Safety Alert 001/13

1st May 2013

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Drug and Therapeutics Committees

Action required by:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations

For response by:

- Directors of Clinical Governance

We recommend you also inform:

- Directors of Pharmacy
- Theatre Managers
- Anaesthetics Heads of Departments
- Directors of Nursing

Deadline for completion of action
15th May 2013

Expert Reference Group
- Advice from TGA

Clinical Excellence Commission

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Risks associated with Wockhardt™ morphine sulfate injection 10mg/mL (preserved) ampoules

Background

Currently, Hospira is experiencing a shortage of DBL™ morphine sulfate injections in various strengths. These products have been replaced with Wockhardt™ morphine sulfate injection 10mg/mL (preserved).

The DBL™ and Wockhardt™ products have critical differences. Wockhardt™ morphine sulfate injection 10mg/mL (preserved) contains the preservative sodium metabisulfite. **If Wockhardt™ morphine sulfate (preserved) is administered by the intrathecal or epidural route, it may cause significant patient harm**. Wockhardt™ morphine sulfate injection 10mg/mL (preserved) **must only** be administered subcutaneously, intravenously or intramuscularly.

Initial advice relating to this situation was issued in December 2012. In many facilities, Wockhardt™ morphine sulfate (preserved) has only recently come into stock following the exhaustion of DBL™ morphine sulfate supplies. This alert provides a reminder to clinicians and managers about the risk associated with this change in product.

Specific Incident

The Australian Commission on Safety and Quality in Health Care has alerted the Clinical Excellence Commission to an incident in which Wockhardt™ morphine sulfate injection 10mg/mL (preserved) was administered by the epidural route. Whilst no patient harm has been reported, this incident highlights the potential for Wockhardt™ morphine sulfate (preserved) to be inadvertently administered by the epidural or intrathecal routes.

Mandatory actions for Local Health Districts/Networks

- Check existing stocks of morphine to determine whether Wockhardt™ morphine sulfate (preserved) is now in stock.
- Confirm that all clinical areas in which intrathecal or epidural morphine is used have access to preservative free morphine.
- Confirm that risk minimising actions have been taken to prevent intrathecal or epidural administration of Wockhardt™ morphine sulfate (preserved).

For Further Information

- For more details and updated information about product availability see http://www.tga.gov.au/hp/information-medicines-morphine-sulfate-products.htm.
- For previous advice refer to Safety Notice 001/12: Morphine sulfate injection 10mg/mL ampoules - supply changes and toxicity issues.

Action required by Local Health Districts /Networks

1. Ensure that the mandatory actions outlined above are completed.
2. Report to CEC by 15th May 2013 when action complete.