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Sandoz recalls wrongly-packed TB drug batch from 5 States

Drug made by third-party manufacturer Themis Medicare

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Drug-maker Sandoz has been asked to recall a batch of wrongly-packaged tuberculosis (TB) drugs from the market. The incorrect packaging was first discovered in Mumbai and the recall will cover five States.

Maharashtra Food and Drug Administration (FDA) Joint Commissioner S. D. Patil said Sandoz has been asked to recall all 4D and 4D-Plus batches of the tuberculosis combination product after a Mumbai-based doctor complained that his patient suffered from stomach ache and vomiting.

"There has been a mix up in the packaging of two products (4D and 4D-Plus), and so all stocks from the private market, stockists and retailers have been recalled," said Patil. The products have been made by a

third-party manufacturer, Themis Medicare of Haridwar. The State FDA in Uttarakhand has also been alerted, he added.

A Sandoz spokesperson said that while 4D was marketed across India, "according to our records, this particular batch is restricted to the domestic private market in the five States of Gujarat, Madhya Pradesh, Maharashtra, Bihar and Chhattisgarh."

Confirming that the third-party drug maker was Themis, the spokesperson added that as investigations were still on, more details were not being shared.

Themis representatives were not willing to comment on the development.

As a precautionary measure, Sandoz is recalling one batch of the product (No DD 4670) pending further investigation.

"In addition, we are investigating a potential second fault related to 4D-Plus, also used to treat tuberculosis, and of a higher strength," the spokesperson said.

RESISTANCE CONCERNS

Though details on the quantum of stocks recalled are not available, the FDA official clarified that the problem did not relate to all stocks. But they were being recalled "as you cannot take a chance with TB drugs".

India faces a huge problem of resistance to tuberculosis drugs, wherein medicines become ineffective in treating patients. Resistance occurs when patients do not follow a doctor's advice and discontinue the medicine or take it erratically.

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