MEDICAL DEVICE SAFETY ALERT

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

To: Chief Executive Officers
District Health Boards and Private Surgical Hospitals

Attention: Chief Medical Officers
Perfusionists
Interventional Radiologists
Staff involved in extra-corporeal medicine
Risk Managers

14 May 2008

MEDICAL DEVICES CONTAINING HEPARIN

It has been identified that heparin contaminated with oversulfated chondroitin sulfate (OSCS) has been used in medical devices supplied in New Zealand.

Contaminated heparin administered by injection has caused adverse reactions (anaphylaxis and hypotension) and deaths internationally. There is currently no information on adverse reactions associated with medical devices containing contaminated heparin.

The magnitude and scope of the problem with medical devices supplied globally and in New Zealand is still being established. Further specific information will be provided as it becomes available.

Clinicians and staff involved in using any medical device containing heparin need to be aware of the potential contamination issue and apply special due diligence when using devices containing heparin. It is possible that repeated exposure to contaminated heparin may increase the risk of an anaphylactic reaction occurring.

In the absence of definitive information about which medical devices contain contaminated heparin, clinical judgment will need to be used to determine whether a medical device containing heparin is used.

Background information

- Contamination with OSCS has affected the global supply of heparin. It has been established that no contaminated heparin injection has been distributed in New Zealand, and measures are in place to ensure that no contaminated product enters the supply chain here.
- Injectable heparin products contaminated with OSCS have been associated with serious adverse reactions and deaths internationally.
- Contaminated heparin has been used in medical devices supplied in New Zealand.
- Medsafe has not received any reports of adverse reactions involving the use of heparin-containing medical devices. However, this may be because contaminated devices have only recently entered the supply chain and only a small number have been used. It is also possible that adverse reactions have occurred but have not been linked to use of the heparin-containing device.
- The magnitude and scope of the medical device contamination problem is still being established. Information is currently being gathered to determine who is distributing medical devices containing heparin and whether those devices contain, or may contain, contaminated heparin.

- There is no test that can be performed on a medical device to determine whether or not it contains contaminated heparin. This determination can only be made by tracing and testing the batch of heparin used in the manufacture of the medical device.
- At this time, one supplier (Medtronic, which distributes Trillium coated cardiopulmonary bypass products) has been able to identify affected product, which was distributed in New Zealand during April and May 2008, and is issuing a safety alert detailing the products and batches affected.
- Until further information becomes available, it would be prudent to consider all other medical devices containing heparin as potentially contaminated.
- This is an international problem and Medsafe is working with overseas regulators to identify the scope of the problem and take appropriate action. Further information will be provided as it becomes available.

Reporting adverse reactions

Any problems associated with the use of medical devices containing heparin should be reported to Medsafe. In particular, we are asking you to report:

- events with signs or symptoms consistent with anaphylactic-type reactions, acute hypotension, and/or acute gastrointestinal distress;
- any other serious reaction that may be attributed to the heparin in a medical product. These may include, but are not limited to:
  - unexplained thrombocytopenia;
  - excessive anticoagulation or haemorrhage;
  - inadequate anticoagulation;
  - unexplained or premature thrombosis of a heparin-coated device;
  - spurious results of in-vitro diagnostic tests that utilise heparin either as part of the assay or as part of the specimen collection.

The Medical Device Incident Reporting Form can be found at http://www.medsafe.govt.nz/downloads/device.doc

Further information

Further information on this issue can be found at:

- www.medsafe.govt.nz
- http://www.fda.gov/cdrh/safety/heparin-device-list.html (FDA list of affected devices
- http://www.fda.gov/cdrh/safety/heparin-notice.html (FDA Notice to medical device manufacturers and distributors)
- http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5705a4.htm
- http://content.nejm.org/cgi/reprint/NEJMoa0803200.pdf?resourcetype=HWCIT
- http://www.nature.com/nbt/journal/vaop/ncurrent/abs/nbt1407.html

Medsafe contact person

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