

BETTER MEDICINE

US FDA to continue focus on India's pharma companies

Himani Chandna Gurtoo

✉ himani.chandna@hindustantimes.com

NEW DELHI: The US health regulator — Food and Drug Administration — which cracked the whip against many Indian pharmaceutical companies in the year gone by including Ranbaxy Laboratories and Wockhardt, will continue to focus its attention on non-compliant companies.

“We will continue to focus our attention on non-compliant companies and facilities that are engaging in unacceptable quality and data integrity practices,” Christopher C Kelly, spokesperson, USFDA told *HT* via e-mail. “We will use all available enforcement tools to bring these facilities into compliance to ensure the public health is protected.”

The FDA's concern is understandable, considering that nearly 40% of the generic drugs and over-the-counter products sold in the US come from India.

The regulator expects Ranbaxy to pull up its socks and address its concerns. “Once the agency is satisfied that Ranbaxy has addressed its manufacturing issues at the Mohali facility, the company will be permitted to resume manufacturing and distribution of FDA-regulated drugs (from Mohali),” Kelly said.

The FDA plans to follow in India the same system of facility inspections as in the US and other developed countries. “India has become a priority location for the FDA as it houses the largest number of FDA-approved drug manufacturing plants outside the US,” said Hitesh Sharma, national leader, life sciences, Ernst & Young. “It is also emerging as the largest exporter of generic drugs to that country.”



BITTER PILL

Indian drug makers have been under the lens of the US regulator. A look at the story so far

WOCKHARDT

✉ Its plant at Chikalthana in Maharashtra gets rap from UK's drugs regulator in Oct and US FDA in Nov 2013

RANBAXY

✉ In May, the company is found guilty in US and pays \$500 million as fine

✉ In Sept, its third plant in India is hit by a US import ban over quality concerns

STRIDES ARCOLAB

✉ A plant of its unit Agila Specialties gets a warning from the FDA after an inspection in June

US: AN IMPORTANT MARKET

\$4.23 bn Or ₹25,800 crore: India's pharma exports to the US in 2012-13, up 32% Y-o-Y

40% India's share of generic and OTC drugs sold in US

TOP EXPORT DESTINATIONS

US	27%
European Union	19%
Africa	17%
West Asia	7%
Latin America	6%
CIS Countries	5%

Regulatory