

**Royal Hospital for Women (RHW)
BUSINESS RULE
COVER SHEET**



Health
South Eastern Sydney
Local Health District

NAME OF DOCUMENT	Safety Alerts, Notices and Product Recalls
TYPE OF DOCUMENT	Clinical Business Rule
DATE OF PUBLICATION	24.2.23
RISK RATING	High
REVIEW DATE	24.2.24
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RELEVANT POLICIES AND PROCEDURES	PD2013_009 Safety Alert Broadcast System Policy Directive SESLHDPR/319 Product – Clinical Product Notices, Recalls and Safety Alerts
EXECUTIVE SPONSOR	RHW General Manager
AUTHOR	Manager Clinical Practice Improvement

Royal Hospital for Women (RHW)




Safety Alerts, Notices and Product Recalls

Safety Alerts, Notices and Product Recalls

1. BACKGROUND

This clinical business rule outlines the process to be undertaken in Royal Hospital for Women (RHW) to ensure compliance with [NSW Health Policy Directive PD2013_009 - Safety Alert Broadcast System](#)¹ and to ensure that all clinical product safety notices, alerts and recalls 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.²

South Eastern Sydney Local Health District (SESLHD) Clinical Governance Unit (CG) receives product safety notifications, alerts and recalls and notifies facilities via email regarding product safety notifications, alerts and recalls for local monitoring and management. Notifications are categorised by:²

- TGA Safety Alerts²
- 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:¹
 -  Safety Alert: 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: –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: 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.

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

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2. RESPONSIBILITIES

As described in [SESLHDPR/319 Product – Clinical Product Notices, Recalls and Safety Alerts](#)²

3. PROCEDURE

Refer to appendix 1

4. NSQHS STANDARDS

Clinical Governance Standard³

5. REVISION AND APPROVAL HISTORY

Date	Revision No.	Reason	Author and Approval
9.1.23	0	New Clinical Business Rule developed	Endorsed by RHW Safety and Quality Committee 16.2.23

6. References

1. NSW Health Policy Directive PD2013_009 - [Safety Alert Broadcast System](#). Accessed 9.1.23
2. SESLHDPR/319 (2022) [Product – Clinical Product Notices, Recalls and Safety Alerts](#). Accessed 9.1.23
3. Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards guide for hospitals. Sydney: ACSQHC; 2017.

Abbreviations

AHNM	After Hours Nurse Manager
CE	Chief Executive
CEC	Clinical Excellence Commission
CG	Clinical Governance Unit
CPIU	Clinical Practice Improvement Unit
GM	General Manager
RHW	Royal Hospital for Women
SABS	Safety Alert Broadcast System
SAPR	Safety Alert Product Recall Response Form
SESLHD	South Eastern Sydney Local Health District
TGA	Therapeutic Goods Association

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Appendix 1

In hours

SESLHD CG sent out safety notice

SABS
Ad hoc high risk

TGA Safety Alerts
SABS

Sent to GM

Sent to RHW
Safety Alert
mailbox

Is CPIU
available to
manage?

Send to CPIU Manager

Is the
safety notice
relevant
to RHW?

no

yes

no

yes

Is the
safety notice
relevant
to RHW?

Complete SAPR and
return to CG

Send out to relevant departments using
email template. Save into Content
Manager

no

yes

Send out to relevant
departments and cc
CPIU Manager to
manage follow up

Recipients
confirm if they are
affected

Enter safety notice into alert and recall
database in Teams

no

yes

Send to CPIU
Manager to
complete feedback
to CG

no

Provide response to
CPIU

Document responses as they come in

After hours

MoH or CEC contact the CE

General manager / Executive On Call and
AHNM advised of safety notice

Is the
safety notice
relevant
to RHW?

no

yes

Respond as per CE
instructions and cc
CPIU Manager

Distribute and follow CE
instructions. CC Manager, CPIU
in all correspondence

no

Provide response to
CPIU

Send out monthly reminder of overdue
notices via Teams

Take actions as per
notice.

yes

Provide a response to CPIU of
actions taken and continue to
monitor

Once all responses received send
SAPR to CG and save into Content
Manager

Yellow: SESLHD
Green is Office of General Manager / After-hours
Blue: CPIU
Pink: Cost Centre Managers / Co-Directors