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CBS News

More blood-pressure pills recalled over cancer-causing chemical

By Kate Gibson

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Torrent Pharmaceuticals is expanding a recall of blood-pressure medication possibly tainted with a cancer-causing chemical. The expansion is the fifth by Torrent involving widely used losartan potassium tablets sold nationwide at retailers including Walmart. Regulators first moved to pull heart drugs with potentially deadly contaminants from store shelves last year.

The contaminant behind the latest Torrent recall is also the same one that prompted Novartis to halt distribution of generic versions of the popular heartburn drug Zantac earlier in the week.

Torrent on Thursday said it was recalling an additional five lots of medication used to treat hypertension after the discovery in the tablets of a chemical called NMBA (for N-Nitroso-N-methyl-4-aminobutyric acid).

The U.S. Food and Drug Administration for the past 14 months has overseen a slew of recalls for a type of generic blood-pressure medication produced in China and India and tainted with NMBA, NDMA (N-nitrosodimethylamine) or NDEA (N-nitrosodiethylamine.)

The FDA has said the impurities in the generic blood pressure pills known as ARB drugs (for angiotensin II receptor blocker drugs) may be the result of chemical reactions that occur in the manufacturing process or from the reuse of materials such as solvents.

If 8,000 people took the highest dose from recalled batches every day for four years, there would likely be one additional case of cancer over the life of those people, the agency estimates.

Torrent said it's only recalling lots containing NMBA above what the FDA considers acceptable for daily use. Overall, Torrent has recalled more than 300 lots of blood-pressure pills since the summer of 2018. It's among a dozen drugmakers that have recalled blood-pressure drugs made with active ingredients from suppliers in China and India.

Other companies to announce recalls include Mylan, Aurobindo Pharma, Camber Pharmaceuticals, Macleods Pharmaceuticals, Legacy Pharmaceuticals, GSMS Inc., WP Westminster Pharmaceuticals, Major Pharmaceuticals, Prinston Pharmaceuticals, Sandoz Novartis and Teva Pharmaceuticals.

While regulators were mostly concerned about the class of hypertension drugs known as ARBs, the FDA and Europe's top drug regulator last week said they were reviewing NDMA levels in Zantac and its generic forms.

Within days, Novartis' Sandoz unit said it was stopping worldwide distribution of generic versions of Zantac.

The maker of Zantac, Sanofi, said it had no plans to halt distribution or sales of the medication in the U.S. or Europe, citing FDA reports that mere trace amounts of NDMA were identified. "We are conducting our own robust investigations to ensure we continue to meet the highest quality safety and quality standards," Sanofi said in a statement.

"Systemic problem" among multiple manufacturers

One consumer advocate, however, called on the FDA to step up its efforts, saying distribution stoppages and even recalls are insufficient responses to what the advocated called an ongoing public health threat.

The FDA should consider requiring any generic manufacturer that has had these issues to stop production until the issues have been resolved, according to Adam Garber, consumer watchdog at U.S. PIRG.

Short of curtailing production, the FDA "should be inspecting every version of this medication, since it seems to be a systemic problem, and it's multiple manufacturers that we're talking about," Garber told CBS MoneyWatch.

"At this point we should be looking at alternative versions, and stopping the sale of the versions that do have these impurities," said Garber, who stressed he was not advocating people taking heart medication to stop, given the potential adverse health risks that move would entail.

An FDA spokesperson said the agency has identified numerous alternative versions and offers an official list of affected products and products without impurities for the public to review.

"Based on our current assessments, including lab testing, the agency has identified 43 ARB medications that have been determined not to contain any nitrosamine impurities," the spokesperson emailed. "As we continue our assessments and as companies continue to manufacture ARBs without nitrosamine impurities to replenish the U.S. supply, we expect this figure to rise."

"Because ARBs treat serious medical conditions, the FDA urges patients to continue taking their current medicine until a doctor or pharmacist gives a replacement or a different treatment option," the spokesperson added.