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Drug Alert

CLASS 1 MEDICINES RECALL

Action Now - including out of hours

Date: 7/03/2008

Our Ref: MDR 3-03/08

Dear Healthcare Professional,

Pharmachemic Trading Agency

**Heparin-Rotexmedica solution for injection 5,000 iu/ml
(heparin natrium)**

Batch Number	Expiry Date	Pack Size	First Distributed
70279	10/2012	Box of 25 vials of 5ml	15/11/2007

Following a Rapid Alert Notification of Heparin-Rotexmedica solution for injection issued by the Federal Institute for Drugs and Medical Devices in Bonn Germany, the Medicines Authority is initiating a Class I recall for the above mentioned batch of Heparin-Rotexmedica solution for injection 5,000iu/ml.

The Medicines Authority has confirmed with the local wholesale dealer, Pharmachemic Trading Agency, that the above batch is the only batch affected in Malta. This batch was supplied to the Government Pharmaceutical Services who have recalled the batch and placed it in quarantine.

This recall is being carried out for reasons of precaution following cases of serious adverse events after intravenous application of Heparin-Rotexmedica solution for injection were reported.

Thanks and regards

Muriel Giglio

Medicines Inspector