Health Canada finds Zhejiang Huahai Pharmaceuticals site non-compliant with requirements for the manufacture of drug ingredients

Report a Concern (http://www.healthycanadians.gc.ca/report-signalez/index-eng.php)

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Issue

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For immediate release

Health Canada has found the Chuannan manufacturing site of Zhejiang Huahai Pharmaceuticals located in Linhai, China, to be non-compliant with requirements for Good Manufacturing Practices (GMPs) for the manufacture of active pharmaceutical ingredients. Health Canada's decision is based on a review of information from a recent inspection (https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM621162.pdf?utm_campaign=VALSARTAN UPDATE: FDA places Zhejiang Huahai Pharmaceuticals on impor&utm_medium=email&utm_source=Eloqua&elqTrackId=BDFAA40E6FA3F85B6257C0F5957CB1AE&elq=3a52b5dd97c8409b885959ec6b72d774&elqaid=5292&elqat=1&elqCampaignId=4221) conducted by the U.S. Food and Drug Administration (FDA).

GMPs are internationally accepted standards that help ensure that drugs are consistently manufactured, tested, stored and distributed in a way that meets Canada's high safety and quality standards.

A non-compliant rating means that Canadian companies can no longer import drugs that contain active pharmaceutical ingredients from this site unless they are medically necessary. Health Canada will allow the continued importation of medically necessary drugs under conditions that verify their safety, such as additional testing. At this time, no products containing active pharmaceutical ingredients from this site have been identified as medically necessary.

Health Canada is assessing what impact the non-compliant rating may have on products in Canada. This includes assessing possible effects on drug supply and whether measures may be needed to mitigate supply concerns or protect the health and safety of Canadians.

No products are being recalled at this time. It is important to note that a non-compliant rating does not necessarily indicate a product safety concern. It means that the Department has identified issues with how the company is following good manufacturing processes and procedures. Health Canada continues to monitor the situation. If at any point a safety concern is identified involving products from this site, Health Canada will take action and inform Canadians.

Zhejiang Huahai Pharmaceuticals is the manufacturer of the valsartan active pharmaceutical ingredient that, to date, is the only active ingredient from this site found to contain the impurities N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA) (https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67746a-eng.php). Health Canada reviewed the FDA inspection as part of its continuing assessment of the issue with valsartan. All drugs containing valsartan manufactured by Zhejiang Huahai Pharmaceuticals have already been recalled (http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67552a-eng.php?) in Canada. Health Canada continues to work with the European Medicines Agency, the U.S. FDA and other international regulatory partners to identify the root cause of the issue and to determine next steps, including identifying what measures may be needed to prevent the situation from reoccurring.

While Health Canada routinely assigns non-compliant ratings as part of regulatory oversight and does not necessarily communicate them to the public, the Department is updating Canadians on this latest measure as part of its commitment to keeping Canadians updated on its activities related to valsartan.

Background

The Chuannan manufacturing site of Zhejiang Huahai Pharmaceuticals in Linhai, China, produces active pharmaceutical ingredients that are used in the manufacture of finished drug products, which are then imported and sold in Canada.

The active pharmaceutical ingredients that are manufactured at this site are:

- candesartan, irbesartan, losartan, olmesartan, telmisartan, and valsartan, which are used in the manufacture of a class of drugs known as angiotension receptor blockers (drugs that are used to treat high blood pressure and heart failure);
- levetiracetam, which is used in the manufacture of an anti-epileptic drug;
- nevirapine, which is used in the manufacture of an antiviral drug; and
- repaglinide, which is used in the manufacture of an anti-diabetic drug.

Canadians with questions or concerns about any health product they are taking should speak to a health care professional. Canadians should not make any changes to their medication without first consulting with a healthcare professional.

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For more information

- Health Canada information update (2018-09-13): Second impurity linked to recalled valsartan drugs (https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67746a-eng.php)
- Health Canada information update (2018-09-10): Valsartan NDMA Health Risk Assessment (https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67734a-eng.php)
- Health Canada information update (2018-08-18): Teva Canada expands recall of valsartan drugs to include additional lots, as a precaution (http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67552a-eng.php?_ga=2.186111849.1130786600.1536540324-1989020253.1520525748)
- Health Canada advisory (2018-07-09): Several drugs containing valsartan being recalled due to contamination with a potential carcinogen (http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67202a-eng.php)

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