Trust Standard Operating Procedure	**NHS** University Hospitals Plymouth **NHS Trust**

Supply Chain Product Recalls and Returns (SC04)

Issue Date	Review Date	Version
23/01/2019	23/01/2022	2

Purpose

To identify the key activities in managing Product Recalls and Returns.

In the case of Product Recalls, this is related to what happens once the Trust is informed by a Supplier or Regulating Body that a Product Recall is necessary. This does not cover what to do in the event of discovering a product defect.

Who should read this document?

All those that are involved in ordering, using and managing product inventory within the Trust should read this document.

Key Messages

SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply to industry or Trust regulations.

Core accountabilities

Owner	Supply Chain Manager
Review	Procurement SMT Meeting
Ratification	Chief Procurement Officer
Dissemination (Raising Awareness)	Head of Supply Chain & E-Procurement
Compliance	Records & Information Forum

Links to other policies and procedures

Supply Chain Inventory Management Policy (SC00v.1)

Version History

1	21st March 2017	Ratified by Chief Procurement Officer and published Trust-wide
2	28th January 2019	Ratified by Chief Procurement Officer and published Trust-wide

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents. Larger text, Braille and Audio versions can be made available upon request.

Standard Operating Procedures are designed to promote consistency in delivery, to the required quality standards, across the Trust. They should be regarded as a key element of the training provision for staff to help them to deliver their roles and responsibilities.

Standard Operating Procedure (SOP)

Supply Chain Product Recall and Returns

1	Introduction

The purpose of this SOP is to identify the key activities involved in Product Recalls and Returns.

This procedure is applicable to all those involved in the ordering, using and managing product inventory within the Trust.

It should be applied across the Trust, with particular relevance to Procurement and Supply Chain functions.

A standalone SOP exists for Pharmacy Returns and Recalls.

2	Definitions

- SOP – Standard Operating Procedure
- SCM – Supply Chain Manager
- CPO – Chief Procurement Officer
- DoF – Director of Finance
- MHRA - Medicines and Healthcare products Regulatory Agency
- SCWM – Supply Chain Warehouse Manager
- NPI – New Product Introduction
- IMS – Inventory Management System
- SCT – Supply Chain Team
- SCTL – Supply Chain Team Leader
- RCA – Root Cause Analysis
- SKU – Stock Keeping Unit

3	Regulatory Background

- Notification of a defect in a medicinal product or withdrawal of a drug can be issued from:
  - The manufacturer
  - The Medicines and Healthcare products Regulatory Agency (MHRA)
  - The trial sponsor
  - Qualified End User
- The MHRA uses an internationally agreed classification system for medicines and medical equipment recalls:
  - Class 1: The defect presents a life threatening or serious risk to health
    - Immediate including out of hours
  - Class 2: The defect may cause mistreatment or harm to the patient, but it is not life-threatening or serious
    - Within 48 hours

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- o Class 3: 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.
  - Within 5 days
- o The MHRA also issues "Caution in Use" notices which are called Class 4 Drug Alerts, 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. These require action within 5 days.

4 Key Duties

Main Roles and typical duties are summarised below;

- **Purchasing**
  - o **Category Manager or Buyer** – Support Product Recall coordinator, liaise with supplier appropriately.
- **Supply Chain**
  - o **Supply Chain Manager (SCM) / Supply Chain Team (SCT)** – Support capture serial numbers and stock locations if required, override replenishment signals that do not accurately reflect requirements. Perform physical audits if required. Support remove items if required. Support quarantine items if required. Support return to supplier if required. Feedback results to Patient Safety.
- **Customer**
  - o **Clinical Teams** – used to provide patient level data or check any stores at the end point of use.

5 Procedure to Follow

The section outlines the key steps to be followed in the case of a Product Recall or Return.

Recalls will be the subject of regulatory control, as discussed above, which will dictate the speed and depth of these actions.

