

European regulator launches review of recalled heart drug

August 2 2018

The European Medicines Agency (EMA) said Thursday it is conducting a review of the health effects on patients of a widely used blood pressure medication recalled around the world last month.

The regulator will analyse the impact of active ingredient valsartan, produced by Chinese manufacturer Zhejiang Huahai Pharmaceutical Company, after warnings of contamination by a cancer-causing impurity.

The company, listed on the Shanghai stock exchange, launched a global recall of the drug on July 18 following warnings by US and European regulators over the presence of N-nitrosodimethylamine (NDMA), which is believed to potentially cause cancer through long-term use.

In a series of pronouncements last month, Huahai said it had moved to suspend supply and had begun the recall.

Valsartan is a generic drug mainly used for treatment of high [blood pressure](#) and [congestive heart failure](#).

NDMA was an unexpected impurity believed to have formed as a side product after Huahai introduced changes to its manufacturing process in 2012, according to the London-based EMA.

It first issued an alert over the drug on July 5, and American regulators followed up with their own [warning](#) a week later.

The EMA repeated Thursday that there was "no immediate risk to patients" and they "should not stop taking their medicines without consulting their doctor or pharmacist".

The EMA said its review is being carried out by the Committee for Medicinal Products for Human Use, which is responsible for probing concerns over patient medicines.

Its opinion will be forwarded to the European Commission, which will issue a final legally binding decision applicable in all countries in the EU.

Huahai's stock has dropped more than 20 percent since the warnings first emerged in early July.

The company could not be reached for immediate comment on Thursday.

© 2018 AFP

Citation: European regulator launches review of recalled heart drug (2018, August 2) retrieved 25 April 2024 from <https://medicalxpress.com/news/2018-08-european-recalled-heart-drug.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.