



Medicines Management Standard Operating Procedure for the Management of Safety, Stock and Other Alerts

Document Reference No:	PTHB / MMP 417	
Version No:	2	
Approved by:	Area Prescribing Group	
Issue Date:	December 2023	
Review Date:	December 2026	
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Document Owner:	Chief Pharmacist	
Accountable Executive:	Medical Director	
Document Type:	SOP	Non-clinical
Scope:	Medicines Management Department	

The latest approved version of this document is online.

This document will be reviewed every three years or earlier should audit results or changes to Legislation or practice with PTHB indicate otherwise.

If the review date has passed please contact the author for advice.

Version Control		
Version	Summary of changes	Issue Date
1	Initial Issue	Oct 20
2	Significant edit of SOP based on current practice and new ways of working	Dec 23

Ref.
PTHB / MMP 417
Version
2.0

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1.0 Introduction

The aim of this procedure is to provide an effective and auditable management system for the receiving, fulfillment, monitoring, and record-keeping of all safety, stock and other alerts received and managed by the medicines management department.

This document applies to a wide variety of alerts issued by numerous bodies, including:

- Links from the Welsh Government including Shared Services Partnership
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- NHS Wales Delivery Unit
- National Institute for Clinical Excellence (NICE)

The list is not exhaustive and other documents may be received which require equivalent action.

Additional training will be given in line with this SOP and may include shadow and observation sessions.

Alerts relating to prescriptions i.e lost / stolen is outside of the scope of this SOP.

2.0 Objectives

- To enable Medicines Management (MM) Staff to process and action received alerts.
- To provide assurance that alerts are managed efficiently.
- To ensure and maintain safety.
- To maintain records of alerts received and actions taken.

3.0 Responsibilities

3.1 The Chief Pharmacist must:

- Ensure all MM staff read and understand this procedure.
- Arrange regular review to monitor compliance with this procedure.
- Ensure that the management of drug alerts and recalls is included and monitored within contractual agreements with primary care contractors (Community Pharmacy, General Medical Services (GMS), dental service and optometry service) and acute providers.

3.2 The Medicines Safety Officer (MSO) must:

- Ensure dissemination of this document among MM staff and that they are trained in using this procedure.
- Support MM staff with implementation of this procedure.
- Ensure the Powys.MSO@wales.nhs.uk inbox is accessed each working day.
- Ensure all alerts are actioned in a timely manner.
- Ensure that the alerts log is updated in a timely manner.
- Assign a deputy in their absence.
- Support the Chief Pharmacist to review and monitor compliance with this procedure.
- Liaise with the relevant service lead(s) to achieve compliance and ensure relevant actions are in place.

3.3 The Medicines Management Service Leads must:

- Work with MSO in the implementation of this procedure.
- Ensure all actions required have been identified for their area and that these actions are completed and recorded.
- Support the MSO to review, update and monitor compliance with this procedure.

3.4 All Medicines Management staff must:

- Be aware and familiar with this standard operating procedure.
- Manage received alerts in line with this procedure and where indicated, take appropriate action as outlined in the alert or by MSO or Service Leads.
- Seek support from senior colleagues where required.

4.0 Managing Alerts

4.1 Processing, Recording and Disseminating Alerts

- The designated Medicines Management staff member must check the Powys.MSO@wales.nhs.uk inbox daily. (The process for monitoring alerts is only operational Monday-Friday, excluding bank holidays. Alerts received outside of this period will be actioned the next working day.)
- All alerts must be recorded on the Alert Log [Spreadsheet](#)
- Columns A-G are to be populated
- A copy of the alert should be saved in the 'Downloaded Alerts' folder on Sharepoint under the corresponding year
- Make an initial assessment to establish which areas(s) of Medicines Management the alert applies to; Primary Care / Community Services / Commissioned Services. Record the actions required and any completed in the corresponding sections on the alert log.
- Email the Service Leads for Primary Care, Community Services, Commissioned Services and the MSO or nominated representatives in their absence, to notify them of the new alert.
- Move the email from the inbox and file under the corresponding year.

4.2 Guidance for Actions

- The actions must be reviewed by the Service Leads or nominated representatives in their absence on receipt of the notification email.
- Any additional /outstanding actions must be identified and completed.
- Update the alert log with details of all actions agreed and progress made toward them.
- Alerts will be deemed "complete" when agreed actions from Primary Care, Community Services and Commissioned Services have been signed and dated in the alert log; if it has been decided that there are no required actions for a particular service, then will need to be documented as "No action required" and specify a reason.
- If there is a need for action beyond the remit of medicines management, the MSO will liaise with the PTHB Quality & Safety Unit to discuss further. In the event of a meeting with the Quality & Safety Unit, the MSO or delegate must attend and record actions and/or outcomes on the Medicines Management Alert Log.

4.2.1 Community Services Actions Guidance

Safety alerts/recalls

- Drug safety alerts and recalls are managed by the supplying hospital pharmacies from neighbouring health boards, including out of hours and at weekends, as the alert response time requires. The supplying pharmacies will base their cascade of information and action on supply information for the drug and with consideration for direct to patient recalls for patient's own drugs.
- The alert will be shared with the Lead Pharmacy Technician who will liaise with the supplying hospital pharmacies to ensure the alert has been actioned appropriately and if any further local assistance is needed.
- Where considered necessary, the alert will be cascaded locally via email. The cascade email must contain a summary of any actions required and any reporting back requirements.
- The Community Services team will update the alert log with feedback from the supplying pharmacies and any local actions undertaken.

