

No. DCG (I)/Misc/2013 (87)
Directorate General of Health Services
Ministry of Health & Family Welfare
O/o Drugs Controller General (I)

FDA Bhawan, New Delhi

Dated: 22-01-14

To

All the State/UT Drugs Controllers

Subject: Bringing details about Drug Import alert / restrictions imposed by regulatory authorities abroad to the notice of CDSCO as well as State Drug Control Authorities – regarding.

Sir


Please refer to this Directorate's earlier letters of even no. dated 26.06.2013 and 11.12.2013 wherein you were requested to direct all the manufacturers in your State, that as and when the issues relating to compliance to Good Manufacturing Practices (GMP) and other aspects in manufacturing of drugs are raised and actions like restrictions / alerts are issued by any Regulatory Authorities abroad in respect of drugs manufactured and exported from India, the details of the same should be brought to the notice of the office of DCG(I) immediately.

In this regard, it is observed that in spite of warning/prohibition issued by various international Regulatory Authorities like USFDA, MHRA etc. to the Indian manufacturers, this office has not received any such information from you.

The matter is serious in nature and therefore, you are once again requested to direct all the drug manufacturers in your State/UT to bring all such matters to the notice of DCG(I) as well as the State Licensing 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.

Further, whenever such warning /alerts are issued by the other drug Regulatory Authorities to the Indian manufacturers, the concerned SLA may inspect such manufacturing facilities to verify compliance to the provisions of Drugs & Cosmetics Act & Rules thereunder specially with respect to GMP so that the products manufactured comply with the prescribed Standards.

Yours faithfully,


(Dr. G. N. Singh)
Drugs Controller General (I)

Copy to :

PPS to Secretary (H & FW)/PPS to DG/PPS to AS & DG/PS to JS (AKP)