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Safety Notice 001/19

Thiopental injection (Pentothal®) disruption to supply

17 January 2019

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:

- Heads of Anaesthetics Departments
- Critical Care Units
- Emergency Departments
- Directors of Medical Services
- Directors of Nursing and Midwifery
- Directors of Pharmacy
- Drug and Therapeutics Committees

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer, MoH
- Chief Pharmacist Unit, MoH
- Director Patient Safety, CEC

Clinical Excellence Commission

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

Review date

January 2020

Background

There is a global shortage of thiopental (also known as thiopentone) 500 mg powder for injection. Stock of thiopental injection (Pentothal®) is estimated to return 1 April 2019. There are no alternative brands of this product available, and no unregistered thiopental products available via the Special Access Scheme (SAS) or Section 19A (S19A). It is not anticipated that SAS or S19A stock will become available during this shortage period.

Thiopental is indicated for the induction of general anaesthesia, as a sole anaesthetic agent in short surgeries and for short term control of seizures in critical care areas. It has accepted use in the treatment of raised intracranial pressure and for cerebral protection, such as in neurosurgery.

A number of alternative agents are available, including propofol, isoflurane, sevoflurane, ketamine and midazolam for anaesthetic induction; propofol and ketamine as sole anaesthetic agents for short surgical procedures; propofol for short term control of seizures in critical care areas; and acetazolamide for the management of raised intracranial pressure.

Hospitals should assess thiopental injection usage across their facility and implement local plans to manage the shortage, this includes use of alternative agents where clinically appropriate.

Thiopental stock should be reserved for patients where there are no other options, such as allergy to alternative agents.

Suggested actions by Local Health Districts/Networks

1. Distribute this notice to all relevant stakeholders and departments.
2. Assess the current status of thiopental injection available in each facility, ensuring all locations of stock are identified.
3. Strategies to manage the shortage of thiopental should be planned and implemented at a local level. These measures should include (after risk assessment at the local level):
 - Remove and quarantine stock from clinical areas where thiopental is not routinely used.
 - Reduce and minimise stock levels in clinical areas where thiopental is routinely used.
 - Reserve stock of thiopental for patients unable to receive alternative agents.
 - Use alternative agents to thiopental where clinically appropriate
 - In the event stock of thiopental is depleted, patients with known contraindications to alternative agents should have a thorough risk assessment completed by a Senior Consultant.
4. Ensure a system is in place to document actions taken.