

Financial Chronicle, Delhi
Saturday 1st March 2014, Page: 1
 Width: 25.95 cms, Height: 17.76 cms, adf, Ref: pmIn.2014-03-01.51.6

RIGHT DOSE

Indian pharma must address quality concerns to penetrate global markets deeper

SUDHONT KANUNGO & TRISHNA UDEKAR
 Mumbai/Hyderabad

INDIAN drugmakers are finally sitting up to take note of how to make medicines the healthy way. They have been forced to tweak age-old practices by cleaning up hygiene issues at their plants. And it's not because the drug controller at home insisted that they get their basics right.

As local generic makers corner a bigger slice of the first-world healthcare market, selling cheaper alternatives to high-priced innovations by big pharma, they are coming under heightened scrutiny by foreign regulators, particularly the US food and drug administration (FDA) and the UK's medicines and healthcare products regulatory

agency (MHRA), on the globally-accepted best manufacturing practices.

The enhanced probes and recent instances of non-compliance on quality and manufacturing practices by Ranbaxy and Wockhardt are cases in point. Some 526 drug manufacturing facilities are approved by the FDA in India. Some 78 of these were issued Form 483s by the FDA, which is 20 per cent of all the Form 483s issued to foreign drugmakers in FY13, ending September 30.

A Form 483 is issued by FDA to notify the company's management of objectionable conditions. Companies must respond in writing to these objections and clarify the corrective steps they are taking, and then, of course, go on to implement the plan.

Worse, till February 19, some 31 Indian manufacturing facilities were under the FDA's import alert, with Ranbaxy's Roansa facility the latest to join the list on January 24.

According to India Ratings and Research, a Fitch group company, the USFDA issued 43 import alerts against pharmaceutical facilities during 2013, of which 21 facilities were in India, taking India's share to 49 per cent of the total.

from to P6
 20% of US import alerts for Indian products P9
 like up this challenge is the standards P10
 Markets must change P11
 Opportunity in costs P12

Musellan