SESLHD PROCEDURE COVER SHEET

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EXECUTIVE SPONSOR	Executive Director Operations
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POSITION RESPONSIBLE FOR THE DOCUMENT	SESLHD Pharmacy Business Support Manager SESLHD-PharmacyBusinessSupport@health.nsw.gov.au
FUNCTIONAL GROUP(S)	Pharmacy/Pharmaceutical
KEY TERMS	Pharmacy, Medicine, Drug, Recall
SUMMARY	This procedure outlines the processes to be undertaken to ensure that all medicines subject to a statutory or voluntary recall are promptly identified, quarantined and and managed as advised in the CEC safety alert or recall notice by SESLHD facilities and services.

1. POLICY STATEMENT

This procedure outlines the process to be undertaken in SESLHD to ensure compliance with NSW Ministry of Health Policy Directive PD2013_009 - Safety Alert Broadcast System and PD2019_019 - Coordination of responses to urgent system-level medicine or medical device issues to ensure that all medicine recalls are actioned appropriately and in a timely manner.

NSW Ministry of Health Policy Directive PD2022_032 – Medication Handling outlines that all facilities must establish internal procedures through the facility's executive to appoint a medication recalls coordinator. The SESLHD Pharmacy Business Support Manager is appointed as the medicine recall coordinator for SESLHD facilities and services.

This procedure does not include the Drug Recall Process which is addressed in SESLHDPR/724 - Medication – Safety Alerts, Notices and Information.

This procedure does not include information about the management of recalls related to clinical or biomedical equipment which is addressed in SESLHDPR/319 - Product – Clinical Product Notices, Recalls and Safety Alerts.

2. BACKGROUND

Medicines may occasionally be subject to recalls for reasons relating to the product's quality, safety or efficacy identified by the manufacturer or Therapeutic Goods Administration (TGA).

As per NSW Ministry of Health Policy Directive PD2019_019 - Coordination of responses to urgent system-level medicine or medical device issues, the Clinical Excellence Commission (CEC) i**s responsible for automatically distributing all formal recall actions issued by the Therapeutic Goods Administration to local health districts.**

Medicine recalls vary in the risk they pose to patient safety. Where any medicine is subject to a recall, stock in the pharmacy and stock in all clinical areas must be identified. Under some circumstances it may also be necessary to trace stock dispensed to outpatients or to patients recently discharged from the hospital. Depending on the identified issue, the actions required in response to the recall may vary. All stock identified as subject to the recall must be returned to the facility pharmacy department, quarantined and handled as specified in the CEC safety alert or recall notice.

This procedure outlines the process to be undertaken to ensure that all medicinal products subject to a recall are promptly identified, quarantined and managed as advised in the CEC safety alert or recall notice.

It outlines the process to be undertaken a) within business hours and b) outside of business hours.

3. RESPONSIBILITIES

3.1 The Chief Executive will:

- Ensure there is an efficient and effective process for managing the receipt, distribution, implementation and effectiveness of medicine recall notices.

3.2 District Executive Services (SESLHD-Mail@health.nsw.gov.au) will:

- Catalogue all medicine recall notices and related information in Content Manager; and allocate by email to the SESLHD Pharmacy Business Support Manager.

3.3 Director of Clinical Governance will:

- Manage requests from the CEC for information on product use/holdings
- Ensure implementation of nominated action/s from safety communiqués (e.g. Safety Alert Broadcast System notices or memos from the CEC) with appropriate documentation recorded in Content Manager
- Coordinate clinical advice on alternative products and their potential use within the health service as requested

3.4 SESLHD Pharmacy Business Support Manager will:

- Act as the nominated medicine recall co-ordinator in accordance with PD2022_032 Medication Handling
- Be notified of recalls
- Co-ordinate dissemination of recall notices to Directors of Pharmacy/Senior Pharmacists for sites and services
- Co-ordinate the identification and quarantining of affected stock
- Oversee return of affected stock to wholesalers and receipt of credit where required.
- Report on stock holdings, actions taken, identified risks and issues as per section 4.6
- In their absence (i.e. planned leave), delegate these responsibilities.

3.5 Directors of Pharmacy / Senior Pharmacists (Drug & Alcohol, Albion Centre, Royal Hospital for Women) will:

- Take overall responsibility for the operational management of the medicine recall process for the site(s) / service(s) that fall within their remit
- Document actions taken in response to the recall
- Report actions taken and issues identified to the Pharmacy Business Support Manager.

3.6 On-call Pharmacists will:

- Co-ordinate the management of the recalls that are notified outside of business hours,
- Ensure that appropriate and prompt action is taken in response to the recall
- Provide response to urgent information requests from the NSW Ministry of Health, the Clinical Excellence Commission the district and facility/service Executive.
- Hand over responsibility for management of the recall to the Director of Pharmacy/ Senior Pharmacist on the next working day.

