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Govt mulls USFDA-like checks to keep MNC drug makers on toes

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CONCERNED by increasing regulatory action against domestic drug makers in the United States and Europe, the government is planning to initiate a similar system of checks on pharma manufacturers, including multinational firms operating out of India.

The Drug Controller General of India is set to start a system of sudden inspections of manufacturing facilities of pharma companies, including those of multi-national companies and will take stringent action against any violations.

"There has to be a level playing field. If foreign regulators can make surprise checks on Indian pharma companies, we can do the same for both domestic as well as foreign drug makers," said GN Singh, Drug Controller General of India (DCGI).

At present, teams from the DCGI and state drug control officers conduct checks but firms are usually notified in advance of such visits. In case of any violations, the facilities are given at least a 45 day window to comply with norms that can be increased on a case-by-case basis.

The move comes soon after the US Food and Drug Administration (USFDA) banned Ranbaxy's fourth unit at Toansa last Friday.

PHARMA EXPORTS FROM INDIA (COUNTRY-WISE)
(In ₹ billion)

COUNTRIES	2011	(%) EXPORTS	2012	(%) EXPORTS
USA	141	24	204	26
UK	25	4	29	4
Germany	20	3	25	3
Russia	16	3	25	3
Brazil	13	2	17	2

SOURCE: Centre for Monitoring Indian Economy, India Ratings

Although the DCGI is also set to inspect the facility to check for manufacturing violations, sources said there is increasing concern in the government over the regulatory action that Indian drug makers are facing abroad.

"Nearly 30 per cent of the generic medicines consumed in the US is manufactured by Indian drug makers. This is not a new phenomena but this has been the same for the last 10 years," pointed out a senior government official.

Over the past few years, a number of Indian drug makers have been hauled up by the USFDA over issues relating to violation of good manufacturing practices. Pharma firms including Wockhardt, Fresenius Kabi, RPG Life Sciences have got warning letters from the USFDA earlier while others including Ranbaxy, Dr Reddy's Labs, Sun Pharma, Cadila, Aurobindo Pharma and Glenmark have faced action for non-compliance with various US regulations.

Also, the UK Medicines and Healthcare Products Regulatory Agency had earlier issued a precautionary recall for sixteen medicines made by Wockhardt's Waluj facility.

With an estimated size of over Rs 72,000 crore in 2013, the Indian pharmaceutical industry is one of the largest exporters of generic drugs in the world.

The United States is the top market for Indian pharma exports, accounting for 26 per cent of all exports in 2012, followed by the United Kingdom (4 per cent) and Germany and Russia (3 per cent each).