

### Issue date

11 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

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### Review date

December 2024

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

### What's new in this Safety Notice?

Safety Notice updated to include an additional product now subject to quarantine and an update to the recommendations. SN:037/23 has been rescinded.

### 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. *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.

### Product subject to recall as of 11 December 2023:

Product	ARTG number	Additional information
InterPharma Sodium chloride 0.9% 30 mL ampoules	370471 (Inhalation) 370408 (Irrigation)	• Urgent medical device recall issued on 1 December 2023 (RC-2023-RN-01044-1).

### Products subject to quarantine as of 11 December 2023:

Product	ARTG number	Additional information
InterPharma Sodium chloride 0.9% 10 mL ampoule	20598 (Injection)	<ul style="list-style-type: none"> <li>• TGA quarantine notice issued on 24 November 2023.</li> <li>• <b>NSW Health facilities are advised to quarantine ALL batches.</b></li> </ul>
YES Medical Non-antimicrobial wound irrigation solution (saline sterile)	409695	<ul style="list-style-type: none"> <li>• TGA quarantine notice issued on 1 December 2023.</li> <li>• <i>Product also known as:</i> LEGENCY REMEDIES sodium chloride 0.9% irrigation (ampoules)/30 mL/Box of 30.</li> <li>• Sponsor: Yes Medical.</li> <li>• <b>NSW Health facilities are advised to quarantine ALL batches.</b></li> </ul>
Irrigation fluid, medical/surgical procedure - Ironbark Creek Investments	404417	<ul style="list-style-type: none"> <li>• TGA quarantine notice issued on 1 December 2023.</li> <li>• <i>Product also known as:</i> LOGIWASH Sodium Chloride for Irrigation 0.9% 30 mL Ampoule.</li> <li>• Sponsor: Ironbark Creek Investments (may also be known as Medilogic).</li> <li>• <b>NSW Health facilities are advised to quarantine ALL batches.</b></li> </ul>
Aero Healthcare – Irrigation fluid, medical/surgical procedure	159438	<ul style="list-style-type: none"> <li>• TGA quarantine notice issued on 11 December 2023.</li> <li>• <i>Product also known as:</i> AEROWASH Eyewash and Wound Irrigation (15 mL &amp; 30 mL)</li> <li>• Sponsor: Aero Health Aust Pty Ltd T/A Aero Healthcare (Australia)</li> <li>• <b>NSW Health facilities are advised to quarantine ALL batches.</b></li> </ul>

### Recommendations

- Ensure that the product subject to recall is identified and not used for patient care. This stock should be returned to the sponsor/wholesaler as per the instructions provided in the Customer Letter prepared by the sponsor.
- Ensure that all products subject to quarantine identified above are quarantined 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](mailto:moh-phlo@health.nsw.gov.au) of 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 related to these products or the quarantine action to [CEC-MedicationSafety@health.nsw.gov.au](mailto: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](mailto: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](mailto:CEC-MedicationSafety@health.nsw.gov.au).

OBSOLETE