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US recalls organ storage fluid over contamination fears

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A major US pharmaceutical company on Thursday issued a wide-spanning global recall of the fluid used to store organs for potential transplants over fears it could be contaminated.

Bristol Myers-Squibb (BMS) said it is recalling the fluid, called Viaspan, across much of Europe as a part of its investigation into the problem that was detected March 19 at a third-party manufacturing facility in Austria.

BMS issued the recall after tests found bacteria in the solution used to monitor the sterility of the storage fluid.

"We are urgently investigating the cause of this issue," the company said in a statement.

"BMS has notified all health authorities in countries where the product is distributed and will provide further updates as the investigation progresses."

Spokesman Ken Dominski told AFP the recall was being issued as a precautionary measure and no evidence of actual contamination had yet been found.

"No evidence has been found at this point (that this) manufacturing issue by our third party manufacturer could lead to a product contamination and therefore we are issuing the recall as a precautionary measure."

The recall applies to Viaspan 50mg/ml in Australia, Italy, Estonia, Slovenia, Argentina, Chile, Germany, France, Ireland, and the United Kingdom -- all places where there are available alternatives.

The company is working with health authorities in countries where a substitute is not available to find alternate solutions -- including Croatia, Finland, New Zealand, Switzerland, Latvia, Lithuania, Spain, Sweden, Norway, Denmark, Netherlands, and Belgium.

"BMS will be working with the local health authorities to find alternative solutions for patients, and sending a Dear Healthcare Provider Letter to physicians which includes a review of the benefit/risk for patients," a statement said.

The company does not sell the fluid in Asia or the United States, so those markets are unaffected, Dominski added.

The British government confirmed that there had been a global recall of the fluid used to store most of its donor organs over fears it may have become contaminated.

The bacteria Bacillus cereus was found in the production line of Viaspan, the world's "gold standard" organ storage fluid, a spokesman for Britain's Medicines and Healthcare products Regulatory Agency (MHRA) told AFP.

The British government stressed that no patients had reported any adverse reactions following transplants, and that it would still use organs currently stored in the fluid.

"Our priority is to ensure patients are safe," said Sally Davies, the government's top health advisor.

The bacteria can cause diarrhea, nausea, vomiting and stomach cramps, but patients can be prescribed antibiotics before their operation as a precautionary measure.

"There is currently no evidence of any problems in patients who have recently had transplants where Viaspan has been used.

"If we were to recall the product immediately it is clear that patients would suffer and some may die," she explained.

The last production-line tests were carried out in July, so any fluid produced since then is at risk of contamination.

The results of ongoing tests on batches on Viaspan are due within two weeks, according to the British health spokesman.