

Press release

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Medicines regulator advises healthcare professionals about heparin injection - Clexane

The Medicines and Healthcare products Regulatory Agency (MHRA) has been made aware by Sanofi-Aventis that some batches of Clexane (enoxaparin) on the UK market contain low levels of an impurity called over-sulphated chondroitin sulphate (OSCS). It must be stressed that there is currently no evidence that this is associated with any risk to the patient. If patients have any concerns however, they should contact their healthcare professional.

As it is important that patients continue to receive Clexane in a clinical setting, the Commission on Human Medicines (CHM) has advised that the product on the UK market can continue to be used and that prescribers should be reminded to be vigilant to possible ADRs. This advice has been communicated by the MHRA to healthcare professionals. It is important to note that there is no evidence of any increase in the number of ADRs as has been seen in other countries with other heparin products.

The MHRA has been informed by the manufacturer Sanofi Aventis that no more Clexane batches manufactured since 1 April 2008 are affected and should be in the supply chain from June 2008.

Ends

Notes to Editors

1. Clexane is an anticoagulant which stops blood clots from forming in the veins (thrombosis) or breaks up blood clots that have already developed in the veins.
2. OSCS is a complex sugar. People can eat chondroitin contained in supplements for arthritis. This impurity is chondroitin that is over-sulphated.
3. Clexane is not the same heparin product that has been implicated in a number of adverse drug reactions (ADRs) in the US and Germany. The heparin products affected in the US and Germany are not used in the UK. The ADRs in the US and Germany were from heparin products primarily manufactured by Baxter and

Rotexmedica respectively and included severe allergic reactions and low blood pressure, mostly occurring shortly after intravenous administration.

4. The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks. We keep watch over medicines and devices, and take any necessary action to protect the public promptly if there is a problem. We encourage everyone –the public and healthcare professionals as well as the industry – to tell us about any problems with a medicine or medical device, so that we can investigate and take any necessary action.

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