Issue date
13 September 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:
- Medical Services
- Pharmacy Services
- Nursing and Midwifery Services
- Cardiac Catherisation Laboratories
- Cardiology
- Emergency
- Neurology
- NSW Ambulance

Drug and Therapeutics Committees
Other relevant staff, committees and departments.

Expert Reference Group
Content reviewed by:
- Chief Pharmacist Unit
- ACI Cardiac Network
- ACI Stroke Network
- Emergency Care Institute
- NSW Ambulance
- HealthShare NSW
- State Preparedness and Response Unit

Clinical Excellence Commission
Tel: 02 9269 5500
Email
Internet Website
Intranet Website

Review date
February 2025

UPDATED: Disruption to supply – tenecteplase (Metalyse®) and alteplase (Actilyse®) injection

What's new in this Safety Notice?

This Safety Notice replaces SN:014/22 and includes an update regarding the expected duration of the disruption to supply and information regarding shelf-life extensions granted by the Therapeutic Goods Administration for existing batches of Metalyse®. The process for obtaining supply remains unchanged.

Situation

There is a current disruption to the supply of tenecteplase (Metalyse®) and alteplase (Actilyse®) injection vials which is expected to continue until the end of 2024. The disruption is due to manufacturing capacity constraints following increases in global demand.

Ensuring continuity of supply

Alteplase

NSW Health continues to secure monthly allocations of the Australian registered product by the drug sponsor, Boehringer Ingelheim.

Tenecteplase

NSW Health continues to secure monthly allocations of the Australian registered product by the drug sponsor, Boehringer Ingelheim. NSW Health also has supply of a Section 19A alternative from ProPharma.

If historical usage patterns remain, there is expected to be sufficient supply in NSW to meet normal demand.

The Therapeutic Goods Administration (TGA) has approved Boehringer Ingelheim to extend the shelf-life of all batches of Metalyse with an original expiry date between January 2022 to March 2025 by 12 months, noting no change to the efficacy or safety of the therapy. Refer to the TGA alert for details, and ensure stock is appropriately re-labelled by the Pharmacy Service to reflect the updated expiry date.

Safety considerations with section 19A alternative

The TGA have approved the supply of two overseas-registered products under Section 19A (S19A) of the Therapeutic Goods Act 1989 – TNKase from USA and Canada. The S19A alternatives contain a water for injection vial from which the diluent must be drawn up prior to reconstitution of the tenecteplase injection. This differs from Metalyse which contains a pre-filled syringe of water for injection. The S19A alternatives also include a TwinPak® Dual Cannula Device in the box, which clinicians may not be familiar with. Clinicians should be alerted to these differences if S19A alternatives are used. Education resources can be found here.

Considerations for clinicians and governance committees

- Drug and Therapeutics Committees (DTCs) should monitor alteplase and tenecteplase use within their facility and ensure use is in accordance with the TGA approved Product Information.

Considerations for clinicians and governance committees (cont.)

- Off-label use (including use within a clinical trial context) must be closely monitored by DTCs and minimised during the disruption to supply.
- Wastage should be minimised by using the most appropriate product based on the required dose. Externally compounded products may be appropriate for when small doses are required.

Process for obtaining supply of alteplase and tenecteplase

During the period of disruption, constraints will be placed on supply to ensure equitable stock distribution. Facilities requiring stock of either medicine are asked to place an order with Symbion. Orders will be reviewed and released on a twice-weekly basis (Mondays and Thursdays). Due to this, orders will appear as a 'backorder' and stock on hand may display as zero on the wholesaler portal. Facilities with an urgent requirement should escalate their order to: CEC-MedicationSafety@health.nsw.gov.au (include purchase order [PO] number in the email).

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians, clinical departments and committees.
2. Report any incidents related to this disruption to supply in the local incident management system.
3. Escalate concerns that are not able to be managed locally (including urgent requirement for stock) to: CEC-MedicationSafety@health.nsw.gov.au
4. Acknowledge receipt and distribution of this **updated** Safety Notice within 72 hours via email.