NSW Health

UPDATED: Anticipated disruption to supply of multiple antiseptic products

SAFETY ALERT 003/25

Issue Date:	4 April 2025
Content reviewed by:	Interagency Management Team (IMT) Health Protection NSW Clinical experts – Anaesthetics, Emergency, Intensive Care, Infection Prevention and Control, Infectious Diseases, Neonatology, NSW Health Pathology, Nursing, Obstetrics, Paediatrics, Paramedicine and Surgical.
Distributed to:	Chief Executives; Directors of Clinical Governance; Director, Regulation and Compliance Unit
KEY MESSAGE:	NSW Health facilities need to be aware of the recent Therapeutic Goods Administration (TGA) recalls, quarantine notices and cancellation of products from the Australian Register of Therapeutic Goods (ARTG) involving multiple antiseptic products, which are expected to cause a disruption to supply. Appropriate action should be taken in response as outlined in this Safety Alert.
ACTION REQUIRED BY:	Chief Executives, Directors of Clinical Governance
REQUIRED ACTION:	1. Distribute this Safety Alert to all relevant clinicians and clinical departments where these antiseptic products are stored and/or used and include this information in relevant handovers and safety huddles. 2. Undertake a local risk assessment and incorporate the below recommendations to manage the recall of affected products. 3. Ensure a system is in place to document actions taken in response to this Safety Alert. 4. Escalate any: a) supply concerns to HealthShare NSW via email HSNSW-PSC-communications@health.nsw.gov.au or for after-hours escalation, phone 02 8893 1586, b) clinical or operational concerns to CEC-MedicationSafety@health.nsw.gov.au (within hours) or to CEC Executive on-call (after hours and on weekends). 5. Report incidents related to the recalled and quarantined products to the drug sponsor, to the TGA and in ims+. 6. Confirm receipt of this Safety Alert and required actions by COB **Monday 7 April 2025** to CEC-MedicationSafety@health.nsw.gov.au.
We recommend you also inform:	Directors, Managers and Staff of: ○ Infectious Diseases and Microbiology ○ Infection Prevention and Control ○ Oncology/Haematology ○ Emergency Departments and Intensive Care Units ○ Neonatal and Paediatric Intensive Care Units ○ Operating Theatres ○ Burns Units ○ Public Health Units ○ All pathology providers and collection centres ○ All outpatient clinics and day centres ○ Medical Services ○ Nursing and Midwifery Services ○ Pharmacy Departments Drug and Therapeutics, and Infection Prevention and Control Committees. Clinical Product Managers and clinicians who may use the identified products.
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html
Review date:	October 2025

Made obsolete 21 May 2025 - Replaced by SN:011/25

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What has been updated from SN:006/25?

This Safety Alert replaces SN:006/25 - *Concerns regarding Achromobacter contamination of antiseptic products,* which has now been **rescinded.** Due to the Therapeutic Goods Administration's (TGA) recent recalls, quarantine notices and cancellation of multiple antiseptic products from Register of Therapeutic Goods (ARTG), a disruption to the supply of some antiseptic products is anticipated. Key changes in this Safety Alert include:

- Updated information surrounding the latest recalls, quarantine notices and product cancellations.
- Link to a factsheet providing information for NSW Health clinicians and procurement teams, including recommendations for managing the shortage of antiseptic products.

Situation

Due to concerns regarding contamination of certain antiseptic products from a specific manufacturer with *Achromobacter* species (an opportunistic Gram-negative bacteria that typically causes infections in people with weakened immune systems and is rarely isolated from blood cultures and sterile sites), the sponsor (Reynard Health supplies), in agreement with the TGA, has conducted a recall of three antiseptic products (TGA reference: RC-2025-RN-00160-1) and quarantine of two additional antiseptic products (TGA reference: RC-2025-RN-00344-1) – see **Table 1** and **Table 2** in the Appendix.

Although a quarantine order for 19 other antiseptic products has now been lifted, the sponsor (Reynard Health Supplies) has decided to cancel the TGA registration for all 24 of their antiseptic product lines, meaning no further supply can be procured. Supply already within the NSW Health system can continue to be used until exhausted, however as a result of the product cancellations **a disruption to the supply of these antiseptic product lines is anticipated.**

Assessment

Products potentially contaminated with *Achromobacter* species

- Use of products contaminated with *Achromobacter* species can potentially result in serious infections (including sepsis and meningitis), which may be life-threatening in patients with compromised immune systems or with underlying health conditions (please note, this species of bacteria cannot spread through airborne or aerosol transmission).
- To reduce the risk of patient harm, it is important that facilities:
  - identify and cease use of the products listed in **Appendix – Tables 1 and 2** immediately, and
  - use alternative antiseptic products (see below).

Use of alternative antiseptic products

- Procurement actions have been taken at a state level to secure sufficient supply of alternative antiseptic products and minimise the impact of this disruption to supply on the NSW Health system.

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- All supply of chlorhexidine in 70% alcohol products (all strengths and formulations) and chlorhexidine gluconate 0.1% ampoules has been centralised via OneLink warehouse and wholesalers (overseen by HealthShare NSW).
- The brand and formulation of products allocated to LHDs/SHNs/Health organisations may differ from week to week. Clinicians and procurement teams must refer to the CEC factsheet: *Information for NSW Health clinicians – Clinical recommendations for managing the shortage of antiseptic products* for advice on indications and clinical areas for which specific antiseptic agents should be prioritised, and associated safety considerations.

