assessment begins

Now!

- Conclude impact assessment
- Updates to QMS
- Updates to systems and tools
- Create or update device-specific PMS system and PMS plans

16 June 2025

- Regulation comes into force
- Compliance is required
- Implement PMS Plan
- Serious incident reporting aligns with EU
- Trend reporting

16 June 2026 and onwards

- 1st PSUR due within 1 year
- 1st PMSR due within 3 years

Impact assessment

01 Device

- Type
- Risk classification
- Lifetime

03 Geography

- Where am I placing the device on the market?

02 Certification

- CE (MDR/IVDR)
- CE (Directives)
- UKCA (UK MDR 2002)

04 QMS

- PMS System in place for each device?
- Gap analysis to requirements 44ZE

05 Systems, procedures and documents

- Update
- New

PMS requirements related to the QMS

UKCA certified devices:

- PMS System which is device-specific and based on a PMS Plan
- Evidence of procedures which cover the requirements listed in Regulation 44ZE (3)
- **Evidence that the PMS System outputs feed into the technical and clinical documentation of the device as described in Regulation 44ZE (4)**

CE (Directives or MDR/IVDR) certified devices:

- PMS System which is device-specific and based on a PMS Plan
- Evidence of procedures which cover the requirements listed in Regulation 44ZE (3)

Periodic Safety Update Reports (PSURs)

Risk of device	Frequency of update under SI 2024/1368	Review by Approved Body?	For UKCA-devices: Standalone review or during ongoing surveillance?	Same as EU MDR/IVDR?
Class III device	Annual	**Only if the device has undergone UKCA conformity assessment by the approved body!**	Stand-alone	✓
Active Implant	Annual		Stand-alone	✓
Class IIb (implantable)	Annual		Stand-alone	✓
Class IIa (implantable)	Biennial		It depends!	✗
Class IIb (non-implantable)	Annual		Surveillance	✓
Class IIa (non-implantable)	Biennial		Surveillance	✓

Periodic Safety Update Reports (PSURs)

Risk of device	Frequency of update under SI 2024/1368	Review by Approved Body?	For UKCA-devices: Standalone review or during ongoing surveillance?	Same as EU MDR/IVDR?
List A IVD	Annual	Yes	Stand-alone	✕
List B IVD	Annual	Yes	It depends!	✕
Class D IVD	Annual	No	N/A	✕
Class C IVD	Annual	No	N/A	✕

PSUR for a UKCA-certified device

Follow the MHRA’s standardised format

Data tables included are suggestions only

Manufacturer should determine the most appropriate data tables and charts

Should be issued within one or two years following the date the device is placed on the market after 16 June 2025

