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GN SINGH/DCGI

Indian pharma firms cannot be judged by US standards

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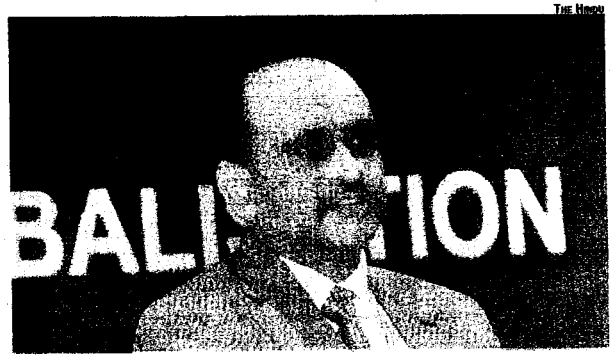
NEW DELHI

Hours after the US drug regulator banned imports from a fourth factory of **Ranbaxy Laboratories Ltd**, the drug controller general of India (DCGI) **G.N. Singh** chose to back the Indian firm, saying the current situation may not require withdrawal of its medicines from the local market.

On Friday, the US food and drug administration (FDA) barred Ranbaxy, a subsidiary of Japan's Daiichi Sankyo, from producing or distributing drug ingredients manufactured at its Toansa plant in Punjab for the US market.

FDA has already banned imports from Ranbaxy's plants in Mohali (Punjab), Dewas (Madhya Pradesh) and Paonta Sahib (Himachal Pradesh). At the Toansa plant, the regulator found the company's workers retested drug products to produce acceptable findings after the items originally failed analytical testing. While the US has banned imports from these facilities, the Indian market continues to use raw materials from these plants. Singh in an interview said, "Indian pharmaceutical companies cannot be judged by American standards." Edited excerpts:



Quality issues: *Singh says the process of streamlining the drug regulation in India is under way and fundamental changes will be taking place soon.*

INTERVIEW

Are you concerned about the quality of drugs Ranbaxy makes?

In this case, we are yet to get specific details. My team is at work and once we have the feedback, we will approach Ranbaxy to clarify the findings. However, it must be stated that every country has different measures and we cannot judge Ranbaxy by standards set up by the American drug regulator. My job is to ensure there is no compromise on safety and efficacy of drugs, and I am doing that. Once we find out the exact nature of violations, we will approach Ranbaxy.

Were the other three plants of the firm found to be in violation of India's Drugs and Cosmetics Act?

We had approached them last year after US FDA flagged certain issues. Some of those were found to be true and my office had told Ranbaxy to take corrective measures. Similar procedures will be followed in this case as well. But I do not think this is a situation which will warrant withdrawal of drugs from the domestic market. Our biggest objective is to maintain good quality of medicines and we are doing that. There are no drugs in the Indian market that are not up to the standards stated under the Drugs and Cosmetics Act. We will shortly be in touch with Ranbaxy's management to find out what went wrong at the Toansa plant.

Will such decisions adversely affect India's image as a manufacturer of safe, affordable drugs?

As of today, India supplies low-cost drugs to over 200 countries. Our pharmaceutical sector is a huge success. We cannot be doing well if our drugs were of substandard quality. Many multinational pharmaceutical companies stand to gain if India loses its image as a supplier of quality drugs. However, we will take appropriate action. We are in the process of streamlining the drug regulation in India and fundamental changes will be taking place soon. I am not worried about issues of quality.

Regd ortsy.