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SECTION: Main Story**LENGTH:** 741 words**HEADLINE:** Ranbaxy's North American Revenues Set to Plummet as Canada Quarantines Paonta Sahib-Manufactured Drugs**BYLINE:** Anupama Bharath**BODY:**

Ranbaxy (India) has agreed to the Canadian regulator's request of quarantining all drugs currently being sold on the country, which are being manufactured at its Paonta Sahib facility in India

Ranbaxy Drugs Quarantined in Canada

Drug regulator Health Canada has requested generic major Ranbaxy (India) to prevent all drugs manufactured at the Paonta Sahib facility, in the Indian state of Himachal Pradesh, from entering the country, reports The Canadian Press agency. Ranbaxy has agreed to this request, the source added.

IHS Global Insight Perspective**Significance**

Ranbaxy's drugs manufactured at its Paonta Sahib facility will not be marketed in Canada until further notice. The development has come in the wake of Health Canada requesting the firm to quarantine import of drugs manufactured at this facility. However the number of drugs affected is not known.

Implications

The Canadian regulator's decision has been influenced by the U.S FDA that has listed Ranbaxy's pending and approved ANDAs (Abbreviated New Drug Application) from its Paonta Sahib facility on the agency's Application Integrity Policy (AIP). According to the U.S FDA Ranbaxy allegedly falsified data on drugs manufactured in this facility to gain marketing approval.

Outlook

The current development will see Ranbaxy's revenues from the North

American market further plummet. As in the case of the U.S, whether the firm will write off some of its Canadian drug inventory in the first quarter of the year remains to be seen.

Ranbaxy currently has approximately 58 product licenses from the Canadian regulator to sell generic versions of some statins, antibiotics, diabetes, and schizophrenia drugs. These are available in multiple-dosage forms and strengths in the country. Given below is the list of molecules sold by the generic firm in Canada.

Molecules Sold by Ranbaxy in Canada

Atenolol	Lovastatin
Carvedilol,	Metformin
Cefprozil	Ondansetron
Ciprofloxacin	Pantoprazole
Citalopram	Pravastatin
Domperidone	Rabeprazole
Fentanyl	Ramipril
Fosinopril	Risperidone
Gabapentin	Tamusolin
Lisinopril	Zopiclone

Source: Health Canada

The Canadian drug regulator and Ranbaxy have not revealed how many of the latter's drugs will be affected by the directive. The regulator has also not offered advice to the Canadian population currently taking the drugs. However its is reportedly reviewing information on the site and the products under question to determine if there is a risk to health and to determine if further regulatory action is necessary.

Outlook and Implications

The above development comes in the wake of the U.S. FDA halting review of new and pending applications from Ranbaxy's Paonta Sahib facility last week due to the Indian firm allegedly "falsifying" laboratory tests in order to receive marketing approval in the United States (see **United States - India: 26 February 2009**:). This was brought to light in July 2008, when U.S. federal authorities decided to sue Ranbaxy, however the legal motion was later withdrawn when Ranbaxy provided the U.S. Department of Justice with all the necessary documents in relation to the alleged "falsification of data" case.

The recent FDA decision will not affect Ranbaxy, as all drugs from this facility have previously been banned from being sold in the country due to certain manufacturing deficiencies. However, the quarantine will mean Ranbaxy's revenues from Canada will dip in the first quarter of 2009 (calendar year). While Canada is a relatively small revenue source for Ranbaxy, at 3% of total sales for 2008, the region still reported the highest year-on-year growth rate (97%) over the same period. Revenues from this region have helped buffer some of the losses Ranbaxy has suffered under the U.S. ban on 30 of its drugs, since the third quarter of 2008. As in the case of the United States, whether the first quarter results will mean Ranbaxy writing off some of its Canadian inventory remains to be seen, and depends on how long the quarantine period lasts.

Ranbaxy's solace over 2009, particularly the first quarter, is the fact that its main source of revenue is derived from emerging markets in Asia and the CIS region. Given no bad news from European Union regulators, Ranbaxy's revenues from this region seem to be safe for now.

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Amid an increasing number of issues related to its Paonta Sahib facility, it is vital for Ranbaxy to hasten its search for a new FDA-approved facility and begin exporting its previous volumes to the North American markets.

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