Q&A RECALL OF CLEXANE SYRINGES

What is Clexane (enoxaparin) and what is it used for?
Clexane is a prescription only medicine with anticoagulant activity. It is authorised for the management of thromboembolic disorders (blood clotting), including DVT (deep vein thrombosis) and pulmonary embolus. It is also used in the treatment of cardiac conditions and in patients undergoing surgery.

Why is Clexane being recalled?
The Irish Medicines Board has instructed the product authorisation holder, sanofi-aventis, to initiate a recall of Clexane Syringes, 80mg / 0.8ml batch number 28043 to patient, pharmacy and wholesale level due to the potential for an over-concentration of up to 50% of the active substance, enoxaparin, in a number of syringes.

What batches are affected?
30 batches of Clexane are known to be affected by this issue. However, only one of these batches is known to have been distributed in Ireland and the details are as follows:

Product Name:	**Clexane Syringes, 80mg/0.8ml**
Batch number:	**28043**
Expiry:	**09/07**

When was the recall initiated?
The IMB instructed sanofi-aventis to initiate the recall as soon as it became aware of this issue on the evening of Thursday 9th February 2006.

How long has this batch of Clexane been on the market?
Packs of Clexane batch number 28043 have been distributed in Ireland since November 22nd 2005. This batch was distributed to 46 hospitals and 12 retail pharmacies.

How many patients are likely to have received this product to date?
It is estimated that approximately 500 patients may have been treated with the affected product.

What adverse reactions are known to be associated with this product?
The main adverse reaction associated with Clexane is bleeding i.e. an exacerbation of its intended action. In the affected batch, over concentration of the active substance has the potential to cause an increased risk of serious bleeding.

When are adverse reactions likely to occur?
Adverse reactions would be expected to occur around the time of treatment.

Have any adverse reactions been reported in association with this batch of Clexane?
To date the IMB has received one report of an adverse reaction (bleeding), which appears to have occurred since the affected batch was distributed.

How did the IMB become aware of this issue?

The product authorisation holder, sanofi-aventis, informed the IMB of the issue following receipt of information from their parent company regarding a problem identified during quality checks of the manufacturing process.

What regulatory action is the IMB taking?
In addition to the recall, the IMB is investigating the issue and will consider the need for further regulatory action.

Is this product manufactured in Ireland?
No, this product is not manufactured in Ireland.

What advice are you giving to consumers?
The Irish Medicines Board is advising all patients who have been dispensed Clexane Syringes since November 22nd 2005 as follows:

1. Check the pack(s) of Clexane Syringes which you have at home, or which you have with you.
2. Check if your pack is the 80mg/0.8ml strength.
3. If your pack is the 80mg/0.8ml strength, check the batch number. (The batch number is a Lot number printed on one side of the outer carton and on the vial label).
4. If the batch (Lot) number is 28043, then this pack is one of the potentially affected packs and **should not be used under any circumstances**.
5. If you do have a pack of batch number 28043 of Clexane Syringes 80mg/0.8ml, you should immediately put this pack in a safe place, and do not use this medicine.
6. You should, as soon as possible, go to your local doctor for further advice and treatment. The IMB can confirm that additional batches of Clexane are available in the marketplace.
7. Finally, any affected batches should be returned to your local pharmacy as soon as possible.