

Wellington

20 June 2008

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## **OSCS Contaminated Sample Containers**

Medsafe, following consultation with the Heparin Technical Advisory Group, is advising suppliers of sample containers manufactured with heparin contaminated with Over Sulphated Chondroitin Sulphate (OSCS) that they may be supplied in New Zealand providing conditions explained below are met.

### **Situation**

A recently discovered contaminant, OSCS, in some batches of heparin has been linked to a number of adverse events in the USA and Germany following the administration of bolus doses of heparin to patients. This contaminant has also been discovered in some batches of heparin that have been used in the manufacture of medical devices, including sample containers. The presence of OSCS is not able to be determined in finished medical devices and must be tested for in the source heparin.

### **Medsafe Action**

Medsafe has convened a Technical Advisory Group (TAG) to review the information available about heparinised medical devices contaminated with OSCS and to provide clinical advice. The TAG has reviewed information provided by manufacturers of medical devices, other regulators, and clinical data. The TAG has endorsed Medsafe's risk management position that;

- OSCS contaminated devices should be separated from non-contaminated devices
- Non-contaminated devices should be used wherever possible
- Contaminated devices should only be used once the clinical risk of using such devices has been evaluated by the clinician

Most recently the TAG has reviewed information about heparinised sample containers. They have agreed with Medsafe's proposal that sample containers contaminated with low levels of OSCS may be supplied in New Zealand. Medsafe has set the following guidelines for the supply of such devices;

- Any contaminated product currently quarantined by suppliers at Medsafe's request and containing less than 6% OSCS may be supplied under a Safety Alert advising the customers of;
  - the existence of the contamination,
  - the potential for the contaminate to affect the results of assays, and
  - if anomalous results are obtained that the patient should be retested
- Product that is shipped to New Zealand after the date of this letter and which contains OSCS contamination of **less than 2%** may be supplied without restriction
- Product that arrives in New Zealand after the date of this letter and which contains OSCS contamination of **between 2% and 6%** may be supplied under a Safety Alert (contents as per above) following consultation with Medsafe
- Product that arrives in New Zealand after the date of this letter and which contains OSCS contamination of **greater than 6%** should be advised to Medsafe and held in quarantine until agreement on its supply is reached between Medsafe and the supplier/manufacturer

Due to the long production period required for heparin, regulators worldwide are monitoring the future supply of uncontaminated heparin. Suppliers of heparinised medical devices are advised to continue to monitor their supplies of product and to contact Medsafe should they receive any devices for supply in New Zealand that contain levels of OSCS in accordance with the above.

Yours sincerely,

**Stewart Jessamine**  
Interim Manager  
Medsafe