

SESLHD PROCEDURE COVER SHEET



Health
South Eastern Sydney
Local Health District

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KEY TERMS	Pharmacy, Drug Recall, Urgent Drug Recalls, On-call
SUMMARY	<p>This procedure outlines the process to be undertaken to ensure that all medicinal products subject to a statutory or voluntary recall are promptly identified, quarantined and returned to the supplier for credit by SESLHD facilities.</p> <p>This includes the process to be undertaken when there is an urgent need for the Clinical Governance Directorate or Hospital Executive to advise the SESLHD Pharmacy Departments of information that requires urgent action both a) within working hours and b) out of working hours.</p>

COMPLIANCE WITH THIS DOCUMENT IS MANDATORY

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1. BACKGROUND

The pharmacy has the responsibility for oversight of all the medicinal (drug) products used in the hospital. Where any of these are subject to a recall due to quality or other problems identified by the manufacturer or Therapeutic Goods Administration (TGA), stock in the pharmacy and stock issued to wards and inpatients must be identified. Under some circumstances it may also be necessary to trace stock dispensed for outpatients. All stock which is identified as subject to the recall must be returned to the pharmacy, quarantined and handled as specified in the recall notice.

This procedure outlines the process to be undertaken to ensure that all medicinal products subject to a statutory or voluntary recall are promptly identified, quarantined and returned to the supplier for credit in each SESLHD facility.

It also outlines the process to be undertaken when there is an urgent need for the Clinical Governance Directorate or Hospital Executive to advise the SELHD Pharmacy Departments of information that requires urgent action both a) within working hours and b) out of working hours.

Local variations to this procedure may exist.

2. RESPONSIBILITIES**2.1 Employees will:**

- Comply with requests made by the relevant Director of Pharmacy/Senior Pharmacist.

2.2 Directors of Pharmacy will:

- Take overall responsibility for managing the urgent drug recall process for their site / service
- Take overall responsibility for the maintenance of an on-call pharmacy roster for their site / service
- Be responsible for ensuring the implementation and compliance with this procedure is carried out at their respective site(s) within the District.

2.3 District Managers / Service Managers will:

- Support the Directors of Pharmacy and their staff to comply with the procedure as required.

3. PROCEDURE**3.1 Receipt of Recall Notice****Within Hours**

The recall notice is usually received by the Directors of Pharmacy at Prince of Wales Hospital, St George Hospital and Sutherland Hospital via email from the Pharmaceutical Services Branch with the heading;

URGENT MEDICINE RECALL

**HOSPITAL RECALL
RETAIL RECALL
CONSUMER RECALL
WHOLESALE RECALL**

Emails with this heading will be automatically forwarded by the Directors of Pharmacy to their Senior Pharmacists. The Director of Pharmacy, Prince of Wales Hospital will automatically forward to the Senior Pharmacists and the Directors of Pharmacy, Sydney/Sydney Eye Hospital, Sydney Children's Hospital (SCH) and the Royal Hospital for Women.

A recall notice may also be received from a pharmaceutical supplier. This may take the form of email, fax or letter. Whoever receives the original notice must immediately alert the persons delegated at each site e.g. Director or Deputy Director of Pharmacy, the Storekeeper and the Senior Pharmacist. Copies of the original notice must be provided to all the above staff.

If there is an urgent need to contact a Pharmacist (for example, in relation to a drug recall) within working hours, a call should be made to the Hospital Dispensary Pharmacist who will be able to contact the Director of Pharmacy or other senior delegate for that hospital.

After Business Hours

Each hospital within SESLHD has an on-call pharmacist who can be contacted after hours either via the Executive on-call, After Hours Nurse Manager or via the hospital switchboard.

The on-call pharmacist is responsible for co-ordinating the handling of the recall and undertaking appropriate action promptly, ensuring timely and appropriate response to urgent requests from the Ministry of Health, the District and the local Executive after hours. If necessary, other pharmacists may be called in to assist in the checking and stock management process.

It is noted that the on-call pharmacist is also responsible for responding to local pharmacy issues from relevant senior personnel within the hospital.

Within and After Hours

The Director of Pharmacy (or delegate) or the pharmacist who is contacted is responsible for ensuring the timely and appropriate response to urgent requests from the Ministry of Health, the District and the local Executive within hours. They are also responsible for reporting outcomes and issues to the relevant Executive (such as the General Manager and the Director Medical Services) as required.

The outcome of the recall; either affected stock and action to be taken or no action required, should be forwarded to the Clinical Practice Improvement Unit, Clinical Governance.

3.2 Checking Pharmacy Stock

The stock checking in pharmacy will be co-ordinated by the person assigned to drug recall, under the supervision of the Director of Pharmacy or delegate.

Checking stock in the Dispensary and the Imprest resupply area is the responsibility of the Senior Pharmacist who has been assigned the responsibility. Checking stock in the Pharmacy Store is the responsibility of the Storekeeper or the pharmacy delegate.

Stock identified as subject to the recall will be transferred back to the store and consolidated for quarantine.

3.3 Checking Issued Stock

Where the recall notice involves a problem likely to affect patient care, stock held on wards must be returned to pharmacy for credit.

The Director of Pharmacy or delegate shall liaise with the ward / unit to ensure that any affected stock has been identified and returned to pharmacy.

All other wards and units will be advised in case stock has been transferred from one area to another.

Where the recall notice advises the necessity of contacting outpatients who may have received the items in question, the Senior Pharmacist, Outpatients, or delegated Pharmacist will arrange to contact patients by phone or mail to advise them of any actions necessary.

3.4 Handling the Affected Stock

All stock affected by the recall will be consolidated in the Pharmacy Store and quarantined away from unaffected stock.

Once all affected stock has been identified, the Pharmacy Storekeeper will notify the manufacturer, as advised in the recall notice, to arrange the return of the stock.

3.5 Return to Vendor of the Affected Stock

The affected stock will be returned to vendor per department policy and procedures.

4. DOCUMENTATION

Documentation may be required as part of the request made by the by the Ministry of Health, the District and the local Executive. Compliance with documentation requests is mandatory.

The Director of Pharmacy or delegate shall maintain a file of recall and document actions taken in accordance with departmental policy and procedures.

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5. AUDIT

An annual audit of the local systems (SharePoint or drug recall folder in either CPIU or Pharmacy Departments) to ensure compliance with procedure is recommended. This should be conducted by the relevant Director of Pharmacy with results reported to the site Executive.

6. REFERENCES

Nil

7. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
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