Southern Hampshire
PRIMARY CARE ALLIANCE

MHRA Alerts Management & Reporting Protocol

1.2

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Version Control

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1.2	21/07/2022	L Busher	Formatting changes and review

Contents

1. OUTLINE

This protocol sets out the SHPCA procedure to follow on receipt of any alerts which originate from the Medicines and Healthcare Products Regulatory Agency (MHRA) and how to report device related incidents.

Alerts received are usually disseminated via the Central Alert System (CAS) and will also apply to Medical Device Alerts, National Patient Safety Alerts, Drug Alerts and similar alerts from official bodies. This procedure will be followed when these, or similar alerts requiring specific safety action are received, such as drug alerts or recalls.

2. RESPONSIBILITY:

The MHRA Alerts Lead is responsible for the ongoing monitoring of MHRA Alerts, escalation to Directors/Board and distribution to appropriate service/operational/clinical leads. The Lead is the Head of Quality, Governance, & Safety.

3. PROCESS

MHRA alerts will come into the central Safety Alerts Mailbox. shpca.safetyalerts@nhs.net

Alerts Lead will monitor the inbox on an ongoing basis and assess alerts for relevance to SHPCA services. The Alerts Lead will go to the MHRA website to investigate and distribute where non-sequential alerts are discovered.

Alerts – Urgent &/Or Clearly Relevant

For any alerts where it is immediately obvious that they are relevant to SHPCA services and/or require urgent action on the day of receipt the Alerts Lead will action as appropriate and inform the Lead Director for Clinical Governance.

This may include liaising directly with service/operational leads to initiate actions required without delay, including communication out to staff as per methods outlined below*

Alerts – Non-Urgent/Less Clearly Relevant

For any alerts where it is not immediately required on receipt to take action and/or it is less clear if the alert will be directly relevant to SHPCA services the following will apply:

1. Filtered alerts will be forwarded to the Duty Director (rota will be maintained by Head of Governance & Quality) for sense check without undue delay.

2. Sense checked alert(s) considered relevant will the be communicated out to staff by*:
   - Adding to the EMIS organisational pad
   - Adding to the Intranet
   - Sending to the service/operational leads for distribution by email to appropriate staff groups.
3. The Duty Alerts Director may identify if any further actions are required, or if there are learning needs identified as a result. Actions may include searches. These will also be captured on the MHRA Alerts Log (link at Section 4. Below).

4. MHRA ALERTS LOGGING & REPORTING TO BOARD

Alerts relevant to SHPCA (including those filtered for sense checking) will be added to MHRA Alerts Log (saved on Sharepoint) with details of Date/Ref No/Hyperlink to Alert and Documents and note any actions taken as a result or training needs identified.

The Board will be informed Quarterly of any Alerts which have been relevant to SHPCA and the actions taken and any outcomes.

5. PROCEDURE FOR REPORTING DEVICE-RELATED ADVERSE INCIDENTS

The MHRA encourages the active reporting of adverse incidents from both clinicians and members of the public involving the use of medical devices via their on-line reporting system (See **Resources,** below) and SHPCA should normally liaise with their local CCG safety officer.

A device-related adverse incident is an event which can produce, or has the potential to produce, unwanted effects involving the safety of patients, users or other people.

An adverse incident can arise from:

Shortcomings in the device, its accessories, its operating instructions, user practice, servicing and maintenance and conditions of use.

- Sometimes the instructions for use or labelling are unclear.
- Sometimes patients and practitioners do not use a device in the way in which the manufacturer intended.
- Adverse incidents can also be the result of user error.

It is important to report all device-related adverse incidents so that these can then be investigated thoroughly, and action taken as appropriate to improve the device and protect other patients and/or users.

Both the MHRA and local NHS organisations and practices may learn from safety incidents and examine their own local procedures to ensure that risks in these areas are minimised.

A report should be made where the incident could lead to:

- Death or serious injury
- The need for medical or surgical intervention
- Unreliable test results

However, lesser incidents or effects should also be reported as these may lead to further trend investigations. Serious incidents should be reported with urgency.

IF AN INCIDENT OCCURS:

Check and take steps necessary for the wellbeing of the patient.

Report the incident to the relevant Service/Operational Manager on duty and record using the SHPCA Incident Reporting Form: Significant Events & Incidents Form

Take the device(s) involved out of action, together with other material evidence, e.g. packaging if available. Label the affected device and retain it securely, pending further instructions.

If this is not possible the state of the device at the time of incident should be recorded, as well as;

- Date and time of the incident
- Device settings if relevant
- Details of incident (how it happened and any outcomes for the person affected)
- Details of device affected and any others (type, make, model and serial numbers)
- Details of any error message or failures

Report the incident to the appropriate Incident Centre listed below:

England & Wales
Adverse Incident Centre Medicines and Healthcare Products Regulatory Agency, 151 Buckingham Palace Road London SW1W 9SZ **Tel:** 020 3080 7080 **Fax:** 020 3118 9814 E-mail: aic@mhra.gsi.gov.uk Web: www.mhra.gov.uk

RESOURCES:

MHRA – Devices in Practice – a guide for health and social care professionals