journey to change

NHS
Tees, Esk and Wear Valleys
NHS Foundation Trust

Public – To be published on the Trust external website

Medicines – management of alerts, recalls, reporting and shortages

Ref: PHARM-0002-008-v6

Status: Approved
Document type: Procedure
Overarching Policy: Medicines Overarching Framework

Contents

1 Introduction

This procedure supports Our Journey to Change as set out in the Medicines Overarching Framework.

2 Purpose

Following this procedure will help the Trust to:

- Maintain systems to ensure that patient safety alerts, medicines recalls, and patient safety recommendations disseminated by the MHRA and supplier-led defective medicine recalls and recalls which require action are acted upon within required time-scales
- Manage medicines shortages with appropriate mitigation and actions.

3 Who this procedure applies to

All staff whose role involves medicines.

4 Related documents

This procedure describes what you need to do to implement the Management section of untoward incidents section of the Medicines Overarching Framework.

This procedure should also be read in conjunction with the Incident reporting and serious incident review policy.

The Medicines Overarching Framework defines the compliance requirements for safe, secure and appropriate handling of medicines which you must read, understand and be trained in before carrying out the procedures described in this document.

5 Adverse Drug Reaction (ADR) reporting

- Any medicine may produce unwanted or unexpected adverse reactions.
- If a patient suffers a suspected adverse reaction to a prescribed, over the counter or herbal medicine, the adverse reaction should be noted in the electronic patient record.
- An incident report does not need to be completed if the ADR is well recognised unless urgent treatment was required. If the ADR is not a known ADR then an incident report is advisable.

- Adverse drug reactions can be reported via the Yellow Card Scheme. Further information from https://yellowcard.mhra.gov.uk/ including which types of adverse reactions / drugs should specifically be reported.
- For further information please read Medication Safety Series MSS15: how to report an adverse drug reaction

Adverse events must not be confused with effects caused by a defective medicine.

6 Defective medicines reporting

During manufacture or distribution of a medicine, an incident may occur which results in the medicine not conforming to its specification. Such a defect may impair the therapeutic effect of the medicine and could adversely affect the patient's health. Examples of defects are:

- Mislabelling
- Mix up of products in a container.
- Faulty closures or packaging
- Wrong product
- Unusual appearance

If a defective medicine is found or suspected the following action must be taken:

- If the product has been administered to a patient inform the doctor responsible for the patient as soon as possible and record the defects in the patient's notes.
- Report the incident to the Appointed or Designated Practitioner in Charge of the ward or department.
- Inform the Medication Safety Officer / Lead Pharmacist for Patient Safety (tewv.mso@nhs.net) who will advise on all reporting, recording and investigating of the defect. If a medicine defect is detected outside of normal working hours the on-call pharmacist should be informed.
- Inform the ward pharmacy technician/pharmacist or a member of the pharmacy team who will inform the supplying dispensary of the suspected defect and arrange an alternative supply of medicine if necessary.
- Retain and quarantine any remaining product and any associated products or equipment (e.g., other containers with the same batch number, administration sets, etc.). Store securely on the ward/department ensuring that it is isolated from medicines in use.
- Record the details of the product and the defect.
- Do not administer further doses of the suspected defective batch.
- A report of the defective medicine must be made via an incident report and can be made here https://yellowcard.mhra.gov.uk/

7 Medicines Recalls & Notification

Relevant medicines recalls and notifications are widely distributed via a cascade system within the Trust, following pharmacy filtering and assessing the relevance and potential impact of the information. Staff in receipt of a medicines recall / notification must take the appropriate action as outlined in the alert. See appendix 3.

