Tees, Esk and Wear Valleys
NHS Foundation Trust

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# Medicines – management of alerts, recalls, reporting

# PHARM-0002-008-v4

**Status: Approved**
**Document type: Procedure**

## Contents

# 1 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

# 2 Related documents

This procedure describes what you need to do to implement the Management 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.

# 3 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 reported via the Yellow Card Scheme. Further information from https://yellowcard.mhra.gov.uk/

A report of the ADR must be made on Datix.

For further information please read Medication Safety Series MSS15: how to report and adverse drug reaction.

# 4 Defective medicines reporting

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

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 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 on Datix and can be made here https://yellowcard.mhra.gov.uk/

# 5 Medicines Recalls & Notifications

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.<br>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.<br>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.<br>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.<br>Note that a NatPSA may be issued for any type of defect that |

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|---|---|
| | 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 maintain a log sheet of all alerts received and the actions taken.

# 6 National Patient Safety Alerts

National Patient Safety alerts are produced for a variety of issues. This procedure relates to the medicines aspects of these.

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

# 7 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 will highlight these in the pharmacy newsletter.

# 8 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 for those products expected to have a wide impact.

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 T:\Intranet Published Documents\Services\Medicines and Pharmacy\Medication Supplies and Dispensary Services

# 9 Document control

| | | |
|---|---|---|
| Date of approval: | 28 January 2021 | |
| Next review date: | 1 February 2024 | |
| This document replaces: | Medicines – management of alerts, recalls, reporting V3 | |
| Lead: | Name | Title |
| | Chris Williams | Chief Pharmacist |
| Members of working party: | Name | Title |
| | Emma Kettle<br>Claire Spinks<br>Amanda Metcalf | Lead Pharmacist<br>Lead Pharmacy Technician<br>Lead Pharmacy Technician |
| This document has been agreed and accepted by: (Director) | Name | Title |
| | Ruth Hill | Chief Operating Officer |
| This document was approved by: | Name of committee/group | Date |
| | Drug & Therapeutics Committee | 28 January 2021 |
| An equality analysis was completed on this document on: | Part of overarching medicines documents EIA | |

**Change record**

| Version | Date | Amendment details | Status |
|---|---|---|---|
| | September 2017 | minor changes throughout with flow charts added into appendices. Title change | |
| | July 2019 | minor changes due to move from Lloyds to internal dispensary. | |
| 4 | January 2021 | full review. Changes throughout. Post D&T approval, changes were made to reflect the new MHRA recalls / notifications titles. NB publication requested 06 April 2021. | Published |

# 10 Appendix 1: Types of Alert & responsible person

| Alert Type | Usual actions<br>(if relevant and after considering level of impact) | Initial responsible person | Initial group oversight | Final sign off group / committee |
|---|---|---|---|---|
| **Medicines Recalls**<br>• Class 1-3 Medicines Recall<br>• Company led medicines recall | Recall & return medicines as required | Lead Pharmacy Technician – Procurement (LPTP) | Pharmacy Leadership Team (Daily Conference Call) | Safe Medication Practice Group |
| **Medicines Notifications**<br>• Class 4 Medicines Defect Information<br>• Company led medicines notification | Initiate any required actions | Lead Pharmacy Technician – Medicines Safety (LPTMS) | Pharmacy Leadership Team (Daily Conference Call) | Safe Medication Practice Group |
| **National Patient Safety Alert** (medicines aspects) | Undertake immediately required actions<br>Develop action plan to complete further actions | Lead Pharmacist – Patient Safety | Pharmacy Leadership Team (Daily Conference Call) | Drug & Therapeutics Committee |
| **Drug Safety Update** | Inclusion of applicable articles in the pharmacy newsletter | Lead Pharmacist – Patient Safety | Safe Medication Practice Group | Drug & Therapeutics Committee |
| **Supply Disruption Alert** | Issue a TEWV Medicine Supply Shortage memo | Lead Pharmacy Technician – Procurement (LPTP) | Pharmacy Leadership Team (Daily Conference Call) | Drug & Therapeutics Committee |
| **Medicines Supply** | Pharmacy managed | Lead Pharmacy Technician – | Pharmacy Leadership Team (Daily | N/A unless the situation can't be managed, then |

| | | | | |
|---|---|---|---|---|
| **Notification** | adjustments to supplies | Procurement (LPTP) | Conference Call) | D&T |

# 11 Appendix 2: Possible actions and routes of cascade

| Potential actions | Description | Stored | Usual cascade route |
|---|---|---|---|
| **Pharmacy Newsletter article** | Published every 1-2 months depending upon volume of information, urgency and capacity of team to produce.<br>Useful signposting summary. | Pharmacy Intranet T Drive | • Email to Pharmacy Distribution list<br>• Link provided through trust eBulletin |
| **Medication Safety Series** | Succinct (1 page in most cases) summary of medication safety issues – provides clear messages and signposting.<br>Ideal response to new national safety issues or incident themes and trends. | Pharmacy Policies & Procedures on trust intranet | • Email to Pharmacy Distribution list<br>• Link provided through trust eBulletin<br>• Highlighted in Pharmacy Newsletter |
| **Medication related policy / procedure or guideline** | Possible enhancement or adjustment to existing document or development of a new document.<br>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<br>• Notification of intranet upload cascaded via policies team<br>• Highlighted in Pharmacy Newsletter |
| **Medicine Supply Shortage** | Localised TEWV memo based on | Pharmacy Intranet T Drive | Possible cascade route, |

| | | | |
|---|---|---|---|
| **memo** | national advice with bespoke information reflecting the local issues | | depending upon affected areas:<br>• Email to Pharmacy Distribution list<br>• Link provided through trust eBulletin<br>• Highlighted in Pharmacy Newsletter<br>• Provided with the alternative product to specific areas |
| **SBARD** | Situation, Background, Assessment, Recommendation, Decision | Held by patient safety team.<br>Medicines related SBARDS stored on Pharmacy Intranet T Drive | • Emailed by patient safety team with requirement for response<br>• Highlighted in Pharmacy Newsletter |

# 12 Appendix 3: Pharmacy action prompts for medicines recalls / notifications

| **GATHERING OF INFORMATION** |
|---|
| Out of hours the on-call pharmacist will be contacted by the Regional Drug & Therapeutics Centre<br>A copy of the Recall Notification can be obtained from https://www.gov.uk/drug-device-alerts<br><br>In-hours, members of PLT will receive the alert by email and will lead the appropriate action. |
| **Out of hours response to class 1 medicines recalls**<br>Determine if / what action is required out of hours:<br>• Does the recall require action at Patient Level, Clinic Level or Pharmacy Level?<br>• Does the alert specify "Immediate action required including out of hours"?<br>**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.<br><br>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:<br>• Is it a drug that is likely to be used in a mental health setting?<br>• Have we supplied the affected product?<br>• Does the alert specify when the product was first distributed? Have we obtained the product since then (check EMIS)?<br>• Have we made any supplies since we received product which may have been from the affected batch(es)?<br>• Is it likely that there are supplies of patients own drugs in use that are the affected products?<br>• Is the product likely to have been obtained via any other route? (e.g. Clinical Trials)<br><br>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.<br>• The Trust Business Continuity Plan may need to be invoked for very large recalls.<br>• Consider calling colleagues for support.<br>• 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. 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 who we have potentially dispensed the medication to.
If the patient is no longer an in-patient, use Paris 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 <u>may</u> 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.