



Department of

**Health, Social Services
and Public Safety**

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AN ROINN

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agus Sábháilteachta Poiblí**

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Date: 24th April 2008

From The Chief Pharmaceutical Officer
Dr Norman Morrow

For Action: Directors of Pharmaceutical Services of the Boards & CSA
Heads of Pharmacy and Medicines Management, HSC Trusts
Regional Quality Improvement Authority

DRUG ALERT

MEDICINES – CAUTION IN USE

Dear Healthcare Professional,

Low molecular weight heparin - Enoxaparin Sodium ("Clexane") pre-filled syringes

MHRA has recently been informed that some batches of Enoxaparin Sodium (Clexane) pre-filled syringes with low levels of Over-Sulphated-Chondroitin-Sulphate (OSCS) have been distributed in the UK over a period of 4 to 6 weeks. There is no evidence that these low levels of OSCS have led to adverse reactions.

It is expected that new and uncontaminated Enoxaparin Sodium (Clexane) stock will become available from June 2008. In the interim period, precautionary advice is being issued to minimise any risk of adverse reactions.

Withdrawal of the contaminated Clexane products could lead to a shortage of low molecular weight heparins. The Commission on Human Medicines has considered the matter and has recommended the continued supply of this product despite the low level contamination.

Prescribing advice

- Enoxaparin is a very important therapy and it is essential that patients continue to receive it as prescribed by their doctor
- As there is no evidence of any specific risks, and to maintain supplies, product on the UK market should continue to be used
- Purely as a precaution, intravenous and arterial administration of Enoxaparin should be avoided if possible. If given by these routes, suitable emergency treatment should be available and patients should be closely observed for signs of possible hypotensive or allergic reactions.

Healthcare professionals or patients should report adverse reactions relating to any Heparin and Enoxaparin Sodium (Clexane) products via the Yellow Card Scheme.

We currently have no similar concerns with other Heparin products in the UK but continue to keep the situation under close review.

Sources of additional information

3.1 For medical information relating to Enoxaparin Sodium (Clexane) products telephone Sanofi-Aventis medical information department on 0800 281973.

3.2 For reporting suspected defects in medicines telephone the MHRA medicines defect centre (DMRC) on 0207 084 2574.

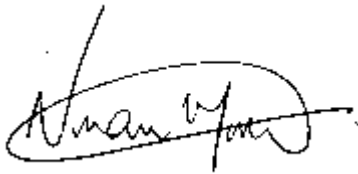
3.3 For questions about adverse event reports and the Yellow Card scheme telephone the MHRA Central Enquiry Point on 0207 7084 2000 or see the website www.yellowcard.gov.uk

The scope of this notification covers both Originator products and products which are parallel imports.

Area Boards/RQIA should bring this information to the attention of private hospitals/clinics registered with them, Out of Hours Centres and any other relevant care facilities.

The Central Services Agency is asked to bring this information to the attention of Community Pharmacists and General Practitioners within **48 hours**

Yours sincerely



DR NORMAN MORROW
Chief Pharmacist

For information:

CMO
CNO
CDO
CISSI
SMO
Director, Health Estates
Public Health Branch
DHSSPS, Library
Extended nurse prescribers
NICPPET

Regional Medicines and Poisons Information Service
Regional Director of Supplies
RPLS
Pharmaceutical Society of NI
Senior Prison Pharmacist
Prison Service, Dundonald House
Nursing Officer, Health Estates
Medical Officer, Castle Buildings
Regional Procurement Pharmacist
Heads of Pharmacy and Medicines Management, HSC Trusts