Medicines Recall / Notification Classification	Defect risk classification
National Patient Safety Alert (NatPSA) - equivalent to Class 1 Medicines Recalls	The defect presents a risk of death or disability. These alerts will be issued via CAS as National Patient Safety Alerts.
Class 2 Medicines Recall	The defect may cause mistreatment or harm to the patient, but it is not life-threatening or serious. Note that a NatPSA may be issued for any type of defect that presents a risk of death or disability.
Class 3 Medicines Recall	The defect is unlikely to cause harm to the patient, and the recall is carried out for other reasons, such as non-compliance with the marketing authorisation or specification. Note that a NatPSA may be issued for any type of defect that presents a risk of death or disability.
Class 4 Medicines Notification	The MHRA also issues “Caution in Use” notices, where there is no threat to patients or no serious defect likely to impair product use or efficacy. These are generally used for minor defects in packaging or other printed materials. “Caution in Use” notices may also be issued where a defect has been identified but due to supply concerns product cannot be recalled, in these instances the alert will be used to provide advice to healthcare professionals. Note that a NatPSA may be issued for any type of defect that presents a risk of death or disability.
Company-led Medicines Recall/Notification	Issued where the licence holder is able to identify the affected customers, therefore it is not necessary to issue an alert to the entire NHS/healthcare system, as the issue is only relevant to a small number of recipients.

Information on specific drug alerts and the action taken can be obtained from the Pharmacy Department. The pharmacy processes in response to alerts and recalls are shown in appendices 1-3.

MHRA alerts can be found here https://www.gov.uk/drug-device-alerts
Pharmacy maintains a log sheet of all alerts received, and the actions taken.

8 National Patient Safety Alerts (NatPSAs)

National Patient Safety alerts are produced for a variety of issues. This procedure relates to the medicine's aspects of these. See appendix 1 for standard actions taken.

NatPSAs can be found here https://www.england.nhs.uk/patient-safety/patient-safety-alerts/

9 Drug Safety Update

The MHRA issue monthly Drug Safety Updates – these can be found here https://www.gov.uk/drug-safety-update

Individual practitioners are encouraged to sign up to these updates directly. To subscribe to monthly email alerts of Drug Safety Update click here

The pharmacy service will filter out messages that are likely to have a direct impact on mental health services and, as a minimum, will highlight these in the medicine's optimisation newsletter.

10 Medication Shortage Alerts

Supply Disruption Alerts (SDA) and Medicine Supply Notifications (MSN) (or variants on these titles) are issued nationally in response to shortages of specific medicines. The shortage may just affect a specific strength or a specific formulation but could be broader and affect all formulations or a drug or drug class. Shortages of medicines will often be managed directly by pharmacy with appropriate brand and formulation substitutions. A supply memo will be issued within TEWV (Tees, Esk and Wear Valleys NHS Foundation Trust) for those products where the impact cannot be solely managed by pharmacy services. Where there is a significant challenge in managing the supply problem a risk register entry will be added to the pharmacy risk register. Additional entries on service risk registers may be required.

- A national guide to managing medication shortage and supplies can be found here https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/
- This links with the Pharmacy Business Continuity Plan (Action Card: Medication Supplier Shortages) available on the intranet https://intranet.tewv.nhs.uk/bcu-plans
- A central repository of alerts and actions taken can be found on the T drive \\tewv.nhs.uk\data\Trustwide Shares\Intranet Published Documents\Services\Medicines and Pharmacy\Medication Supplies and Dispensary Services\Medication Supply Issues

11 Definitions

Term	Definition
CAS	• 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 to the NHS and others, including independent providers of health and social care.
MHRA	• Medicines and Healthcare products Regulatory Agency

12 How this procedure will be implemented

- This procedure will be published on the Trust intranet and website.
- Line managers will disseminate this procedure to all Trust employees through a line management briefing.

