SESLHD PROCEDURE COVER SHEET

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SUMMARY	This procedure outlines the process for managing all medication safety alerts, notices and information in SESLHD.

Feedback about this document can be sent to SESLHD-Policy@health.nsw.gov.au

Medication – Safety Alerts, Notices and Information

SESLHDPR/724

1. POLICY STATEMENT

This procedure outlines the process to be undertaken in SESLHD to ensure compliance with NSW Health Policy Directive PD2013_009 - Safety Alert Broadcast System and to ensure that all medication safety alerts, notices and information from external sources including the Ministry of Health (MOH); Clinical Excellence Commission (CEC); Therapeutic Goods Association (TGA) or suppliers and vendors are appropriately disseminated, monitored and actioned.

This procedure does not include the Drug Recall Process which is addressed in SESLHDPR/438 - Drug Recall Process.

This procedure does not include information safety alerts, notices and information related to clinical or biomedical equipment which is addressed in SESLHDPR/319 - Product – Clinical Product Notices, Recalls and Safety Alerts.

2. BACKGROUND

SESLHD receives product safety alerts, notifications and information from the Clinical Excellence Commission (CEC), as well as from individual suppliers and vendors directly to individual facilities and departments, on occasion. The CEC distributes a daily tranche via QARS ReACT at 9am each business day. The emails are sent to SESLHD-Mail@health.nsw.gov.au.

The Safety Alert Broadcast System (SABS) notifications are issued by the MOH and CEC as per NSW Health Policy Directive PD2013_009 - Safety Alert Broadcast System. These consist of a three tiered approach to distribution, prioritisation and management.

Safety Alert – The aim of a safety alert is to quickly disseminate information to health services about a safety matter requiring immediate attention and action which may include a **product recall**. The colour coding for safety alerts is **RED.**

Safety Notice – The aim of a safety notice is to inform health services about potential quality and safety issues requiring risk assessment at the local level. The colour coding for safety notices is **AMBER**.

Safety Information – The aim of safety information is to disseminate quality and safety information to health services to ensure lessons are learnt from state, national and international sources. The colour coding for safety Information is **GREEN**.

Occasionally patient safety information is notified via a direct memo from the CEC to SESLHD mail. These are managed in a similar manner by SESLHD.

The purpose of this document is to establish a clear process within SESLHD for the management of medication related safety alerts, notices and information received.

3. RESPONSIBILITIES

3.1 Chief Executive will:

- Ensure there is an efficient and effective process for managing the receipt, distribution, implementation and effectiveness of medication related safety alerts, notices and information.

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

- Catalogue all medication related safety alerts, notices and information in Content Manager; and allocate by email to the District Clinical Governance Unit with cc to District Director Pharmacy Services

3.3 Director Clinical Governance (DCG) will:

- Ensure that all medication related safety alerts, notices and information are disseminated as per Appendix 1.
- Ensure all correspondence regarding the medication related safety alerts, notices and information is catalogued in Content Manager.

3.4 Quality Use of Medicines (QUM) Lead Pharmacist will:

- Receive all medication related safety alerts, notices and information.
- Ensure dissemination of all medication related safety alerts, notices and information as per Appendix 1.
- Notify District CGU when medication related safety alerts, notices and information are disseminated and actioned within 2 weeks (unless required more urgently).
- Ensure a response is provided to the CEC when requested.
- On behalf of the Quality Use of Medicines Committee, record implementation of nominated actions and monitor risks to the District in relation to medication related safety alerts, notices and information.
- Ensure all correspondence regarding the medication related safety alerts, notices or information is appropriately recorded and documented.
- In their absence (i.e. planned or unplanned leave) delegate these responsibilities.

3.5 General Manager/ Service Directors will:

- Ensure that Cost Centre Managers affected by the medication related safety alerts, notices or information act in accordance with this procedure.
- Notify the DCG of any medication related safety alerts, notices or information received directly to the hospital.
- Ensure that any medication related risks to the organisation are reported to the SESLHD Quality Use of Medicines Committee (via the QUM Lead Pharmacist).
- Ensure there is completion of acknowledgement forms and a response is provided to the QUM Lead Pharmacist if requested.
- When required After Hours, notify affected departments within their facilities immediately as per section 4.3

3.6 Local site/service medication related committees will:

- When required by the QUM Lead Pharmacist Action Plan, ensure that medication related safety alerts, notices or information are tabled at the local site/service medication related committees and are acted on in accordance with this procedure.

