

MEDICATION RECALLS

POLICY®

DOCUMENT SUMMARY/KEY POINTS

- This policy provides information regarding medicine recalls, the procedures to follow and notifications
- This document should be read in conjunction with [PD2013_043 Medication Handling in NSW Public Health Facilities, section 3.4.2](#)
- This does not include the management of medical device recalls - this is managed by the Clinical Product Managers across SCHN in conjunction with the Clinical Governance Unit (CGU).

CHANGE SUMMARY

- Due for review
- Inclusion of PD2019_019, Coordination of Responses to Urgent System-level Medicine or Medical Device Issues

READ ACKNOWLEDGEMENT

- All doctors, nursing staff and pharmacists should read this policy

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1 st December 2021	Review Period: 3 years
Team Leader:	Medication Safety Pharmacist	Area/Dept: Pharmacy

Introduction

- A medication recall is an action taken to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy or presentation.
- The majority of these issues can be managed locally, however, in some circumstances a centrally coordinated response to address critical patient safety concerns and mitigate a broader risk to the health system may be required. Information in relation to this can be found in [PD2019 019](#).

Notification

- The Directors of Pharmacy and the Clinical Governance Unit may receive notification that a product has been recalled. This notification may be from the Therapeutic Goods Administration or directly from the manufacturer.
- The Directors of Pharmacy or delegates will coordinate the recall for the local site, ensuring remote locations, including Bear Cottage, Hospital in the Home and the Newborn and paediatric Emergency Transport Service (NETS) are informed of any recalls.
- The Nurse Unit Managers (NUMs) of all relevant clinical areas are informed by the Department of Pharmacy. The patients are informed by the treating team (the Department of Pharmacy will contact relevant teams with the details of the patients who may have affected stock).

Procedure on Wards

- NUMs (or delegate) to identify if stock on hand is affected by the recall.
 - **At CHW** Pharmacy staff will assist in this process during business hours.
 - **At SCH**, identified stock should be returned to the Pharmacy imprest collection area during business hours
- Automated Dispensing Cabinets (ADCs) will require an 'Open Cycle Count' A Quick Start is available on [learning.kids](#)
- Affected stock must be quarantined. It should be separated from all other medicines and labelled clearly as "**Recalled stock- not for use**".
- After hours this is coordinated by the After Hours Nurse Manger in consultation with the on-call pharmacist.
 - **At CHW**, the [MedLocator webpage](#) can be used to find the imprest locations of medications within CHW. A Quick Start is available on [learning.kids](#)
 - **At SCH**, the Afterhours Nurse Manager will liaise with the Team Leader on each ward with advice from the On-Call Pharmacist. The On-Call Pharmacist may be

required to perform a callback if it is deemed this cannot wait until the next business day.

- For any stock quarantine, the details of the stock removed should be documented, including the quantity, batch number and expiry. All affected stock must be returned to the Department of Pharmacy.
- If there is sufficient unaffected stock, then Pharmacy will organise replacement, otherwise an alternative medicine may need to be prescribed. This will be done in consultation with the relevant medical teams and should be endorsed at the site based and/or Network Drug Committees.

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