Medicines shortages

- Review the medicines shortages alert and forward to Lead Pharmacy Technician for Community Services Pharmacy.
- Where relevant, the Lead Pharmacy Technician will cascade the alert as appropriate e.g. to community services based pharmacy teams and any other relevant community services-based professionals such as specialist care teams.
- Ensure that the cascade email contains any actions required such as consideration of any alternative options.
- Update the alert log documenting above actions taken and responses received.

4.2.2 Primary Care Actions Guidance

- Review the alert and consider the impact to primary care.
Primary Care prescribing data (i.e. CASPA) can be used to identify the level of prescribing of the product associated with the alert.
- Review the original distribution list and consider if further cascade is required e.g. GP practice managers, community pharmacies, primary care based pharmacy professionals, care homes, etc.
(To avoid duplication, alerts should not normally be cascaded to those included in the original distribution list.)
- The Primary Care Service Lead and / or Lead Technician for Primary Care must identify and outline any action(s) required.
- There may be occasions e.g. regarding the use of critical medicines, when a GP practice or community pharmacy is directly contacted in relation to an alert.
- Ensure any required actions are clear, along with reporting back requirements and timescale.
- Update the alert log documenting any actions taken and responses as received.

Safety alerts/recalls

Should a safety message need to be added to Decision Support Software, the Primary Care Service Lead or Technician Responsible for managing Decision Support Software must draft a message immediately for approval and prompt addition to Decision Support Software.

Medicines Shortages

Adding and updating 'out of stock' information messages on Decision Support Software is completed fortnightly by the MM Primary Care Team and is outside of the scope of this SOP.

4.2.3 Commissioned Services Guidance

- In the event of the alert concerning commissioned services, MSO will liaise with the commissioning lead within MM to discuss what actions are required and document in the alert log.
- The commissioning lead is responsible for liaising with external providers and ensuring that the alert is appropriately fulfilled for PTHB.
- The commissioning lead will update the actions undertaken in the alert log and inform the MSO.

N.B. Expectations of the commissioned services' responsibilities regarding patient safety have been included in the document 'Commissioning for Quality in Medicines Management' to be embedded into Long Term Agreements with providers from 2024-25.

5.0 Monitoring Compliance, Audit & Review

5.1 Hospital Pharmacies Supplying Community Services

The community services pharmacy team will conduct ad-hoc spot checks of alerts and recall response by the supplying hospital pharmacy. Further biannual check will take place and the MSO and Chief Pharmacist should be updated if there is a risk of non-compliance or incomplete actions are identified after the spot checks.

5.2 All Primary Care Contractors (Community Pharmacy, General Medical Services (GMS), Dental Service and Optometry Service).

Response to medicines safety and stock alerts are monitored as part of Contractual Frameworks.

Community Pharmacy:

Community Pharmacy contractors must provide evidence of routine access to approved NHS emails during Contract Monitoring visits (undertaken bi-annually by the Medicines Management Team).

Contractors must also provide evidence that they have a procedure in place for managing alerts and maintaining records to ensure all alerts have been seen and actioned as appropriate.

General Medical Services (GMS)

[The NHS Wales Unified Contract Assurance Framework 2023](#) states:

Domain of Quality and Indicator: 1.2 Compliance with national patient safety alerts that apply to Primary Care
What triggers further scrutiny? Failure to provide reassurance to Health Board Primary Care Management team that mandated actions in Drug and Safety Alerts from CMO have been undertaken.

Dental Service:

NHSBSA are notified regarding alerts related to the Dental Service and subsequently disseminate the alerts to the providers.

There is duplication of alerts with Public Health Wales to provide contingency within the system.

Alerts particularly pertinent to the Dental Service will be forwarded to the optometry team by the PTHB MSO.

The Dental Director has a responsibility to gain assurance that alerts are managed within their service.

Independent dental contractors have their own responsibility in ensuring that they receive the alerts, with adherence to this monitored by Healthcare Inspectorate Wales (HIW).

Optometry Service:

The Optometry Service subscribes to medicines safety and stock alerts via email, with onward distribution of the information to all practices.

Alerts particularly pertinent to the Optometry Service will be forwarded to the optometry team by the PTHB MSO. The Optometry Advisor has a responsibility to gain assurance that alerts are managed within their service.

5.3 Care Home Managers

Response to medicines safety alerts are monitored as part of annual/biennial audits carried out by the Medicines Management team.

Managers are required to provide evidence that they have a procedure in place for managing alerts and maintaining records that the alerts have been seen and actioned.

5.4 The Alert Log

Status of the Alerts in the Alert Log:

In the event of any alert(s) with a yellow “pending action” status, the MSO / delegate must send a weekly email as a reminder to the service leads to complete and record outstanding actions.

Regular Review of the Action Log

The alerts log should be reviewed quarterly by the MSO to ensure that appropriate records are being maintained.