3.7 CPIU Managers will:

- When required by the QUM Lead Pharmacist Action Plan, ensure that medication related safety alerts, notices or information are acted on in accordance with this procedure.

3.8 Cost Centre Managers will:

- Send any medication related information that was not received in the department via the Clinical Governance Unit to SESLHD-Mail@health.nsw.gov.au to ensure the District is aware and can coordinate the response to any District risks.
- When required by the QUM Lead Pharmacist Action Plan, ensure that medication related safety alerts, notices or information are acted on in accordance with this procedure.

3.9 District Director Pharmacy Services, Directors of Pharmacy and Pharmacy Business Manager will:

- Provide any additional information concerning medication related safety alerts, notices or information to the QUM Lead Pharmacist for further dissemination.

4. PROCEDURE

4.1 Receipt of Medication Related Safety Alerts, Notices or Information

A medication related safety alerts, notices or information will usually be received from the Clinical Excellence Commission (CEC), using QARS ReACT.

Occasionally companies will contact facilities directly. In this instance, information should be sent to the District Clinical Governance Unit via SESLHD-Mail@health.nsw.gov.au to be entered into Content Manager.

4.2 Dissemination of Medication Related Safety Alerts, Notices or Information

Upon receipt from SESLHD mail, District CGU will process the medication related safety alerts, notices or information by creating a new container in Content Manager, update Safety Alert Database and create a Safety Alert Response Form.

All medication related safety alerts, notices or information will be sent by the District CGU to the QUM Lead Pharmacist for review and the District Director of Pharmacy Service for their information. The QUM Lead Pharmacist will disseminate to the appropriate persons for acknowledgement and coordinate the response for tabling at the Quality Use of Medicines Committee.

The medication related safety alerts, notices or information will be sent by the QUM Lead Pharmacist to medication related committees, General Managers and CPIU Managers at each facility for their information.

The TGA Distribution Lists for recall notices are commercially sensitive and are not to be distributed further.

If no SESLHD sites are affected, the medication related safety alerts, notices or information is saved in a separate Content Manager container.

4.3 Actions for Local Site/Service

Actions at the local site/service occur at the request of the QUM Lead Pharmacist in accordance with the management pathway (see appendix 1)

- **GREEN** and **AMBER** pathway: information must be tabled at the next local site/service medication related committee meeting. No further action is required unless explicitly stated.
- **RED** pathway: information must be tabled at the next local site/service medication related committee and a coordinated response returned to SESLHD-DrugCommittee@health.nsw.gov.au. When requested, the local site/service medication related committee must develop a local action plan.

4.4 After Hours Procedure on Receipt of Medication Related Safety Alerts, Notices or Information

Out of business hours, the MOH or CEC will contact the CE by telephone should there be a need to disseminate an urgent medication related safety alert.

The General Manager/ Service Director, Executive On-Call and AH Nurse Manager, when advised of urgent medication related safety alerts, will contact the relevant On-Call Pharmacist and refer to SESLHDPR/438 - Drug Recall Process to ensure that the recommendations are actioned.

The QUM Lead Pharmacist will action the formal Safety Alert as per section 4.2 when received on the first day of the CEC's normal business hours.

5. DOCUMENTATION

Records to be catalogued in the Electronic Document Records Management System (HP Content Manager)

6. REPORTING

Monthly medication related safety alerts, notices and information is reported to the SESLHD Clinical and Quality Council, via the SESLHD Quality Use of Medicines Committee.

7. AUDIT

The SESLHD Quality Use of Medicines Committee will monitor implementation of nominated actions and risks to the District in relation to medication related safety alerts, notices and information.

8. REFERENCES

NSW Health Policy Directive PD2013_009 - Safety Alert Broadcast System
SESLHDPR/254 - Goods Return Advice
SESLHDPR/438 - Drug Recall Process
SESLHDPR/319 - Product – Clinical Product Notices, Recalls and Safety Alerts

9. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
November 2021	Draft	Erica Wales, QUM Lead Pharmacist, SESLHD
February 2022	Draft	Approved at Quality Use of Medicines Committee. To be tabled at Clinical and Quality Council.
March 2022	1	Approved by Clinical and Quality Council.

Appendix 1 – SESLHD Medication Safety Alerts, Notice and Information Management Pathway