3.7 After-hours Nurse Managers will:

- In the case of a medicine recall notified outside of business hours physically locate and quarantine all affected stock in liaison with the on-call pharmacist.

3.8 Nurse Unit Managers, and Facility/Service Executive will:

- Assist with identification and quarantining of affected stock in response to a medicine recall at the request of the Director of Pharmacy or on-call pharmacist.

3.9 Employees will:

- Comply with requests made by the Pharmacy Business Support Manager and relevant Director of Pharmacy/Senior Pharmacist or their delegates in response to a medicine recall.

4. PROCEDURE

4.1 Receipt and Dissemination of Medicine Recall Notices

SESLHD receives medicine recall notifications from the Clinical Excellence Commission (CEC) via email to SESLHD-Mail@health.nsw.gov.au. Recall notifications are also sent directly to the nominated recall coordinator for the district, being the Pharmacy Business Support Manager and to the Director of Clinical Governance.

Medicine recall notices may also be received from individual suppliers and vendors directly to individual facilities and departments on occasion.

Out of business hours, the CEC will contact the Chief Executive (CE) or executive on-call by telephone should there be a need to disseminate an urgent medicine recall notice.

Within Business Hours (8.30am - 5.00pm Monday to Friday)
District Executive Services will assign the medicine recall notice to the Pharmacy Business Support Manager via email, copying the District Director Pharmacy Services and SESLHD Clinical Governance Unit.

The Pharmacy Business Support Manager will disseminate the notification with detail of actions to be taken to the Director of Pharmacy or Senior Pharmacist for each site or service.

A recall notice may also be received from a pharmaceutical supplier in the form of email, fax or letter. Whoever receives the original notice must immediately provide a copy of the original notice to the Pharmacy Business Support Manager, copying the District Director Pharmacy Services. The Pharmacy Business Support Manager will assess the notification, gather necessary information and co-ordinate a response as required.

Outside of Business Hours
On receipt of an urgent recall notice, the CE or executive on-call should notify the executive on-call for each site/service. In sites with an on-call pharmacist, the pharmacist should be contacted either by the executive on-call or After Hours Nurse Manager (AHNM) via the hospital switchboard with details of the recall.

The on-call pharmacist will liaise with the AHNM to identify, and quarantine affected stock. Any external services supplied by the facility pharmacy department should be contacted, for example Mental Health Services and Population and Community Health Services, particularly where those services are operational outside of business hours.

Where there is no on-call pharmacist (e.g., War Memorial Hospital, Calvary Health Care) the executive on-call is responsible for seeking relevant information and coordinating the recall.

4.2 Checking Pharmacy Stock

One or more recall co-ordinators will be assigned by the Director of Pharmacy/Senior Pharmacist. This may be the dispensary manager, senior stores person or other designated staff members. The assigned person(s) will co-ordinate stock checking in each SESLHD pharmacy department under the supervision of the Director of Pharmacy or delegate. In most circumstances, checking of pharmacy stock does not need to occur after-hours and can wait until the next business day (with exception of stock held in the after-hours drug cupboard).

4.3 Checking Stock in Clinical Areas

Where the recall notice involves a problem likely to affect patient care, all stock held in clinical areas must be identified and returned to pharmacy for management. The SESLHD Pharmacy Business Manager (in hours) or on-call pharmacist (out-of-hours) should make an assessment of the urgency of action and advise others involved in the recall process.

iPharmacy reports can be used to identify:

1. Clinical areas which hold the medicine as imprest stock
2. Areas where the medicine has been dispensed to for an individual patient within the last 28 days.

Where used, the medicine formulary stock locator on the hospital intranet page may also be useful to assist with locating stock.

Within business hours

The Director of Pharmacy (or delegate) shall liaise with the Nurse Unit Manager (NUM) of each identified clinical area to ensure that any affected stock has been identified and returned to pharmacy. The Director of Pharmacy will notify the NUM of all other clinical areas of the recall in case stock has been transferred from one area to another. NUMs must provide a response confirming that the area has been checked for affected stock.

Outside business hours

The on-call pharmacist will advise the AHNM of the areas identified as having stock. In liaison with the on-call pharmacist, the AHNM is responsible for physically identifying and quarantining all affected stock. The AHNM will notify all other clinical areas of the recall in case stock has been transferred from one area to another. A record of the areas checked and stock identified should be kept and provided to the Director of Pharmacy on the next business day.

If necessary and at the direction of the facility Director of Pharmacy, other pharmacists may be called in to assist in the checking and stock management process.

