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Jolted by US ban, Indian regulators wake up to review Ranbaxy units

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NEW DELHI, JANUARY 27

DRUG Controller General of India (DCGI) inspectors are set to inspect pharma giant Ranbaxy's Toansa unit in Punjab this week, days after the US Food and Drug Administration banned import of products made there for manufacturing violations.

"We will be sending a team of officials to inspect the plant to test the product. If there are any violations, we will take action," DCGI G N Singh told *The Indian Express*.

Until now, the Indian drug regulator had maintained that all samples from the four Ranbaxy plants —all of which have been banned by the USFDA — were found to be okay. Also, it has conducted only three such inspections in the last seven years, while the USFDA has done one almost every year.

Singh said Ranbaxy has not informed the regulator so far about the USFDA visit and its fallout. "We have not got any filing from Ranbaxy till now and so will be writing to them to provide information," he said.

While Ranbaxy products cannot be sold in the US, the same drugs continue to be sold in India as standards applied by regulators in the two countries differ.

Pharma entrepreneur and former Pfizer employee Praful Akeli said failure to clear USFDA tests did not mean medicines from Ranbaxy were less effective. "The DCGI standards are lower but can we as a nation invest on each facility

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Regulatory

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Ranbaxy review

at par with USFDA standards? The almost doubling of costs is something we need to factor in," he said.

For instance, good manufacturing as defined by the USFDA includes detailed documentation of the process of manufacture of each batch.

Indian documentation is easier and depends on the schedule of the Drugs and Cosmetics Act under which the medicine is classified. So unless they are life-saving drugs for instance, some Ranbaxy products could escape some tests.

Under DCGI norms, the focus is mainly on ensuring the final product meets tolerance zones.

The US regulator's report highlighted eight observations where "corrective action" is required, including the presence of "too numerous to count" flies in the sample preparation room and raw materials, intermediates and API analytical results that were found to be failing specifications.

Pointing out that Ranbaxy had repeated errors the USFDA had pointed out in an earlier investigation in December 2012, the report said, "Appropriate controls are not established over computerised systems".

It has also pulled up Ranbaxy for not maintaining its laboratory facilities properly and said they are in disrepair. For instance, windows in the instrumentation room were found to be "un-closeable".

DCGI inspections of Ranbaxy's facilities last year after the drug manufacturer had pleaded guilty to felony charges in May 2013 in the US contained none of these observations.

Indian reports had found only minor anomalies that Ranbaxy claims it has fixed although it is still trying to comply with norms on shelf-life of products.

Ranbaxy refused to comment for this report and instead reiterated CEO Arun Sawhney's statement issued Friday in which he said the USFDA ban "is clearly unacceptable and an appropriate management action will be taken upon completion of the internal investigation".

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