PSUR to be submitted directly to the Approved Body for review

BSI Clients will upload PSUR to the Client Portal

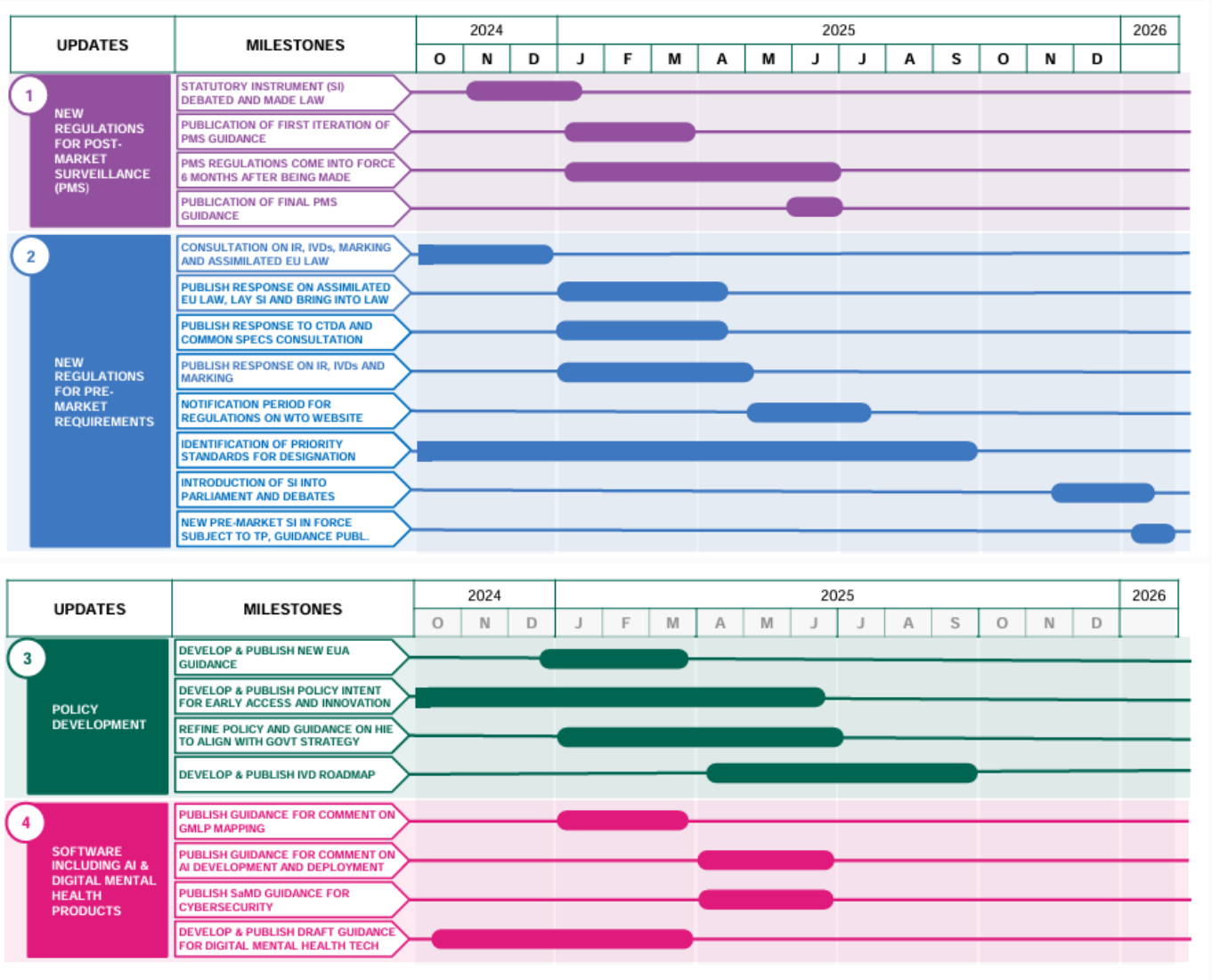
Send to the MHRA upon request

Combined review of PSUR for EU MDR or IVDR and UKCA scheme

What the manufacturer needs to deliver to BSI:

- Upload a PSUR which meets the requirements of both regulations to the BSI client portal
- Identify the certificate numbers to which the PSUR relates MDR or IVDR and UKCA
- Use the PSUR cover page to state which regulations, devices, data collection period are covered by the document
- Present data in a clear and structured manner. UK or GB data sets presented alongside EU and Worldwide data as required by regulation 44ZM.
- Address specific GB content requirements e.g. feedback gained from patient and public engagement (44ZF 3(v))

Future look at UK MDR 2002- Roadmap



Key Dates:

1. PMS SI- **In Force June 16th 2025**
2. New Updated regulations- **Draft-** Q3 2025 **In force-** Q1 2026
3. Current legislation to be accepted beyond July 2025

Future look at UK MDR 2002- Dec 2024 Consultation

International Reliance

- 4 Routes to market
- Covering EU MDR/IVDR, US FDA, CAN and AUS

Removal of UKCA Marking

- Physical UKCA Mark removed
- Introduction of UDI

IVD Reclassification

- Class B IVDs incl. self-test, Self-Declared + QMS certification

Assimilated EU Law

- Removal revocation dates for:
  - 2002/364- IVD Common Specs
  - 207/2012- eIFU
  - 722/2012- Tissues of Animal Origin
  - 920/2013- Designation and Supervision of ABs

Key Take Away Messages

01

PMS Regulation applies to the Great Britain market.

MDR & IVDR applies in Northern Ireland

02

Following a 6-month transition period, compliance with the regulation is required from 16 June 2025

03

Applies to all devices placed on the market or put into service in Great Britain, regardless of whether device is certified under the UKCA scheme or has CE certification

04

New reporting requirements for manufacturers:

- Shorter timelines to report serious incidents
- Trend reporting
- PMSR or PSUR

05

BSI will be looking to confirm manufacturers have updated their QMS to address the new PMS requirements during surveillance audits

Any Questions?

Thank you for your Attention!