

Managing MHRA Safety Alerts Procedures

CP500 Common Policies

March 2025

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1. Introduction
   1. This policy document outlines the procedures for managing safety alerts issued by the Medicines and Healthcare products Regulatory Agency (MHRA), ensuring timely action and compliance with regulatory requirements to maintain

the safety and well-being of people supported in MHA services.

1. Scope and Purpose
   1. This policy applies to all colleagues and responsible managers in all MHA services.
   2. This policy and associated documents have been developed based on current legislation and best practice guidance for regulated services where providers must comply with relevant Patient Safety Alerts, recalls and rapid response reports issued from the Medicines and Healthcare products Regulatory Agency (MHRA) and through the Central Alerting System (CAS):
   * Care Quality Commission (CQC) Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 for adult care homes Regulation 12:Safe Care and Treatment.
   * Care Inspectorate Wales (CIW) The Regulation and Inspection of Social Care (Wales) Act 2016, Regulations 44/45: Requirements on service providers as to premises, facilities, and equipment (Part 12).
2. Definitions

| Term | Definition |
| --- | --- |
| **Adverse Incident** | * An event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of people supported or other persons. |
| **Central Alerting System (CAS)** | * The Central Alerting System (CAS) is a web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information and guidance on behalf of the MHRA to NHS and independent providers of health and social care. |
| **Medical Devices** | * A medical device is an instrument, apparatus, appliance, material, or article used for the diagnosis / investigation, prevention, monitoring, or treatment for the alleviation of disease or compensation of impairment (including for instance, wheelchairs, syringe drivers, catheters, spatulas, etc.). |
| **MHRA Safety Alerts**: | Notifications issued by the MHRA regarding potential risks  associated with medical devices, medicines, and other healthcare  products. Alerts from the MHRA include:   * National Patient Safety Alerts for high-risk issues. * Drug alerts on defective medicines. * Medical Device Safety Bulletins. * Safety warnings and messages about medicines, blood and blood products often indicating changes in practice and process * MHRA is the designated authority that administers and enforces the law on medical devices in the UK. It has a range of investigatory and enforcement powers to ensure their safety and quality. |
| **Yellow Card Scheme** | * The Yellow Card scheme is run by the [Medicines and Healthcare products Regulatory Agency (MHRA)](https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency), which safeguards medical products quality and efficacy in the United Kingdom. * Anyone is able to report an issue with medicines, vaccines, medical devices, blood products and e-cigarettes. |

1. Medical Devices
   1. Medical devices may be for single use, such as a catheter or may be reusable, such as a syringe driver. Single use devices must never be reused and carry an international symbol to indicate this on their packaging (as below)



* 1. A medical device should be suitable for its intended use, with this use properly understood by the user, and should also be maintained to an appropriate standard.
  2. Some devices, such as medical gloves, dressings, catheters, and syringes are delivered in bulk packs, so it would be inappropriate to check each one on delivery. For such consumable devices key issues to check are:
  + Expiry dates are clearly shown on packaging, as required
  + Appropriate marking for tracing lots, if there is a recall or modification required
  + Instructions and safety information are available, as necessary
  + Packaging is appropriate for storage
  + Environmental conditions for storage are clear.
  1. Before using any medical device, colleagues must be:
  + Be appropriately trained.
  + Always visually inspect the medical device for signs of damage, ‘use by’ dates, or other concerns prior to use.
  + Know where the equipment is kept and have read and understood the user manual / instructions.
  + Be aware of procedures for reporting an incident or near miss event - both internally and externally.
  1. If a device has been involved in an incident, do not dispose or repair it. If the police or coroner is involved in the investigation, the device will be required for further examination. Retain the device until contacted by the MHRA. If not required by the police or coroner the device can be made available to the manufacturer for analysis.
  2. Adverse incidents requiring reporting might include –
  + Injury as a result of failure or misuse of a medical device or equipment.
  + Treatment being interrupted or compromised by a medical device or equipment failure.
  + Misdiagnosis due to failure or misuse of a medical device or equipment, which leads or could have led to inappropriate treatment.
  + Deterioration in health as a result of failure or misuse of a medical device or equipment.

1. Standard Operating Procedures
   1. The Standards and Policy team will screen MHRA and similar alerts and, if relevant to our services, send a targeted group email for the sharing of the alert to relevant colleagues and services. Managers receiving any such alert must decide if it is applicable to their service. A copy of the alert will be published on MHA Connect [MHRA and similar safety alerts](https://intranet.mha.org.uk/page/16148).

Safety Alert Not Applicable to the Service

* + 1. The most senior colleague receiving the alert will need to write ‘no’ on the alert, sign, date and return to the Manager. The alert and register must be filed and retained for future reference and internal audits.

