MedicalXpress

J&J recalls 32M contraceptive packages outside US

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Johnson & Johnson is conducting a voluntary recall of millions of oral contraceptive packages in 43 countries outside the U.S., but the health care giant says there's a "very low" risk that the flawed tablets could cause unplanned pregnancies.

It's the latest in a series of about 40 product recalls announced by the U.S.-based company since 2009.

The birth control pills are being recalled—from pharmacies and wholesalers, but not from women—because tests last month showed one of the two hormones in them was being released more slowly than it should.

The recall technically covers all 179 lots, or batches, of the contraceptive Cilest distributed since 2011 in Europe, Asia and Latin America. Each lot contains about 180,000 monthly contraceptive packages, meaning more than 32.2 million packages are covered. Only about 800,000 packages are estimated to still be in inventory at wholesalers and drugstores.

Medicine manufacturers are required to hold back samples from the lots they produce for periodic stability testing. While the two-year-old packages had been fine, tests last month showed that the female hormone in the pills, norgestimate, was no longer dissolving at the specified rate, said Michelle Romano, a spokeswoman for J&J's Janssen Pharmaceuticals business.

"There's no impact on safety or efficacy. Women are not likely to get pregnant," so the packages are not being recalled from individual consumers, Romano said. She said women with questions should contact their doctor.

J&J has been wrestling with trying to upgrade manufacturing plants while it slowly restores supply of recalled products to the market. The company is operating under an agreement with the Food and Drug Administration requiring increased inspections and oversight at the factories involved. Lost product sales and factory upgrades have cost J&J well over $1 billion.

In trading Tuesday, J&J shares fell 61 cents to $84.10.

The prior recalls mostly covered nonprescription medicines such as adult and children's Tylenol and Motrin, but they have included faulty hip implants and contact lenses. Reasons range from contamination with bacteria and incorrect levels of a drug's active ingredient to liquid medicines that may contain metal particles and nauseating smells on containers.

J&J CEO Alex Gorsky and his predecessor, Bill Weldon, have pledged to resolve problems, but they continue.

Over the last four months, J&J has recalled Adept hip implants that were failing and had to be replaced prematurely, OneTouch VerioIQ blood glucose meters that shut off rather than issuing a warning when blood sugar levels get dangerously high, Children's Tylenol made in South Korea that contained too much acetaminophen and versions of K-Y Jelly personal lubricant that potentially never got required regulatory approval.