Recommendations

Recall and quarantine management:

- Ensure that all stock of the products subject to TGA recall and quarantine (see **Table 1** and **Table 2** in the Appendix) is inspected and immediately quarantined to prevent further use.
    - For products subject to the **recall notice**, facilities are to dispose of all stock of affected products. For further information regarding the process for returning or disposing of stock, refer to the Customer Letter distributed by sponsors.
    - For products subject to **quarantine notices**, facilities are to clearly mark all stock as 'UNDER TGA QUARANTINE – NOT FOR PATIENT USE'. Note: these products are generally low use, and do not contain 70% alcohol.
        - All supply must be quarantined in a central location or location(s) within each facility.
        - The area supply is quarantined must be outside of the clinical area.
        - Liaise with Corporate Services for advice on quarantining large amounts of alcohol containing products (due to fire hazard, multiple quarantine locations may be required).

Managing anticipated disruption to supply:

- An LHD/SHN-wide review of antiseptic stock holdings must be conducted (particularly those subject to central allocations), ensuring all locations of stock are identified. Identify all excess stock in wards/clinical areas and ensure mechanisms are in place to share stock both within and between facilities in your district/network.
- LHDs/SHNs/Health organisations must **cease all direct purchasing of these antiseptic products.** Clinical Product Managers have been contacted surrounding the particulars of the centralised allocation model this week.
- To assist with the management of the anticipated shortage of various antiseptic products, information has been provided in the following factsheets:
    - CEC factsheet: *Information for NSW Health clinicians – Clinical recommendations for managing the shortage of antiseptic products*.
    - Australian Commission on Safety and Quality in Health Care (ACSQHC) factsheet: *Appropriate and safe use of chlorhexidine in healthcare settings*.

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SAFETY ALERT 003/25

The content within the above factsheets is subject to change as further information becomes available and the supply situation evolves. Refer to the **electronic versions** of these factsheets using the above hyperlinks for the most up-to-date information as printed versions are uncontrolled.

- LHDs/SHNs are to establish governance processes to ensure the judicious use of antiseptic products, and the appropriate distribution of alternative(s) to clinical areas based on individual product specifications, patient populations, and clinical indications to minimise risk to patient safety.

Achromobacter Pathology Notifications (public and private pathology providers)

- For any detection of *Achromobacter* species in blood cultures and sterile site cultures between 7 March and 11 May 2025:
    - Report to NSW Health Pathology Public Health Pathology (NSWHP PHP) within 24 hours: NSWPATH-PublicHealthPathology@health.nsw.gov.au via the pathology provider. **Do not wait until the sensitivity results and final pathology report are generated.**
    - Store all *Achromobacter* species isolates from blood cultures and sterile sites until advised by NSWHP PHP of the laboratory actions to take.
    - Engage the local Public Health Unit to undertake a thorough case review to determine whether patient(s) were exposed to any of the quarantined or recalled products.
- Patients with suspected infection should be managed as per usual practice with antimicrobial therapy guided by susceptibility results. Business as usual processes for reporting positive cultures (including *Achromobacter* species) in specimens should be maintained in addition to the above. Generally, this should involve notification to the treating medical team by the microbiology laboratory, and appropriate consultation with the clinical microbiologist and/or infectious diseases physician for management advice.
- Continue to ensure aseptic technique is maintained in accordance with NSW Health *Infection Prevention and Control in Healthcare Settings* Policy Directive (PD2023_025) and NSW Health *Intravascular Access Devices (IVAD) - Infection Prevention & Control* Policy Directive (PD2019_040).
- Report any incidents relating to this recall to the sponsor and the TGA via the Medical device incident reporting and investigation scheme (IRIS), including the batch number where possible, as well as in the local incident management system (e.g. ims+).
- Escalate any concerns regarding procurement or supply of alternatives to HealthShare NSW via email HSNSW-PSC-communications@health.nsw.gov.au or for after-hours escalation, phone 02 8893 1186.
- Escalate any clinical or operational concerns to the Clinical Excellence Commission via CEC-MedicationSafety@health.nsw.gov.au or to CEC Executive on-call (after hours and on weekends).

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APPENDIX – List of antiseptic products affected by the TGA recall and quarantine notices.

Table 1. Antiseptic products affected by the TGA recall (5 March 2025) – **not to be used.**

ARTG number	Sponsor	Product code	Product name	Product image
309237	Reynard Health Supplies	RHS477	0.5% Chlorhexidine Foam Swabstick	
		RHS478	0.5% Chlorhexidine Lge Foam Swabstick	
		RHS479	0.5% Chlorhexidine Prep Pads 6 cm x 6 cm	

OBSOLETE

Note: Batch numbers 240810, 221010, 210610, 20200610 and 20231113 are affected by the recall, however all batches of these products should **not** be used.

Table 2. Antiseptic products affected by the TGA quarantine notice (26 March 2025) that do not contain 70% alcohol – **not to be used.**

ARTG number	Sponsor	Product code	Product name	Product image
309237	Reynard Health Supplies	RHS421	2% Chlorhexidine Prep Pads 4.5 cm x 8.5 cm	
		RHS475	2% Chlorhexidine Regular Foam Swabstick	

Note: All batch numbers are affected.

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