13 How the implementation of this procedure will be monitored

Number	Auditable Standard/Key Performance Indicators	Frequency/Method/Person Responsible	Where results and any Associate Action Plan will be reported to, implemented and monitored; (this will usually be via the relevant Governance Group).
1	Closure of all applicable alerts	Frequency =6 months Method =D&T report Responsible =Lead pharmacist (Patient Safety)	Drug & Therapeutics Committee

14 Document control (external)

To be recorded on the policy register by Policy Coordinator

Required information type	Information
Date of approval	23 January 2025
Next review date	01 February 2028
This document replaces	Medicines – Management of alerts, recalls, reporting v5
This document was approved by	TEWV Drug and Therapeutics Committee
This document was approved	23 January 2025
An equality analysis was completed on this policy on	Pharmacy Overarching EA
Document type	Public

Change record

Version	Date	Amendment details	Status
1	28 September 2017	PHARM-0002-008-v1 Medicines – management of untoward occurrences Document replaces Section 14 – PHARM-002-v5 Medicines code Minor amendments throughout flow charts added into appendices – Title change	Superseded
2	July 2019	Minor changes due to move from Lloyds to internal dispensary.	Superseded
3	29 September 2017	July 2019 –January 2021 – full review. Changes throughout. Post D&T approval, changes were made to reflect the new MHRA recalls / notifications titles November 2023 – full review. Legacy changes: • Datix references removed • Pharmacy newsletter is now the medicines optimisation newsletter • SMPG processes changed so D&T final sign off group under appendix 1 – a regular report will be scheduled into the D&T workplan (in development) • SBARDs no longer used by pharmacy – medication safety bulletins now referenced (app. 2) • Appendix 3 – updated note re: class 1 alerts out of hours	Superseded

V4	April 2020	Full document review	Superseded

V5	23rd November 2023	Full document review
		• Legacy changes:
		  ○ DATIX references removed
		  ○ Pharmacy newsletter is now the medicines optimisation newsletter
		  ○ Safe Medication Practice Group changed, Drug & Therapeutics Committee final sign-off group under appendix 1
		  ○ SBARDs no longer used by pharmacy – medication safety bulleting now referenced (Appendix 2)
		• Appendix 2
		  ○ The regional drug & therapeutics centre (RDTC) no longer provide a service for cascading out of hours class 1 alerts
			Superseded

V6	23 January 2025	Added “shortages” to document title. Removed duplicated section (between NPSA & DSU). Blue box moved from section 6 to section 5. Section 10 – new references to risk register entries Updated some terminology.	Published

Appendix 1: Types of alerts & responsible person

Alert Type	Usual actions (if relevant and after considering level of impact)	Initial responsible person	Initial group oversight	Final sign off group / committee
Medicines Recalls • **Class 1-3 Medicines Recall** • **Company led medicines recall**	Recall & return medicines as required	Lead Pharmacy Technician – Procurement (LPTP)	Pharmacy Leadership Team (Daily Conference Call)	Drug & Therapeutics Committee (usually via 6 monthly report)
Medicines Notifications • **Class 4 Medicines Defect Information** • **Company led medicines notification**	Initiate any required actions	Lead Pharmacy Technician – Medicines Safety (LPTMS)	Pharmacy Leadership Team (Daily Conference Call)	Drug & Therapeutics Committee (usually via 6 monthly report)
National Patient Safety Alert (medicines aspects)	• Undertake immediately required actions • Develop action plan to complete further actions • Issue a medication shortage memo • Consider risk register entry	Lead Pharmacist – Patient Safety	Pharmacy Leadership Team (Daily Conference Call)	Drug & Therapeutics Committee
Drug Safety Update	Inclusion of applicable articles in the medicines optimisation newsletter & medicines management group	Lead Pharmacist – Patient Safety	Pharmacy Leadership	Drug & Therapeutics Committee

			Team (Daily Conference Call)	
Supply Disruption Alert	Issue a TEWV Medicine Supply Shortage memo Consider risk register entry	Lead Pharmacy Technician – Procurement (LPTP)	Pharmacy Leadership Team (Daily Conference Call)	Drug & Therapeutics Committee
Medicines Supply Notification	Pharmacy managed adjustments to supplies	Lead Pharmacy Technician – Procurement (LPTP)	Pharmacy Leadership Team (Daily Conference Call)	N/A unless the situation cannot be managed, then Drug & Therapeutics Committee