1. Product Recalls

Upon notification of a Product Recall, the following steps should be followed, within the time constraints outlined in the Recall notice;

See separate document *Procedure for the Management of Safety Alerts.*

Annex 1:
- **Physical actions for stock containment**
- **Electronic/System actions for returns and replenishment**

2. Product Returns

Returns can also occur without a Recall notification, reasons for returns could be;
- o Item bought in error
- o Item surplus to requirements following product/method change (New Product Introduction (NPI)/Obsolescence)
- o Item found to have a defect not highlighted by official recall

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SCT identify potential return items, return to stock or return appropriate items to level 2 following the below process flow and then update Oracle with return details.

SCT to follow *Returned Stock Corrective Action Process*. See process map in appendix.

Annex 2:
- **Returns from a Non Store Location to a Store Location**
- **Returns from a Store Location to another Store Location**

6   Document Ratification Process

The design and process of review and revision of this procedural document will comply with The Development and Management of Trust Wide Documents.

The review period for this document is set as default of three years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved and ratified by the CPO.

Non-significant amendments to this document may be made, under delegated authority from the CPO, by the nominated author.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes

7   Dissemination and Implementation

Following approval and ratification, this procedural document will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

8   Monitoring and Assurance

- Accountability for adherence to this procedure will be monitored by the Senior Supply Chain management.

- Each Category Manager or Buyer will be responsible for ensuring this procedure is followed operationally, with support from the SCM.

- Adherence to the identified procedure will be monitored through recording each product recall and reviewing it for conformance

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- Root cause analysis (RCA) will be performed for any product recall or return that is not managed using this SOP

- For every RCA conducted, findings need to be reported to the Senior Supply Chain Management via a monthly review

9	Reference Material

- Medicines & Healthcare products Regulatory Agency
- Medicines for Human use (Clinical Trials) Regulations 2004 and subsequent amendments

Annex 1:
- **Physical actions for stock containment;**
    - A product recall coordinator needs allocating to each occurrence
    - If the Inventory Management System (IMS) has individual serial number records, use the system to identify stock on site or consumed/issued
    - If the IMS is unable to trace items by serial number;
        - Stock needs to be located, through identifying which Warehouse, Store and Requesting Location uses or holds stock of the recalled item
        - Requesting Locations may hold manual records, which should be requested
        - Requesting Locations, Stores and Warehouses will need to manually locate the relevant products
        - Depending on the type of Product Recall, Requesting Locations may be required to provide a list affected patients
    - Once stock is found, the following steps need to be taken;
        - Stock needs isolating and marking as quarantined
        - Stock needs placing in quarantined area to prevent incorrect usage
        - Stock should be returned, in line with the Recall or Returns advice from the supplier
- **Electronic/System actions for returns and replenishment;**
    - Returning Stock
        - The progress of the return shall be recorded and monitored by the recall coordinator; so that the quantity of goods returned, can be reconciled against the amount ordered, distributed and still held in stock
        - Credit notes should be expedited against the relevant returns note
    - Replacing recalled stock
        - Stock identified as quarantined should be labelled as such, with replacement orders being triggered as necessary through auto replenishment
        - If the IMS cannot label stock as 'in quarantine' then manual overrides need to be carried out, in order to trigger replacements, which may include writing off the quarantined stock level

Annex 2:

Returns from a Non Store Location to a Store Location

- For Stock Items that were received from an internal store, not direct from a supplier, the returns process is subtly different.
- Unless faulty, products can be returned back to the Issuing Store providing the following conditions are met;
    - Goods returned to the Issuing Store by the Requesting Location End User
    - Items should be placed into a quarantined and segregated area awaiting inspection
    - The item must be a stock item at the Store to which it is being returned
    - The item must have been delivered through this Issuing Store originally
    - The item must be an entire Stock Keeping Unit (SKU)/whole pack
    - Item should be in the same condition as when received
    - Item should not have passed the expiry date
- Only staff authorised for returns will be able to receive items back into stock, both physically and systematically
- The staff at the receiving store will conduct the system alternation to ensure a suitable credit is received
- The staff at the Requesting Location will be responsible for returning the stock physically to the Store for assessment

Returns from a Store Location to another Store Location

The process for this type of return is the same as the process for 'Returns from a Non Store Location to a Store Location'. It is the responsibility of the area returning stock to ensure the stock arrives at the appropriate store.

Returned Stock Corrective Action Process

TRW.PRO.SOP.1062.2 Supply Chain Product Recalls and Returns (SC04)