

# Health Canada enforces import ban on Dr Reddy's and Ipca Lab's products

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**Mumbai:** In another setback, Indian drug manufacturers have now come under the scanner of the Canadian health regulator, Health Canada. A number of pharma companies are already under the lens of the US Food and Drug Administration (FDA) over compliance-related issues.

Health Canada, on Tuesday, said that Canadian importers have agreed to stop the importation and distribution of products from the Srikakulam facility of Dr Reddy's Laboratories and Pithampur facility of Ipca Laboratories.

The Canadian medical regulator in its website said, "At Health Canada's request, Canadian importers have agreed to quarantine health products from the following two India-based sites due to data integrity concerns. This action comes in light of recent information from a trusted regulatory partner that raises concerns about the reliability of the laboratory data generated at these sites. Health Canada is taking this action as an interim precautionary measure to help mitigate any potential risk."

The agency further said that at this time there is no identified risk to health, and Health Canada is not requesting a recall of any of the products.

Health Canada's action applies to active pharmaceutical

## Drugs under the scanner

List of products manufactured at Dr Reddy's API facility

Company	Product name
Mylan Pharmaceuticals	Mylan - Domperidone
Pharmascience	Desloratadine Allergy Control
	PMS-Domperidone
	PMS-Valsartan
Sandoz Canada Inc	Sandoz Cefepime
	Sandoz Naratriptan
Teva Canada	Teva - Naratriptan

List of finished products from IPCA Laboratories

Company	Product name
International Pharmaceutical Generics (IPG)	Quetiapine
Jamp Pharma	Jamp-Quetiapine
Marcan Pharmaceuticals	MAR-Quetiapine
	MAR-Tramadol/Acet
Mint Pharmaceuticals	Mint-Ondansetron
	Mint-Tramadol/Acet
Pharmaper	PRVA-Quetiapine
Ranbaxy Pharmaceuticals	RAN-Tramadol/Acet
Riva Laboratories	RIVA-Tramadol/Acet

Source: Health Canada

ingredients (APIs) from Dr Reddy's Laboratories as well as to finished drug products from a different Ipca Laboratories facility than is currently subject to import restrictions by Health Canada. Health Canada has compiled an initial list of products affected by the quarantine. "To date, none of the affected products have been determined by Health Canada to be medically necessary," the agency added.

Only a few months back, Health Canada, took action against Ipca Lab raising concerns over reliability of data on "safety and quality" grounds and issued an import ban on the products manufactured at one of its facilities.

A spokesperson of Dr Reddy's said, "We have voluntarily placed under quarantine all APIs and the formulation based on APIs produced at our API facility in Srikakulam district of Andhra Pradesh intended for use in Canada."

We believe our APIs and finished drug products manufactured using these APIs pose no risk to the health and safety of the Canadian people. At this stage, production is continuing in the normal course and we are working with the agency for a satisfactory resolution of the matter."

Both Srikakulam facility of Dr Reddy's and Pithampur facility of Ipca Lab have recently come under the scanner of the

US FDA. The US drug regulator has issued Form 483 to both these facilities and raised nine inspectional observations on Hyderabad-based Dr Reddy's Srikakulam facility. According to a research report by an international brokerage, FDA also raised six observations on the Ipca's Indore facility out of which two are critical observations and could delay recovery of Ipca's US sales.

Earlier in July this year, Ipca voluntarily stopped shipments from its APIs manufacturing facility at Ratlam (Madhya Pradesh) after an US FDA inspection raised certain observations in Form 483.

The company had then said that it temporarily suspended the shipments till the issue is addressed. It had also said that the decision would impact the company's formulations export business to the US market since the formulations manufacturing units at Piparia (Silvassa) and SEZ, Indore (Pithampur) use the API manufactured from the Ratlam facility.

Sarabjit Kour Nangra, VP research - pharma, Angel Broking, said, "The US FDA, being the reference for the Health Canada, it is likely to rely on US FDA's inspection and their reports to take future course of action. Both Dr Reddy's and Ipca Labs do not derive significant revenues from these facilities and hence we don't think the development would have an impact on the companies."

Regulatory