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EU suspends sale of 700 generic drugs made in India

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European Union nations have until August 20 to suspend the sale of some 700 generic drugs made in India, the EU's executive confirmed on Monday.

The European Commission took the action after an Indian firm contracted by drug companies to test the medications was found to have manipulated data.

On-site verifications last year at GVK Biosciences showed irregularities "in each and every one of the nine trials inspected," the European Medicines Agency said in a May report recommending the suspension.

The broad scope of the problems, which stretched back years, "highlights critical deficiencies in the quality system in place at GVK Bio's clinic in Hyderabad," the EMA said.

The company tests for "bio-equivalence," to see if the generic versions of drugs are identical in impact to the original.

Commission officials were quick to say that there was no reason to suspect the drugs—including some brands of common pain relievers such as ibuprofen—had caused any health problems, or that suspending sales would create shortages.

"There is no evidence of harm or lack of effectiveness," a spokesman said.

Removing the medications from shelves "has been important both for ensuring patient safety and for retaining the confidence in the EU marketing authorisation system," he added.

Several European nations—including France, Germany, Belgium and Luxembourg—did not wait for the EU to act, blocking sales in December or earlier this year.

A few of the medications covered by the suspension have already been reauthorized based on data from other inspection centres.

The decision in Brussels was published on July 20, and specified that EU members had one month to comply.

Countries that declare a particular drug to be "critical" can take up to 24 months to implement the measure, the Commission said.

Specifically, GVK Bio was found to have manipulated electrocardiograms (ECGs).

"Even if ECGs do not provide the most essential data for testing bio-equivalence, GVK did not respect good practices," noted Francois Hebert, deputy head of France's National Agency for Medicines and Health Products Safety, which carried out the inspections.