

Issue date
15 December 2023

Distributed to:

Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:

Chief Executives
Directors of Clinical Governance

We recommend you also inform:

Directors, Managers and Staff of:

- Infectious Diseases and Microbiology
- Medical Services
- Nursing and Midwifery Services
- Pharmacy
- Clinical Product Managers

Clinicians who may use the identified products
Drug and Therapeutics Committees

Content reviewed by:

- CEC Healthcare Associated Infection
- Health Protection NSW
- Medication Shortage Assessment and Management Team

Clinical Excellence Commission

Tel: 02 9269 5500

[Email](#)

[Internet](#)

[Intranet](#)

Review date
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UPDATED: Possible contamination of multiple sodium chloride products – Quarantine and recall actions

What's new in this Safety Notice?

This Safety Notice replaces SN:039/23. TGA quarantine notice for two products has been escalated to an urgent medical device recall on 15 December 2023.

Situation

NSW Health is aware of the possible contamination of multiple sodium chloride 0.9% ampoule products. This is due to reported cases of *Ralstonia pickettii* being detected in multiple jurisdictions in patients exposed to these products. *Ralstonia pickettii* is a bacterium which is commonly found in the environment, and rarely causes infection. It may cause infection in people with weakened immune systems. NSW Health continues to work closely with the Therapeutic Goods Administration (TGA), Commonwealth Department of Health and Aged Care and other jurisdictions to investigate detections of *Ralstonia pickettii* in patients in NSW and other states and territories.

Further recalls may occur over the coming weeks - the list below may not be exhaustive and therefore, all staff are advised to check the TGA website or contact their local Recalls Coordinator for advice.

Product subject to recall as of 15 December 2023:

Product	ARTG number	Additional information
InterPharma Sodium chloride 0.9% 30 mL ampoules	370471 (Inhalation) 370408 (Irrigation)	TGA urgent medical device recall issued on 1 December 2023 (RC-2023-RN-01044-1). All batches
YES Medical – Non-antimicrobial wound irrigation solution, saline, sterile	409695	<ul style="list-style-type: none"> • Previously under quarantine, TGA urgent medical device recall issued on 15 December 2023 (RC-2023-RN-01048-1). Batch number: 2386055E and expiry date: 05/2028. • <i>Product also known as:</i> LEGENCY REMEDIES sodium chloride 0.9% irrigation (ampoules)/30 mL/Box of 30. • Sponsor: Yes Medical.
Irrigation fluid, medical/surgical procedure – Ironbark Creek Investments	404417	<ul style="list-style-type: none"> • Previously under quarantine, TGA urgent medical device recall issued on 15 December 2023 (RC-2023-RN-01047-1). All batches: (2386053E and 2386054E) and expiry date: 03/2028. • <i>Product also known as:</i> LOGIWASH Sodium Chloride for Irrigation 0.9% 30 mL Ampoule. • Sponsor: Ironbark Creek Investments (may also be known as Medilogic).

Products subject to quarantine as of 15 December 2023:

Product	ARTG number	Additional information
Aero Healthcare – Irrigation fluid, medical/surgical procedure	159438	<ul style="list-style-type: none"> • TGA quarantine notice issued on 11 December 2023. • <i>Product also known as:</i> AEROWASH Eyewash and Wound Irrigation (15 mL & 30 mL) • Sponsor: Aero Health Aust Pty Ltd T/A Aero Healthcare (Australia) • NSW Health facilities are advised to quarantine ALL batches. • This product appears in first aid kits.

Recommendations

- Ensure that products subject to recall are identified and not used for patient care. Stock should be returned to the sponsor/wholesaler as per the instructions provided in the Customer Letter prepared by the sponsor.
- Ensure that the product subject to quarantine are identified until further notice, and not used for patient care.
- Ensure that all potential areas for the storage of the identified products have been determined and checked (including, but not limited to; trolleys, wound packs, bedside drawers, procedure kits and first aid kits).
Particular attention should be placed on outpatient clinics and rooms.
- Liaise with the local Pharmacy Department and Clinical Product Managers to access supply of alternative products. HealthShare NSW has procured additional quantities of alternatives brands and formulations to ensure continuity of supply.
- Continue to ensure aseptic technique is maintained for all medium and high-risk procedures in accordance with NSW Health Policy Directive Infection Prevention and Control in Healthcare Settings [PD2023_025](#).
- Notify moh-phlo@health.nsw.gov.au any suspected or confirmed cases of infection with *Ralstonia pickettii*.

Required actions for the Local Health Districts/Networks

1. Distribute this **updated** Safety Notice to all relevant clinicians, clinical departments, and include it in relevant handovers and safety huddles.
2. Escalate any concerns to related to these products or the quarantine action to CEC-MedicationSafety@health.nsw.gov.au.
3. Report all suspected and confirmed cases of infection with *Ralstonia pickettii* to moh-phlo@health.nsw.gov.au.
4. Confirm receipt and distribution of this Safety Notice, and associated quarantine actions **within 72 hours** to CEC-MedicationSafety@health.nsw.gov.au.