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Chinese blood pressure pills sold in US recalled over cancer-linked ingredient

Company raises alarm, voluntarily suspends supplies in international market after detecting impurity

Topic | China Society

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A listed Chinese pharmaceutical firm that makes and sells generic drugs to the global market including the US and Europe, has recalled some of its products after finding that they may have been tainted by a cancer-causing substance.

Zhejiang Huahai Pharmaceutical – a major supplier of the active ingredient valsartan that it uses to make a generic blood pressure drug – raised the alarm and voluntarily suspended its supplies in the international market after detecting an impurity, N-nitrosodimethylamine (NDMA) in the product.

Huahai is a Shanghai-listed company based in Linhai, Zhejiang province.

Valsartan medicines are used to treat patients with high blood pressure to reduce complications such as heart attack and stroke. They are also used by patients who have had heart failure or a recent heart attack.

NDMA is classified as a probable human cancer-causing substance and is not expected to be found in the drug.

Huahai-produced active valsartan substances, sales of which topped 328.3 million yuan (US$49 million) last year, are mainly sold to North America, Europe, India, Russia and South America, according to a series of statements released by the firm over the past week.

Two generic drugs produced by Huahai that contained the problematic ingredient were also recalled. The two drugs are Valsartan, which entered the US market in September 2015, and Valsartan/Hydrochlorothiazide, which has been sold in the US since May 2016.

Some US$20 million of the two drugs were sold in the US last year and US$11 million for the first half of the year, according to Huahai's statement.

The US Food and Drug Administration issued a voluntary recall of two drugs on Friday. Photo: AP

The drugs obtained approval in China earlier this year but had not yet been sold in the domestic market.

The US Food and Drug Administration (FDA) issued a voluntary recall of the medication on Friday. The drugs have been distributed by Major Pharmaceuticals, Teva Pharmaceutical Industries and Solco Healthcare, according to the FDA.

"We have carefully assessed the valsartan-containing medications sold in the United States, and we've found that the valsartan sold by these specific companies does not meet our safety standards. This is why we've asked these companies to take immediate action to protect patients," said Janet Woodcock, director of the FDA's Centre for Drug Evaluation and Research.

China's drug safety worries FDA

[1]

European countries, including Germany, Italy, Finland and Australia, have recalled drugs using valsartan supplied by Huahai following the Europe Medicines Agency issuing an alert to review such drugs earlier this month.

In Europe, Novartis is recalling Sandoz' valsartan and valsartan HCT film-coated tablets in 23 countries.

"EMA's review will investigate the levels of NDMA in these valsartan medicines, its possible impact on patients who have been taking them and what measures can be taken to reduce or eliminate the impurity from future batches produced by the company," said an EMA statement. "As a precaution, the review will also consider whether other valsartan medicines may be affected."

Recall for five heart drugs containing valsartan that was made in China

[2]

The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured. Huahai said in its statement that all the process change has been reported to and approved by drug regulators.

Shi Lichen, founder of Dingchen Pharmaceutical Management Consulting, said the recall might affect the company's profits this year, but would not affect the image of Chinese generic drugs.

"Chinese-made generic drugs are not considered top-quality, anyway. The voluntary recall showed the company's research and development competence has reached a certain level and it is being responsible," he said.

The EMA advised patients not to stop taking valsartan medicine without professional advice.

The FDA said patients should continue with the recalled medicine until they have a replacement as valsartan is used to treat serious medical conditions.

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