Appendix 2: Possible actions and routes of cascade

Potential actions	Description	Stored	Usual cascade route
Medicines Optimisation Newsletter article	Published several times a year depending upon volume of information, urgency, and capacity of team to produce. Useful signposting summary.	Pharmacy Intranet T Drive	• Email to Pharmacy Distribution list • Link provided through trust All Staff Briefing
Medication Safety Series	Succinct (1 page in most cases) summary of medication safety issues – provides clear messages and signposting. Ideal response to new national safety issues or incident themes and trends.	Pharmacy Policies & Procedures on trust intranet	• Email to Pharmacy Distribution list • Link provided through trust All Staff Briefing • Highlighted in Medicines Optimisation Newsletter
Medication related policy / procedure or guideline	Possible enhancement or adjustment to existing document or development of a new document. Usually shared and approved across the interface with primary care and other secondary care organisations.	Pharmacy Policies & Procedures on trust intranet	• Advance notice of publication through D&T summary • Notification of intranet upload cascaded via policies team • Highlighted in Medicines Optimisation Newsletter
Medicine Supply Shortage memo	Localised TEWV memo based on national advice with bespoke information reflecting the local issues	Pharmacy Intranet T Drive	Possible cascade route, depending upon affected areas: • Email to Pharmacy Distribution list

			• Link provided through Trust All Staff Briefing • Highlighted in Medicines Optimisation Newsletter • Provided with the alternative product to specific areas
Medication Safety Bulletin	A specific medication bulletin highlighting an issue or theme with recommended actions	Pharmacy & Medication Alerts | TEWV Intranet	• Emailed by patient safety team with requirement for response • Highlighted in Medicines Optimisation Newsletter

Appendix 3: Pharmacy action prompts for medicines recalls / notifications.

GATHERING OF INFORMATION

A copy of the Recall Notification can be obtained from https://www.gov.uk/drug-device-alerts

Members of PLT will receive the alert by email and will lead the appropriate action.

Out of hours response to class 1 medicines recalls

It is extremely unlikely that a class 1 medicines recall with applicability to TEWV will be cascaded in the out of hours period. If this does happen there is no robust process for flagging the alert for action. It is likely that the alert will have made the news or professional cascades via social media. Action would be triggered through available Pharmacy Leadership Team (PLT) members and the on-call pharmacist / weekend pharmacy service.

Determine if / what action is required out of hours:

- Does the recall require action at Patient Level, Clinic Level or Pharmacy Level?
- Does the alert specify "Immediate action required including out of hours"?

Please note: It is not the responsibility of the trust to determine if they feel the recall is clinically important. If the MHRA have asked for action out of hours the trust should take this action.

Use the following questions to determine the action required out of hours and any follow up required in-hours. Ensure PLT members informed.

Consider the following questions:

- Is it a drug that is likely to be used in a mental health setting?
- Have we supplied the affected product?
- Does the alert specify when the product was first distributed? Have we obtained the product since then (check EMIS)?
- Have we made any supplies since we received product which may have been from the affected batch(es)?
- Is it likely that there are supplies of patients own drugs in use that are the affected products?
- Is the product likely to have been obtained via any other route? (e.g. Clinical Trials)

If it is not possible to check this, a judgement should be made regarding likelihood of product being in use against the nature of the alert. If in doubt an assumption should be made that the affected product is in use and appropriate action should be taken.

PLANNING ACTION

Consider if any additional help will be required to cascade the recall. A large patient level recall affecting a widely used medication will require more resource than a pharmacy level recall of a rarely used medication.

- The Trust Business Continuity Plan may need to be invoked for very large recalls.
- Consider calling colleagues for support.
- Consider seeking support from others outside of pharmacy (Director On-Call when out-of-hours)

Consider what alternative treatments a patient may require:

- Will there be an urgent need for an alternative?
- Is the alternative available in clinical areas?
- Will pharmacy need to order additional stock of alternatives? Does this need to be done utilising the weekend dispensary service?

TAKING ACTION – ALL RECALLS

Communicate with the dispensaries to ensure all stock is quarantined within each locality to prevent any further supply.

