European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency recommends measures to manage contamination of heparin-containing medicines

The European Medicines Agency has reviewed the risks associated with the use of heparin medicinal products contaminated with oversulphated chondroitin sulphate (OSCS). Heparins are used to prevent and treat blood clots. They are used widely in patients who could have, or have had a heart attack, in patients who have undergone major surgery, or patients on dialysis.

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that:

- OSCS has been found in unfractionated (standard) and low-molecular-weight heparin;
- there is a link between contamination with high levels of OSCS and serious side effects seen in some patients who have received contaminated standard heparin. All batches of affected standard heparin have been identified by regulatory authorities worldwide and removed from the market;
- low levels of OSCS have also been identified in some batches of the low-molecular-weight heparin enoxaparin. However, no similar side effects have been observed when enoxaparin has been used. A total removal of contaminated enoxaparin from the market in countries where it is used would lead to a shortage of supply and patients would not be able to continue their treatment.

The Committee concluded that doctors can continue to use enoxaparin with low levels of OSCS to treat patients temporarily until the situation is resolved. However, a series of measures should be put in place to minimise the risk of side effects. These include:

- avoiding intravenous or intra-arterial administration of enoxaparin;
- monitoring patients closely for signs of allergic reactions. Patients should receive anti-allergy treatments if reactions occur;
- as a precautionary measure, avoiding administration to pregnant women if alternative products or uncontaminated enoxaparin are available.

The CHMP also looked at long-term approaches to minimise the possibility of future contamination. It recommended any inspection of the heparin supply-chain requires a coordinated approach between European and international partners and that modifications to the existing legal and regulatory framework for strengthening the supply-chain control should be explored with the European Commission;

Specific tests for OSCS and other possible contaminants should be included in the heparin monographs in the European Pharmacopoeia.

Heparin medicines are authorised at the level of the Member States. Country-specific advice and information on stocks and potential shortages are available in all affected Member States.

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Notes:

1. More information is available in a question-and-answer document.
2. The review was initiated by Germany under Article 5(3) of Regulation (EC) No 726/2004 following detection of a contaminant in a limited number of batches in some Member States of the European Union.
3. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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