Prognosis

FDA Finds Carcinogen in Some Versions of Popular Diabetes Drug

By Anna Edney
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- Agency contacting makers of metformin with high NDMA levels
- Similar problems previously seen with stomach, heart drugs

U.S. regulators are contacting pharmaceutical companies that make a popular diabetes medication after some of the pills were found to contain high levels of a chemical that can cause cancer.

The Food and Drug Administration discovered N-Nitrosodimethylamine, or NDMA, beyond acceptable amounts in some extended-release versions of metformin, Sarah Peddicord, an agency spokeswoman, said in a statement to Bloomberg. The World Health Organization classifies NDMA as a probable human carcinogen.

People with type 2 diabetes take metformin to control high blood sugar. About 21 million prescriptions for the extended-release version were written in the U.S. last year, according to data compiled by Bloomberg Intelligence, accounting for roughly a quarter of metformin prescriptions overall.

Some metformin recalls are expected as soon as this week, though it wasn't clear which companies were planning to remove their products from pharmacy shelves, according to a person familiar with the matter. Metformin is manufactured for the U.S. market by numerous generic drugmakers worldwide.

"We cannot confirm or deny a recall action before it has taken place," Peddicord said. The FDA "will continue to take quick and appropriate action when needed to protect American consumers."

The agency hasn't found elevated NDMA levels in immediate-release metformin, Peddicord said. She said patients shouldn't stop taking the drugs without first consulting their health-care provider.

The FDA began investigating metformin in December after some versions of the medication sold in other countries were found to be contaminated with NDMA. In February, the agency said it hadn't found NDMA in excess of acceptable limits.

Metformin would be the third widely used medication in recent years to face recalls related to NDMA.

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Millions of blood-pressure pills known as angiotensin II receptor blockers were recalled beginning in July 2018 after being contaminated with the chemical during the manufacturing process, mainly at factories in China and India. The Senate Finance Committee is planning to hold a hearing next week to examine the FDA's ability to adequately inspect drug-production facilities overseas.

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Last month, the FDA asked for a recall of all versions of Zantac, which is also sold under the name ranitidine, after the agency determined that the chemical makeup of the stomach drug can cause NDMA to form and increase when stored at high temperatures.

The online pharmacy Valisure, which tests all the drugs it sells, had raised red flags about NDMA in Zantac in September and pressed the FDA for recalls. The agency had questioned the company's testing methods.

In March, Valisure did an analysis of regular and extended-releasemetformin and found NDMA exceeding acceptable limits in versions made by Amneal Pharmaceuticals LLC, Aurobindo Pharma Ltd. and Lupin Ltd., among other companies. Valisure again pressed the FDA to conduct recalls.

Amneal, Aurobindo and Lupin didn't respond to requests for comment.

In a report posted Tuesday, Valisure analyzed metformin sent to it by

people around the U.S. and found that of 128 samples, 36% contained levels of NDMA that exceeded daily acceptable limits set by the FDA.

"The presence of this carcinogen in metformin where multiple tablets can be taken daily and often for a lifetime diabetic condition, makes this finding particularly concerning," Deanna Akinbajo, chief pharmacist at Valisure, said in a statement.

Metformin was recalled in Singapore late last year and in Canada earlier this year because of concerns about NDMA contamination.