Safety Alert – Action Required

* + 1. Managers must retain a record of all MHRA and similar safety alerts by completing the MHRA and Similar Safety Alerts Register, which must be kept for future reference and inspection in order to comply with internal audits and regulatory requirements. This record can be competed and retained electronically.
    2. Clearly label and remove the device from use, if the alert refers to a medical device contact the manufacturer and record actions on the MHRA and Similar Safety Alerts - Actions Record.
    3. All safety alerts must be shared with relevant and appropriate colleagues who must sign the action record to confirm the information has been received and they are aware of any actions to be completed.

1. Reporting
   1. All adverse events relating to a device including user problems with a device, software failures, or problems with the instructions for use must be recorded on RADAR.
   2. Adverse incidents involving medical devices must be reported online through [The Yellow Card Scheme](https://yellowcard.mhra.gov.uk/), including issues and concerns relating to medication.
2. Roles and Responsibilities

| Role | Responsibilities |
| --- | --- |
| **Home and Scheme Managers** | Responsible for the safe use of medical devices within their location by:   * Ensuring colleagues are adequately trained and that records can evidence the training received. * Ensuring that colleagues are aware of their responsibilities regarding the safe use of medical devices. * Completing necessary risk assessments on devices to reduce the potential for harm to people. * Ensuring medical devices and equipment is stored in an appropriately safe and secure location when not in use. * Ensuring equipment is kept in an appropriate state of repair and is cleaned according to manufacturer’s instructions and infection control policies. * Reporting any incidents or accidents involving medical devices. |
| **MHA Colleagues** | It is the responsibility of employees involved in the use of medical devices to ensure:   * They are trained and competent in the use of the medical devices and equipment and can evidence this. * They only use medical devices and equipment if authorised to do so. * They follow procedures regarding the management and use of medical devices and equipment, * All medical devices and equipment are suitably decontaminated after each use. * All medical devices and equipment are appropriately stored and maintained when not in use. * They report any defects, faults or other problems with medical devices or equipment immediately. * They clearly label defective medical devices and equipment and ensure they are taken out of action. |
| **Quality Governance Group** | * Review internal incidents, assess any associated risks, and agree appropriate action to reduce further risks i.e., Learning to Improve Safety Memos. * Review external safety alerts, discuss, agree action to reduce probability of incidents occurring and methods of sharing information with appropriate teams. |

1. Training and Monitoring
   1. Monitoring compliance with this policy and associated procedures will be included as part of MHA’s internal auditing schedules and governance arrangements.
   2. Training for medical devices will be made available as required and will be included in clinical policies as appropriate, for example Catheter Management. Where additional training is required managers should submit a request to [peopledevelopment@mha.org.uk](mailto:peopledevelopment@mha.org.uk).
2. Communication and Dissemination
   1. This policy is disseminated and implemented within all MHA services through MHA’s channels of communication.
   2. Each colleague’s line manager must ensure that all teams are aware of their roles, responsibilities, and accountability.
   3. This policy will be available to the people we support and their representatives in alternate formats, as required.
   4. Any review of this policy will include consultation with our colleagues, review of incident reports, quality audits and feedback from other agencies.
   5. Queries and issues relating to this policy should be referred to the Standards and Policy Team [policies@mha.org.uk](mailto:policies@mha.org.uk)
3. Resources
   1. MHA policy documents, procedures, and guidance
   * Bullet Points
   * Name of Policy only
   1. External Resources
   * [MHRA; Yellow Card Website](https://yellowcard.mhra.gov.uk/)
   * [MHRA; Managing Medical Devices, Guidance for Health and Social care Organisations](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/982127/Managing_medical_devices.pdf)
   * [National Patient Safety Alerts in adult social care - Care Quality Commission](https://www.cqc.org.uk/guidance-providers/adult-social-care/national-patient-safety-alerts-adult-social-care)
   * [Learning from safety incidents - Care Quality Commission](https://www.cqc.org.uk/guidance-providers/learning-safety-incidents)
   * [GOV.UK: MHRA Medical devices: the regulations and how we enforce them: May 2024](https://www.gov.uk/government/publications/report-a-non-compliant-medical-device-enforcement-process/how-mhra-ensures-the-safety-and-quality-of-medical-devices)
4. Version Control

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| --- | --- | --- | --- | --- |
| Version | Version Date | Revision Description / Summary of Changes | Author and Review Panel | Next Review Date |
| 5 | March 2025 | * Compliance review, transferred to standard template * Policy and associated documents transferred to common policies as agreed with head of Risk Management * Resources checked and updated | Author  Head of Standards and Policy | March 2027 |