

# Drug exports: Indian pharma's charm offensive

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India is launching a campaign to repair its reputation as a global supplier of cheap high-quality drugs, responding to bans imposed by US Food and Drug Administration (FDA) on several suppliers.

As part of the charm offensive, New Delhi has invited global regulators, including the FDA, to visit Indian production units to get first-hand evidence of measures taken to ensure the quality of locally manufactured generics.

The move seeks to address US quality concerns that have prompted the FDA to slap a slew of sanctions on Indian generics, choking off growth in drug exports.

"Our quality standards are among the best in the world. If a neutral audit is done, it will find our true capabilities and strengths," Ashutosh Gupta, chairman of the Pharmaceuticals Export Promotion Council (Pharmexcil), which groups more than 3,700 exporters.

"The US is the biggest market for us. We are dealing with a lot of care. We want to fight these issues head on," said Gupta, also executive director at Medicaments, which supplies anti-malarials and other drugs to over 80 countries.

Worries about quality control in India's \$15 billion drug industry have come to the fore in the past year as plants run by Ranbaxy Laboratories Ltd and rival Wockhardt Ltd have been barred from sending drugs to the United States after falling

short of the FDA's "good manufacturing practices".

The FDA has also issued import alerts — allowing the FDA to automatically detain products — to more than 20 Indian facilities since January 2013 on quality concerns, including plants of Ranbaxy, India's top drugmaker, and Sun Pharmaceutical Industries Ltd.

That has hurt India's reputation as a supplier of safe, affordable drugs. Exports grew by just 2.6 per cent in the 2013-14 fiscal year ending in March to \$15.04 billion. Two years ago, the growth rate was 23 per cent.

Gupta said the FDA has issued import alerts over issues of data documentation, testing facilities and procedures at Indian facilities. However, there was no issue with drug quality, he said. New Delhi plans to strengthen oversight following a US threat to launch a special review of India's regulation of drug patents and rule on market access to US companies.

It is also inviting Washington to hold broader trade talks once a new government is formed after a general election. Opinion polls show that opposition nationalist Narendra Modi's Bharatiya Janata Party (BJP) is likely to win the vote that ends on May 12. Results are due on May 16.

## Brand Pharma

India is second only to Canada as a drug exporter to the United States, where it supplies about 40 percent of generic and over-



**India wants neutral audits at its plants to gauge the true capabilities and strengths of its pharma firms**

the-counter drugs. The industry, which supplies drugs to nearly 200 countries, is concerned that curbs by the FDA have encouraged even regulators from Kenya and Ghana to seek plant audits.

"It is a challenge for us," P V Appaji, director-general of Pharmexcil, told reporters. "But in future, it can be a positive for us because it will help us improve the dark areas."

The industry, in collaboration with the Ministry of Commerce, is organising the IPHEX international summit in Mumbai

from May 21-23 to address buyer concerns. Over 500 importers and 25 regulators from US, Europe, Africa and Latin America are likely to attend the meet, some of whom would visit plants and meet Indian regulators. The exporter body has also invited FDA and India regulators to meet suppliers in Hyderabad, Goa, Chandigarh and Ahmedabad to create awareness about required standards.

## Operating procedures

"We are upgrading standard operating procedures in plants such as testing, documenting and packaging," Gupta told a news conference. Trade Ministry officials said the government planned to spend up to Rs 3,000 crore (\$500 million) over five years to strengthen pharmaceutical education and research and train manpower and state regulators.

"There can be no compromise on the regulatory standards, quality parameters," said Sudhanshu Pandey, joint secretary in the Ministry of Commerce.

Analysts said India would need more time and efforts to address the quality concerns of the US and other regulators.

"It is not a panacea to solve the problems of the pharmaceutical sector," said Utkarsh Pantkar, head of the life sciences practice at KPMG, who said he works closely with Pharmexcil. "You can't do it only by promotion, but focused promotion clearly will help put out the right message."

Reuters

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