

Health Canada issues import ban on Apotex India, Ipca Labs

Raises yet another question mark on India-made drugs

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IN a yet another incident that could draw attention to the alleged quality irregularities of India-made drugs, Canada's health regulator has halted the import of products from three drug manufacturers- IPCA Labs, Apotex Pharmachem and Apotex Research on account of 'serious doubts about quality' of the products manufactured in India.

"The action applies to finished products from ARPL (Apotex Pharmachem), as well as active pharmaceutical ingredients and products made with APIs from Apotex and IPCA. Certain medically necessary products may be excluded from the action on the condition they are tested by an independent third party before being released for use or sale," the federal agency said in a statement.

The health products watchdog website points out that the action was taken after data integrity issues were first identified at each of these sites by the US food and drug administration.

Health Canada also says that based on the information gathered so far, there are "significant concerns with the manner in which data are collected and reported raising serious doubts about the quality and safety of finished products and APIs produced at these sites."

However, the additional precautionary steps are only until the agency is sat-



Under scrutiny

■ The health products watchdog website said that the action was taken after data integrity issues were identified at these sites

■ For the APIs manufactured by IPCA, importers include Ranbaxy, Teva, Mylan and others

■ In July, IPCA had voluntarily halted shipments of its APIs, manufactured at the Madhya Pradesh facility, to the US markets

■ Health Canada says that based on the information gathered so far, there are "significant concerns with data"

isfied with the production processes. This should not encourage consumers to change medicines in the prescription, as there have been no recalls yet, the regulator said.

"But when trust between a regulator and a company is broken, strong actions are required. The import ban will remain in place until such time as the Department is satisfied that the data integrity problems have been resolved," federal minister of health (for Canada) Rona Ambrose said in another statement.

For the APIs manufactured by IPCA, importers include Ranbaxy, Teva, Mylan, Sandoz, Silem among others, according to the list of finished products put by the regulator. While IPCA is India based, Canada's Apotex has a manufacturing and research facility at Bangalore in the country.

"New powers proposed in Vanessa's Law (Bill C-17) will provide the tools to better respond to drug safety issues including powers to order mandatory recalls of unsafe drugs so that Health Canada does not have to negotiate with

companies when safety issues are identified, tough new fines for companies who put Canadians at risk, and the authorities required to publish even more data from drug reviews and clinical trials," she said.

In July this year, IPCA had voluntarily halted shipments of its APIs, manufactured at the Ratlam (Madhya Pradesh) facility, to the US markets. The company had received Form 483 inspection observations from the USFDA.

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Regulatory