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Canadian regulator aks Ipca to halt API exports

Pallavi All
Mumbai, Sept 21

Health Canada has said it has requested Ipca Laboratories to voluntarily stop shipping active pharmaceutical ingredients (APIs) to Canada following adverse observations by the US Food and Drug Administration, during its inspection conducted in July.

Bitter pill

- Health Canada issues notice Sept 17 asking Ipca to stop API shipments voluntarily
- Ipca has only one facility which manufactures APIs in India located in Ratlam, Madhya Pradesh
- Health Canada notice comes within 2 months of company halting shipments to US following receipt of Form 483 for Ratlam facility
- Regulator says it issued notice after noting observations in the USFDA inspection

The Canadian regulator said it initiated the request, "based on a review of a recent good manufacturing practices (GMP) inspection report by the US Food and Drug Administration (FDA) where they identified falsification and manipulation of data issues at the company."

"Ipca has not disputed the FDA findings with Health Canada," the regulator said. Health Canada expects the halt in shipments would adversely affect approximately 21 active APIs.

"The Department has also asked Canadian companies that import product containing APIs from the Ipca facilities to temporarily quarantine these products," the notice said.

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Regulatory

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largely to APIs - which is a low revenue, low margin product. The impact could be about 1% of total consolidated sales with barely a dent on the EBITDA," Aditya Khemka, senior analyst at Ambit Capital said.

The Mumbai-based company posted net profit of Rs 478.5 crore on net sales of Rs 3228.7 crore for fiscal 2014.

The Health Canada notice comes within two months of the company voluntarily halting shipments of APIs manufactured in its Ratlam facility in Madhya Pradesh. The company management, during a conference call said that the US health regulator made six observations in the Form 483, of which two were related to data integrity. "The USFDA usually views data integrity issues seriously," said Nitin Agarwal, an IDFC Institutional Equities analyst, who tracks pharmaceutical space.

As a result of the stoppage, the company's formulation manufacturing units located in Silvassa and Indore were also adversely affected as both used APIs produced at Ratlam.

"Management indicated in the conference call that FY15 revenue growth guidance, assuming impact from voluntary stoppage of shipment at Ratlam plant through the year would be 12% vs. 17-18% guidance previously," JP Morgan analyst Neha Manpuria said in a note dated August 1.

US business would also be impacted with management pegging the potential effect to be approximately Rs 296 crore in FY14, which is about 9% of revenue, the JP Morgan report said.

"Third-party sourcing arrangement is not viable for short-term disruption and management expects to increase supply to Europe markets from the Indore SEZ facility," Manpuria said adding that the management said it does not expect the voluntary stoppage impact development work or ANDA filing processes from the formulation plants, but the company could look at risk mitigation measures for filings going forward.

Ipca had said in July that it appointed US-based Lachman Consultants to advise them on the manufacturing discrepancies and will incur $1 million as fees for the process.

They said, according to analysts, that expected to tackle the issues within the next six months.

Ipca shares have dropped about 7% from July 24, when it first made an announcement of the issues with Ratlam facility. The company's shares have been up 13% for the 12-month period till July 24. Ipca's shares closed up 0.4% at Rs 781.30 on Friday on the Bombay Stock Exchange.

Canadian...

The Canadian regulator did not name the facility in its notice but analysts believe it could be the company's Ratlam facility since it is the company's sole API production unit. "Canada is a small market for Ipca. The shipment halt pertains