Safety Alert 004/22

Critical disruption to supply – tenecteplase (Metalyse®) injection

3 August 2022

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:

- Drug and Therapeutics Committees
- Directors of Medical Services
- Directors of Pharmacy
- Directors of Nursing
- Directors and Managers of
  - Cardiac Catherisation Laboratories
  - Cardiology
  - Emergency
  - Neurology
  - NSW Ambulance

Deadline for completion of action – see actions.

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

Fax: 02 9269 5599

Email: CEC-MedicationSafety@health.nsw.gov.au

Internet Website: http://health.nsw.gov.au/sabs

Intranet Website: http://internal.health.nsw.gov.au/quality/sabs

Review date

December 2023

Situation

There is a critical disruption to the supply of tenecteplase (Metalyse®) 40 mg and 50 mg powder for injection vials, which is expected to continue until the end of 2023. Intermittent supply will be available, however will not be sufficient to meet normal demand. The disruption is due to manufacturing capacity constraints following increases in global demand.

Metalyse® injection is the only tenecteplase product registered for use in Australia. It is approved for the thrombolytic treatment of the acute phase of myocardial infarction.

Need for urgent stock preservation across NSW Health and alternative supply

Stock preservation strategies are to be implemented by LHDs, SHNs and NSW Ambulance immediately to reduce the risk of stock being exhausted. There are also likely to be flow-on effects to the supply of alteplase injection, and therefore its use should also be considered.

The Therapeutic Goods Administration (TGA) has approved Boehringer Ingelheim to extend the shelf-life of certain batches of Metalyse® by 12 months, noting no change to the efficacy or safety of the therapy. Refer to the TGA alert for details. NSW Health is aware that there are further batches in circulation with short expiry dates. **Out of date tenecteplase should not be disposed of, pending further decisions on expiry date extension by the TGA.** This stock should be returned to a NSW Health Pharmacy Department for quarantined storage.

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.

Clinical and governance recommendations and conservation strategies

- Drug and Therapeutics Committees (DTCs) must ensure that a process is in place to preserve remaining supplies of tenecteplase.
- Supply of tenecteplase must be prioritised for indications where alternatives are not available or cannot be used: **pre-hospital thrombolysis** or **nurse administered thrombolysis,** for patients who are not able to access timely intervention in a cardiac catherisation laboratory.
- Wastage should be minimised by using the most appropriate product (40 mg or 50 mg) based on the required dose of tenecteplase.
- Remove tenecteplase from imprest in areas other than Emergency Departments. Provisions must be in place for timely access to this medicine outside of normal Pharmacy operating hours.
- Clinicians should be reminded that use of tenecteplase outside the indication listed in TGA approved Product Information is "off-label". Off-label use (for example use of tenecteplase for; ischaemic stroke via the intravenous or intra-arterial route, the management of massive pulmonary embolism and in a clinical trial setting) must be closely monitored by DTCs and minimised during the disruption to supply.

Actions required by Local Health Districts/Networks

1. **Immediately upon receipt**, distribute this Safety Alert to all relevant clinicians and committees.
2. **Within 24 hours**, acknowledge receipt of this Safety Alert and confirm distribution.
3. **Within 72 hours**, confirm that the Drug and Therapeutics Committee has processes in place to preserve remaining supplies of tenecteplase including close monitoring and minimisation of off-label use.
4. Quarantine batches of out-of-date tenecteplase not addressed by the recent TGA alert pending further advice.
5. Report any incidents related to this disruption to supply in the local incident management system.
6. Escalate concerns that are not able to be managed locally to CEC-MedicationSafety@health.nsw.gov.au