Medicines & Healthcare products Regulatory Agency

The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024

Summary of main changes introduced with the statutory instrument (SI) and associated guidance

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Contents

Summary of main changes introduced with the post-market surveillance statutory instrument and associated guidance

In 2024, the government put in place legislation to clarify and strengthen the post-market surveillance requirements for medical devices in use in Great Britain. These measures apply to medical devices placed on the market or put into service from 16 June 2025 onwards and will facilitate greater traceability of incidents and trends and allow the MHRA to act swiftly when needed, supporting better risk management and containment of safety issues and reducing harm.

The new set of regulations The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 amends the UK Medical Devices Regulations (MDR) 2002 by inserting a new Part 4A on post- market surveillance (PMS) requirements for medical devices, including in vitro diagnostic (IVD) devices and active implantable medical devices which apply in Great Britain (GB).

Comprehensive guidance on this topic can be found here: Medical devices: post-market surveillance - GOV.UK

The following table highlights the main changes introduced by this new regulation.

Regulation number	Key changes introduced with the new regulation/associated guidance compared to prior regulation/associated guidance	Requirement applies to:
44ZC	Definition of the PMS Period	Manufacturer
44ZC	Definition for reportable side-effects	Manufacturer
44ZC	Clarification that interventions to prevent serious deterioration in health include self-administered treatment	Manufacturer
44ZC	Serious deterioration in health need not have occurred for a use error to be reportable, just the risk it could occur.	Manufacturer or delegated to UK RP or Authorised Rep for Northern Ireland (NI)
44ZD (2)	Trend reports are not required for custom-made devices	Manufacturer or delegated to UK

		RP or Authorised Rep for NI
44ZF	Requirement for a PMS plan now mandatory within the regulations	Manufacturer
44ZF	Clarification that feedback should include patient and public engagement.	Manufacturer
44ZG (2)	Requirement to inform the UK responsible person (UK RP) and approved body (where have one) of all preventive and corrective actions taken to address a risk or non-conformity compromising the performance or safety of the device	Manufacturer
44ZG (3)	Approved body to review preventive and corrective actions for impact on certification	Approved Body
44ZH (3)(b)	15 days to report anticipated serious deterioration in health (was 30).	Manufacturer or delegated to UK RP or Authorised Rep for NI
44ZH (2)(d)	Inclusion of a unique device identifier (where available) within the incident report	Manufacturer or delegated to UK RP or Authorised Rep for NI
44ZI (3)(b) **44ZJ (8)**	Provide MHRA within 3 working days any information requested relating to an ongoing incident investigation or field safety corrective action (FSCA).	Manufacturer or delegated to UK RP or Authorised Rep for NI
44ZI (3)(c)	Detailed requirements on commencement of destructive device testing following notification to MHRA of intention to do so.	Manufacturer or delegated to UK RP or Authorised Rep for NI
44ZJ (1) and (3)	Requirement to submit proposed field safety notice (FSN) to MHRA prior to sharing with customers. And detailed requirements on subsequent timing of distribution to affected customers.	Manufacturer or delegated to UK RP or Authorised Rep for NI
44ZJ (6)(a)	The FSN must contain UDI information where available and must be sent in a searchable format.	Manufacturer or delegated to UK RP or Authorised Rep for NI
44ZK (1)	If the manufacturer is undertaking FSCA outside Great Britain and the same type of devices are supplied in	Manufacturer or delegated to UK

	Great Britain but are not affected, they must notify MHRA	RP or Authorised Rep for NI
44ZL	Provision of PMS report (PMSR) to MHRA on request within 3 working days	Manufacturer
44ZL	Timing of requirement to prepare first PMSR, and to update at least every 3 years	Manufacturer
44ZM	Provision of periodic safety update report (PSUR) to MHRA on request within 3 working days	Manufacturer
44ZM	Preparation of a PSUR to a standardised format, updated at set intervals	Manufacturer
44ZM	Submission of PSUR to approved Body	Manufacturer
44ZM	Approved body to review PSUR for any impact on device certification	Approved Body
44ZM	Approved body to prepare a report on review of PSUR for certain device classifications	Approved Body
44ZN(1)	Trend reports should be submitted for incidents which are reportable individually, as well as those which do not meet the criteria for individual reporting	Manufacturer or delegated to UK RP or Authorised Rep for NI
44ZN(5)	Detailed requirements for information to be included within a Trend report.	Manufacturer or delegated to UK RP or Authorised Rep for NI
44ZO	Detailed requirements on action in response to notification of an incident by MHRA	Manufacturer or delegated to UK RP or Authorised Rep for NI
44ZP(2)	Investigation and reporting in response to risk or safety concern MHRA brings to manufacturer's attention	Manufacturer or delegated to UK RP or Authorised Rep for NI