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Half of all safety warnings issued to drug manufacturers in India and China

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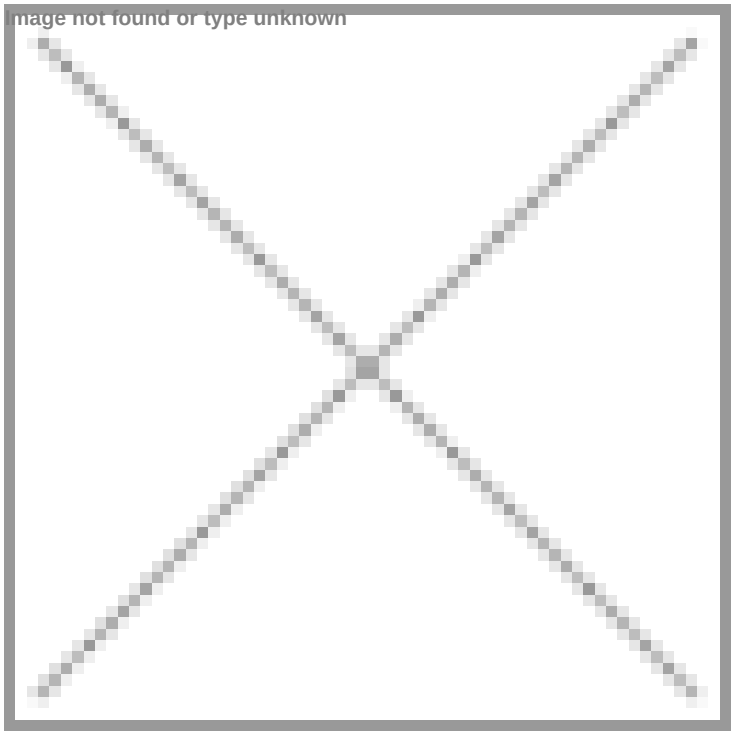
he number of regulatory breaches at drug manufacturing sites in India and China raises concerns about the fragility of the global supply chain, says a report by The Pharmaceutical Journal



According to a report by *The Pharmaceutical Journal,* The majority of warnings from European and US drug regulators are to drug manufacturing sites in India and China, raising concerns about the fragility of the global supply chain.

The analysis of publically available data by *The Pharmaceutical Journal* shows that from early 2018 until August 2019, the FDA's Office of Manufacturing Quality has published 75 warning letters to pharmaceutical manufacturers that have violated its safety and/or quality standards. Half of these warning letters (49%) — which could result in the regulator taking enforcement action — were sent to companies based in China (18) or India (19).

In the same period, the European Medicines Agency published 22 compliance notices, of which 14 (64%) were for medicines manufacturers based in India or China, said the report

The figures are being analysed after several incidents at factories in India and China have caused global shortages of essential medicines, mentioned the report.

In June 2018, regulators around the world recalled thousands of batches of valsartan-containing products that were found to

be contaminated with potential carcinogens. The affected products were detected during inspections of two factories in China.

In 2016, an explosion at a factory in China — a major producer of the API for piperacillin-tazobactam — caused severe global shortages.

Compliance notices are issued when manufacturers do not comply with the standards of Good Manufacturing Practice, as provided by EU legislation.

As a result of the compliance issues, regulators put restricted bans or special measures in place instead of suspending or closing the manufacturer as doing so could have caused critical medicines shortages — including for the broad-spectrum antibiotic piperacillin-tazobactam.