



Department of

**Health, Social Services
and Public Safety**

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From The Chief Pharmaceutical Officer
Dr Norman Morrow

For Action: Directors of Pharmaceutical Services of the Boards & CSA
Directors of Pharmaceutical Services of HSC Trusts
Regional Quality Improvement Authority

Our reference: PHC/05/08

Date: 12th May 2008

DRUG ALERT

MEDICINES - CAUTION IN USE

Dear Healthcare Professional,

Parallel imports of low molecular weight heparin - Enoxaparin sodium (“Clexane”) pre-filled syringes

Further to our Drug Alert PHC/04/08 issued on 24 April 2008 the Medicines and Healthcare Regulatory Agency has advised Parallel Importers of concerns about higher levels of contamination in some lots of Clexane syringes which have been supplied to some overseas markets. MHRA has indicated that it does not wish to see these batches supplied to the UK market as parallel imports.

This notice provides advice for any recipient who may have concerns about existing stocks of parallel imported Clexane syringes.

In our previous notification we stated that the Commission of Human Medicines (CHM) recommended the continuation of supply of batches of Clexane pre-filled syringes contaminated with low levels (below 5%) of Over Sulphated Chondroitin Sulphate (OSCS). This is still valid and all such batches can remain in use.

In some overseas markets, batches of Clexane pre-filled syringes have been supplied with higher levels of OSCS contamination than that considered acceptable by CHM. Batch numbers are quoted in the table below.

Batch number	Original overseas pack details
291	CLEXANE 6KIU/0.6ML INJ PS2 H IT
291	CLEXANE 6KIU/0.6ML INJ PS2 H IT
1982	CLEXANE 100MG/ML INJ PS10 H IE
2990	LOVENOX 2KIU/0.2ML INJ PS6 ERIS H FR
2991	LOVENOX 2KIU/0.2ML INJ PS6 ERIS H FR
5553	LOVENOX 4KIU/0.4ML INJ PS6 ERIS H FR
5566	LOVENOX 4KIU/0.4ML INJ PS6 ERIS H FR
08001 See note below	CLEXANE 90MG/0.6ML INJ PS10 ES
08003	CLEXANE 100MG/ML INJ PS10 ES
08003	CLEXANE 100MG/ML INJ PS10 SE
08005	CLEXANE 40MG/0.4ML INJ PS10 ES
08006	CLEXANE 40MG/0.4ML INJ PS50 ES
08008	CLEXANE 40MG/0.4ML INJ PS50 ES
08009	CLEXANE 40MG/0.4ML INJ PS10 ES
08010	CLEXANE 40MG/0.4ML INJ PS50 ES
08016	CLEXANE 40MG/0.4ML INJ PS50 ES
08017	CLEXANE 40MG/0.4ML INJ PS10 ES
08019	CLEXANE 40MG/0.4ML INJ PS10 ES
08021	CLEXANE 40MG/0.4ML INJ PS30 ES
14110	CLEXANE 4KIU/0.4ML INJ PS6 IT
14110	CLEXANE 4KIU/0.4ML INJ PS6 IT
14113	CLEXANE 4KIU/0.4ML INJ PS6 IT
14114	CLEXANE 40MG/0.4ML INJ PS10 BE
14310	LOVENOX 4KIU/0.4ML INJ PS6 ERIS H FR
14312	LOVENOX 4KIU/0.4ML INJ PS6 ERIS H FR
14504	CLEXANE 4KIU/0.4ML INJ PS6 H IT
14508	CLEXANE 4KIU/0.4ML INJ PS6 H IT
15131	CLEXANE 150MG 10 SRG 1ML XH
904151	CLEXANE 4KIU/0.4ML INJ PS6 H IT
904152	CLEXANE 4KIU/0.4ML INJ PS6 H IT
904531	CLEXANE 40MG/0.4ML INJ PS2 GR
904532	CLEXANE 4KIU/0.4ML INJ PS6 H IT

Please note, we understand that batch 08001 in bold text above is only problematic in the 90mg/0.6ml strength listed above. We understand that batch 08001 has also been applied to other strengths of Clexane or Lovenox overseas packs of pre-filled syringes that are not affected.

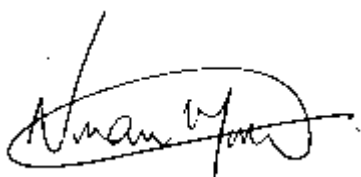
Parallel Importers who have processed any of the batches in the above table have been requested to contact the Defective Medicines Reporting Centre immediately on 0207 084 2574 irrespective of whether stock has already been distributed.

Recipients of this notice are reminded that Parallel Importers may modify the originators batch number by adding a prefix or suffix or use their own number. If you have any concerns about parallel import packs of Clexane pre-filled syringes you should contact the Parallel Importer for clarification.

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 Dispensing Doctors and GP's within **48 hours**

Yours sincerely



DR NORMAN MORROW
Chief Pharmacist

For information:

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Public Health Branch
DHSSPS, Library
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