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Safety Notice 008/08

16 May 2008

Clexane

Usage during heparin-based product shortages

Distributed to:

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

Action required by:

- Directors of Clinical Governance

For response by:

No response to Quality and Safety Branch required

We recommend you also inform:

- Area Directors of Medical Services
- Area Directors of Nursing and Midwifery
- Medical staff
- Nursing staff

Deadline for completion of action

Not applicable

Quality and Safety Branch

NSW Department of Health

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Email

quality@doh.health.nsw.gov.au

<http://www.health.nsw.gov.au/quality/sabs/index.html>

Background

In early 2008 the Therapeutic Goods Administration implemented a recall of Clexane (enoxaparin) and heparinised-saline batches that were contaminated with over-sulphated chondroitin sulphate. This impurity has been implicated in severe reactions in the USA and Europe. While there have been no reports of adverse events in Australia associated with Clexane or any other heparin based products, the Therapeutic Goods Administration decided to quarantine the affected batches of Clexane as a precaution to protect patient safety.

Since the Australian recall the Australian Health Protection Committee, augmented by representatives of the Committee of Presidents of Medical Colleges and the President of the Australian Medical Association, has been convened and has met regularly to monitor the supply situation and develop contingency plans to mitigate the risk of potential future shortages of heparin-based products in Australia.

The Australian Department of Health and Ageing has released consensus guidelines for Australian clinicians. These Guidelines are for the use of anti-coagulants during heparin-based product shortages. They are a precaution intended to extend the availability of heparin-based products by prioritising their use according to clinical need, and facilitate national consistency in the utilisation of remaining supplies.

Current situation

The Therapeutic Goods Administration is exploring all options to secure supplies and clarify future product availability. At this stage it remains uncertain whether Australia will experience a shortage of heparin-based products, and if a shortage occurs how long it might last.

With effect from Friday 16 May 2008 all States and Territories in Australia will move to Stage One of the Consensus Guidelines.

This means clinicians are requested to avoid the use of heparin-based products that is **NOT** evidence-based and are to consider the use of alternatives in place of low molecular weight heparin where evidence suggests no disadvantage nor additional risk to the patient, nor adverse impact on health care delivery.

The NSW Department of Health is working with the Health Service Directors of Clinical Governance and the Clinical Excellence Commission to provide advice on best practice usage of heparin-based products and will provide this information to clinicians through the Directors of Clinical Governance.

References

[Consensus Guidelines for Australian Clinicians for the usage of anti-coagulants during heparin-based product shortages. Department of Health and Ageing, Canberra, 15 May 2008.](#)

[FAQs – for members of the public](#)

[FAQs – for Health Professionals](#)

Suggested Action by Area Health Services

1. Ensure this Safety Notice is distributed to all relevant clinical staff.