PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Pioneer, Delhi
Saturday 1st February 2014, Page: 5
Width: 25.32 cms, Height: 10.41 cms, a4r, Ref: pmin.2014-02-01.31.43

State Govts ignoring pharma restrictions

PNS ■ NEW DELHI

Much to the chagrin of the Centre, almost all the State Governments are turning a Nelson's eye to its repeated missives seeking details about the cases of alerts and restrictions by other countries issued against the Indian pharma manufacturers.

With not a single State coming forward to give any information on the details of such incidents since its first letter last year in November, the exasperated Drug Controller General of India (DCGI) has once again written for the third time in a row to them.

It has been observed that in spite of warnings or prohibition issued by various international regulatory authorities like USFDA and others to the Indian manufacturers, the State Governments are not coming forward to share the information with DCGI, said a senior official from the DCGI.

He was referring to the cases pertaining to Ranbaxy and a few other pharma majors whose medicines are under the scanner of the USFDA accusing them of not following good manufacturing practices at their some plants.

Besides Ranbaxy and Strides, other domestic companies like Wockhardt, RPG Life Sciences and Fresenius Kabi's West Bengal facility have also allegedly come under the scanner of the US regulator last year.

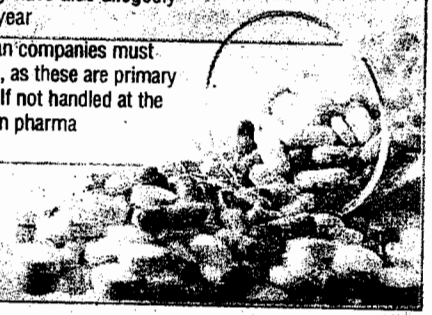
Though, we do get reports about such cases from our sources but the information need to come through proper sources, the DCGI official said.

"There are serious compliance issues and the Indian companies must focus on ensuring quality and regulatory compliance, as these are primary fundamentals for all Governments across the world. If not handled at the earliest, such cases do give bad name to entire Indian pharma industry," said the official.

"The matter is serious in nature and therefore, you are once again requested to direct all the drug manufacturers in your state/union territory to bring all such matters to the notice of DCGI as well as the State licencing authority (SLA) concerned so that immediate action in the matter could be taken to ensure the quality, safety and efficacy of the drugs marketed in the country," the letter said.

UNDER SCANNER?

- With not a single State coming forward to give any information on the details of such incidents since its first letter last year in November, the exasperated Drug Controller General of India (DCGI) has once again written for the third time in a row to them
- Besides Ranbaxy and Strides, other domestic companies like Wockhardt, RPG Life Sciences and Fresenius Kabi's West Bengal facility have also allegedly come under the scanner of the US regulator last year
- There are serious compliance issues and the Indian companies must focus on ensuring quality and regulatory compliance, as these are primary fundamentals for all Governments across the world. If not handled at the earliest, such cases do give bad name to entire Indian pharma industry, said an official
- The DCGI has also asked the SLAs concerned, in such alerts are issued, to inspect the manufacturing facilities to verify compliance to the provisions of the Drugs and Cosmetics Act and rules especially with regard good manufacturing practice



The DCGI has also asked the SLAs concerned, in such alerts are issued, to inspect the manufacturing facilities to verify compliance to the provisions of the Drugs and Cosmetics Act and rules especially with regard good manufacturing practice.

Govt.