

▲ SAFETY ALERT 003/25

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: KEY MESSAGE: NSW Health facilities need to be aware of the recent Veraro ditic Goods Administration (Tog recalls, quarantine notices and cancellation of protects for the bustralian Register of Therapeutic Goods (ARTG) involving multiple anti-eptic products, which are expected to cause a disruption to supply. Appropriate action should be taken in vesponse as outlined in this Safety Alert. ACTION REQUIRED BY: Chief Executives, Directors of Clinical Governance: Chief Executives, Directors of Clinical Governance: 1. Distribute this Safety Alert to all health of the same in vesponse as outlined in this Safety Alert. 2. Undertake a local risk assess heart of incorporate the below recommendations to manage the recall of affected by ducts. 3. Ensure a system il in place in document actions taken in response to this Safety Alert. 4. Escalate and the same an		
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Contact: Clinical Excellence Commission

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A SAFETY ALERT 003/25

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Alert replaces SN:006/25 - Concerns regarding Achromobacter contamination of antiseptic products, which has now been **rescinded**.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 potegrand product cancellations.
- Link to a factsheet providing information for NSW Health climians and recurrement teams, including recommendations for managing the shortage of antiseptic products.

Situation

Due to concerns regarding contamination of certain antheptic products from a specific manufacturer with *Achromobacter* species (an opportunistic Gram-negative bester), that typically causes infections in people with weakened immune systems and is rarely iso ated from beood cultures and sterile sites), the sponsor (Reynard Health supplies), in agreement with the TGA, had conducted a recall of three antiseptic products (TGA reference: RC-2025-RN-00160-1) and cause stipe 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 FG/ 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 on 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 agent should be prioritised, and associated safety considerations.

Recommendations

Recall and quarantine management:

- Ensure that all stock of the products subject to TGA recall and grantine (see Table 1 and Table 2 in the Appendix) is inspected and immediately quarantine to preven further use.
 - For products subject to the **recall notice**, reallith size 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 spon-
 - For products subject to **quara** tine notices, facilities are to clearly mark all stock as 'UNDER TGA QUARANTINE NOT FOR PANCAL USE'. Note: these products are generally low use, and do not contain 70% alcohol.
 - All supply must quar intined in a central location or location(s) within each facility.
 - rantined must be outside of the clinical area.
 - Liaise with Corporate Services for advice on quarantining large amounts of alcohol containing arounds (due to fire hazard, multiple guarantine 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:
 - o 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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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 server.

Achromobacter Pathology Notifications (public and private pathology privide)

- For any detection of *Achromobacter* species in blood cultures and starile site cultures between 7 March and 11 May 2025:
 - Report to NSW Health Pathology Public Health Pathology (NSWHP PHP) within 24 hours: <u>NSWPATH-PublicHealthPathology@health.nsw.gov.uu</u> viz. the pathology provider. **Do not wait until** the sensitivity results and final pathology report are governated.
 - o Store all Achromobacter species isolates in militoor cultures and sterile sites until advised by NSWHP PHP of the laboratory actions to tak
 - Engage the local Public Health Unit to undertake a thorough case review to determine whether
 patient(s) were exposed to an of the guarantined or recalled products.
- Patients with suspected infection should be minaged as per usual practice with antimicrobial therapy guided by susceptibility results bus ness a daual processes for reporting positive cultures (including Achromobacter species) in specime is a puld be maintained in addition to the above. Generally, this should involve notification to the testing 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 Secungs 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 <u>Medical device incident</u> 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 <u>CEC-</u> 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
	Reynard Health Supplies	RHS477	0.5% Chlorhexidine Foam Swabstick	Regular Regular Swall Sticks Swall Sticks The professional and heaptild are Regular Reg
		l	0.5% Chorhexidine Lge Foam Swabstick	Chiarhooddine Swabsticks For professional and heappilal and Chiarhooddine For professional and heappilal and Chiarhooddine Reynard Reynard Mark
		H/2479	0.5% Chlorhexidine Prep Pads 6 cm x 6 cm	Chlorhexidine Prep pads For protestant are so SN Commistre Regynard Regyn

Note: Batch numbers 240810, 3210.0, 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.**

70 % atcorder – not to be used.							
ARTG number	Sponsor	Product code	Product name	Product image			
	Reynard Health Supplies	RHS421	2% Chlorhexidine Prep Pads 4.5 cm x 8.5 cm	Charleston Prep pads			
309237		RHS475	2% Chlorhexidine Regular Foam Swabstick	Accountable Services Swabsticks For personnel and with oil nor Reginard Accountable Services Reginard Accountable Servic			

Note: All batch numbers are affected. Made obsolete 21 May 2025 - Replaced by SN:011/25

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