Stock in the after-hours drug cupboard must also be checked and affected stock quarantined.

On the next working day a detailed handover of actions taken should be provided by the on-call pharmacist to the Director of Pharmacy. The Director of Pharmacy will then take over co-ordination of recall actions including the identification of stock in areas that do not operate outside of business hours.

4.4 Contacting patients

Where the recall notice advises the necessity of contacting outpatients or recently discharged patients who may have received the recalled medicine, a delegated pharmacist will arrange to contact patients by phone or mail to advise them of any actions necessary.

4.5 Handling the Affected Stock

All stock affected by the recall will be marked with the location from where it was returned, clearly marked as quarantined stock, and stored away from unaffected stock.

After hours, affected stock that has been removed from clinical areas should be marked with the location from where it was returned and placed in the after-hours drug cupboard.

During business hours all affected stock should be consolidated in the Pharmacy Store.

Quarantined stock should be kept under the product's usual storage conditions, i.e. if the recall affects a refrigerated product it should be quarantined in the fridge separate from unaffected stock.

If the recall affects a Schedule 8 or S4D medicine, stock must be consolidated in the Pharmacy controlled drug room separately from unaffected stock (applies both within and after business hours).

4.6 Return to Vendor of the Affected Stock

If stock is to be returned to the vendor, the Pharmacy Business Support Manager with coordinate notification of the supplier, as advised in the recall notice, to arrange the return and credit or replacement of the stock.

4.7 Reporting

The Pharmacy Business Support Manager is responsible for consolidating information from all sites and services and reporting, as follows:

- SESLHD Safety Alert/Product Recall Response form to be completed and returned to the SESLHD Clinical Governance Unit by the next working day after the recall.

- The facility executive (General Manager or Director Clinical Services) and SESLHD Clinical Governance Unit to be notified of circumstances where a medicine recall could pose a significant risk to patient care.

- Facility Medication Safety Committee (for affected facilities) and district Quality Use of Medicines Committee to be notified of outcomes and outstanding issues following the recall.

5. DOCUMENTATION

Detailed records should be kept to ensure that all clinical areas are checked for affected stock. Records of the quantity and location of affected stock should be kept to enable the stock to be credited and replaced. Records from each site should be provided to the Pharmacy Business Manager.

Any incidents that occur, such as administration of a medicine following its recall, or patient harm identified following a recall, should be recorded in the SESLHD incident management system.

Documentation may be required as part of the request made by the by NSW Ministry of Health, the Clinical Excellence Commission, the district and the facility/service Executive. Compliance with documentation requests is mandatory.

The SESLHD Safety Alert/Product Recall Response form should be retained by the SESLHD Clinical Governance Unit Facility. Clinical Practice Improvement Units may also require a copy of this documentation, according to local processes.

6. AUDIT

An annual audit of the completion of SESLHD Safety Alert/Product Recall Response forms to ensure compliance with procedure is recommended. This should be coordinated by the SESLHD Clinical Governance Unit with results reported to the SESLHD Drug and Therapeutics Committee.

It is also recommended that a debrief be undertaken following any major medicine recall to identify any opportunities for process improvement.

7. REFERENCES

- NSW Ministry of Health Policy Directive PD2022_032 - Medication Handling
- NSW Ministry of Health Policy Directive PD2013_009 - Safety Alert Broadcast System
- NSW Ministry of Health Policy Directive PD2019_019 - Coordination of responses to urgent system-level medicine or medical device issues

7. VERSION AND APPROVAL HISTORY

Date	Version	Author and approval notes
Dec 2011/ Updated February 2012	1	Director Allied Health and SES LHD Directors of Pharmacy
May 2012	1	Approved by SESLHD Clinical and Quality Council
July 2015	2	Acting Director Allied Health and SESLHD Directors of Pharmacy Merged SESLHDPD/167 and SESLHDPD/168 to one document
September 2015	2	Endorsed by Executive Sponsor for Draft for Comment
November 2015	2	Endorsed by DQUMC
February 2016	2	Endorsed by SESLHD Clinical and Quality Council
May 2018	3	Minor review approved by Claire O'Connor, Director Allied Health
May 2018	3	Processed by Executive Services prior to progression to SESLHD Quality Use of Medicine Committee – minor review
July 2018	3	Endorsed by SESLHD Quality Use of Medicine Committee
November 2021	4	Major review in line with Pharmacy Services restructure
December 2021	4	Draft for Comment period
January 2022	4	Endorsed by Executive Sponsor
8 February 2024	4.1	Reviewed by SESLHD A/Pharmacy Business Support Manager. Minor review. Updated reference to MoH PD2022_032 – Medication Handling. Approved by SESLHD Drug and Therapeutics Committee.