

Issue date

1 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

Expert Reference Group

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

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

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.

Timeline of events

- NSW Health facilities were informed via local Recall coordinators and Directors of Clinical Governance to quarantine supply of identified InterPharma® products on Friday 24 November 2023 and not to use them for patient care until further advised. This was followed by a formal TGA Quarantine notice that afternoon.
- An updated Quarantine notice was released on Tuesday 28 November 2023 as well as a [Safety alert](#) on the TGA website on the same day.
- An urgent medical device recall (PS-2023-RM-01044-1) was issued by the TGA on Friday 1 December 2023 for the **InterPharma Sodium chloride 0.9% 30 mL ampoules** – AUST R: 370471 (Inhalation product), 370408 (Irrigation product).

Products subject to quarantine or recall to date

- **InterPharma Sodium chloride 0.9% 30 mL ampoules** – AUST R: 370471 (Inhalation product), 370408 (Irrigation product) subject to an urgent recall from the TGA. Stock should continue to be quarantined pending further information from the drug sponsor/wholesaler about the return of stock.
- **InterPharma Sodium chloride 0.9% 10 mL ampoule** – AUST R: 235989 (Injection product) continues to be subject to quarantine pending further advice. NSW Health facilities are advised to quarantine ALL batches.

Recommendations

- NSW Health facilities are now instructed to quarantine supply of additional products which are identified in Appendix A as they are from the same manufacturer as the sodium chloride 0.9% 30 mL ampoules identified above, and not procure further supply of these products. Formal TGA quarantine notice expected shortly.
- 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).
- 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 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 by **5pm on 1 December 2023** to CEC-MedicationSafety@health.nsw.gov.au.



Appendix A. Products manufactured in the same facility as the identified sodium chloride 0.9% 30 mL ampoules.

| ARTG ID | Product name | Additional information | Sponsor name |
|---------|--|---|---|
| 409695 | Non-antimicrobial wound irrigation solution, saline, sterile | <i>Product also known as:</i> SODIUM CHLORIDE 0.9% IRRIGATION (AMPOULES) / 30ML All batches to be quarantined. Further detail will be shared when available. | YES Medical |
| 404417 | Irrigation fluid, medical/surgical procedure | <i>Product also known as:</i> LOGIWASH Sodium Chloride for Irrigation 0.9% 30 mL Ampoule All batches to be quarantined. Further detail will be shared when available. | Ironbark Creek Investments (may also be known as Medilogic) |

OBSOLETE