

QSM/MC/IEA.118

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Information Exchange System

Alert No. 118

Contaminant detected in heparin material of specified origin in the USA and in Germany; serious adverse events reported; recall measures initiated

The United States Food and Drug Administration (US FDA) has detected a contaminant in Heparin active pharmaceutical ingredient (API) and crude heparin sourced from Changzhou SPL, Changzhou, China, as well as in the API from Scientific Protein Labs, Waunakee, Wisconsin U.S. In the U.S., this API was used in finished product distributed by Baxter Healthcare. This contaminant is a Heparin-like compound, but it is not Heparin. Heparin with this contaminant has been associated with serious adverse events (allergic symptoms with or without hypotension) and deaths in the U.S., although the US FDA has not established a causal link between the contaminated Heparin and the adverse events at this time. The US FDA does not know if the contaminant is naturally or artificially caused. As a precaution, Baxter healthcare has initiated a recall of all its batches of heparin sodium injection and heparin lock flush solution. Alternate heparin manufacturers are being contacted by the US FDA to ensure sufficient heparin production and supply in the US market.

German authorities have also recalled certain batches of Heparin-Rotexmedica manufactured by Rotexmedica GmbH Arzneimittelwerk. The Rotexmedica product was associated with adverse events similar to those associated with the contaminated Heparin in the U.S. The German authorities (BfArM) received reports of about 80 cases of serious adverse events (shock-like symptoms, decrease in systolic blood pressure, anaphylaxis) following the intravenous use of some batches of Heparin-Rotexmedica solution. Changzhou Quianhong Bio Pharma Co. Ltd., China and Yantai Dongcheng Biochemicals Co., China were the API manufacturers of some of the batches of the API which were then used in the manufacture of more medicinal product batches in Germany. The Agency has therefore initiated the recall of all the following affected batches:

70448, 70587, 70699: distribution center supplying e.g. dialysis centers in Germany, pharmacies, hospital pharmacies, wholesalers in Germany;

70030: Germany;

70056, 70136, 70276, 70097, 70137, 70279: worldwide.

Both US FDA and BfArM have issued Rapid Alerts on the above information. This WHO Alert is being issued for wider dissemination of this information and for appropriate actions in national settings as needed.

References:

1. Rapid alert notification of a defect (heparin material of specified origin). US FDA, 6 March 2008 (<http://www.fda.gov/cder/drug/infopage/heparin/default.htm>).
2. Rapid alert notification of a quality defect/recall (Heparin-Rotexmedica solution for injection). BfArM, 5 March 2008.