- Consider additional stock locations e.g. wards & emergency cupboards?

TAKING ACTION – CLINIC LEVEL RECALLS

Contact all clinical areas where the medication has been supplied with details of the recall (in hours via patient safety cascade process). Provide a copy of the recall by email whenever possible.

Record (via email to Chief / Deputy Chief Pharmacist if out of hours or on actions spreadsheet if in-hours):

- Which areas contacted
- Who you spoke to
- If they had any affected stock

For clinical areas which are closed (ECT Suites, Community Clinics etc.), keep a list of areas that still need to be contacted the next working day.

In-hours it is expected that the recall from in-patient wards will be undertaken by the pharmacy team, where possible.

For large scale recalls affecting multiple departments – send an email containing the details of the recall to the pharmacy distribution list.

This email should indicate what action they need to take.

For class 1 alerts this method of communication is unreliable especially out of hours and at weekends and should not be considered as having effectively cascaded the information. Telephoning applicable areas out-of-hours will be required.

For all other alert classes, the approach should be tailored to the level of recall and the scale of the supplies that might be in use across the organisation.

TAKING ACTION – PATIENT LEVEL RECALLS

Use EMIS to identify the patients to whom we have potentially dispensed the medication.

If the patient is no longer an in-patient, use their electronic care record to obtain their contact telephone number and home address. Check that the patient is not marked as deceased.

Prioritise patients who have been dispensed medication most recently and so will still have a supply of medication to take. Contact each patient systematically and explain:

- Who you are
- That the Medicines Regulator has identified a problem with a batch of medication that may have been dispensed by TEWV to them.
- Provide reassurance where appropriate (e.g. using words like “as a precaution”)
- Explain how they would identify the batch number (e.g. on the box or blister)
- Explain what they need to do. Stop taking the medication? Are we supplying replacements?

Document

- Who you contacted.
- If they had any affected stock
- What further action is required (e.g., replacement stock)

Keep a list of patients that still need to be contacted and ensure that these are being followed up by an appropriate team member.

Appendix 4: Approval checklist

Title of document being reviewed:	Yes / No / Not applicable	Comments
1. Title		
Is the title clear and unambiguous?	Y	
Is it clear whether the document is a guideline, policy, protocol or standard?	Y	
2. Rationale		
Are reasons for development of the document stated?	Y	
3. Development Process		
Are people involved in the development identified?	Y	
Has relevant expertise has been sought/used?	Y	
Is there evidence of consultation with stakeholders and users?	Y	
Have any related documents or documents that are impacted by this change been identified and updated?	Y	
4. Content		
Is the objective of the document clear?	Y	
Is the target population clear and unambiguous?	Y	
Are the intended outcomes described?	Y	
Are the statements clear and unambiguous?	Y	
5. Evidence Base		
Is the type of evidence to support the document identified explicitly?	Y	
Are key references cited?	Y	
Are supporting documents referenced?	Y	

6. Training		
Have training needs been considered?	Y	
Are training needs included in the document?	Y	
7. Implementation and monitoring		
Does the document identify how it will be implemented and monitored?	Y	
8. Equality analysis		
Has an equality analysis been completed for the document?	N	EA undertaken in Medicines Overarching Framework
Have Equality and Diversity reviewed and approved the equality analysis?	Y	Involved in EA for Medicines Overarching Framework
9. Approval		
Does the document identify which committee/group will approve it?	Y	
10. Publication		
Has the policy been reviewed for harm?	Y	
Does the document identify whether it is private or public?	Y	
If private, does the document identify which clause of the Freedom of Information Act 2000 applies?	N/A	
11. Accessibility (See intranet accessibility page for more information)		
Have you run the Microsoft Word Accessibility Checker? (Under the review tab, 'check accessibility.' You must remove all errors)	Y	
Do all pictures and tables have meaningful alternative text?	N/A	
Do all hyperlinks have a meaningful description? (do not use something generic like 'click here')	y	