

DCG (I)/MISC/2013(87)
Directorate General of Health Services
O/o Drugs Controller General India
FDA Bhawan, Kotla Road, New Delhi

Dated: 11th December, 2013.

To

All State/UTs 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/Madam,

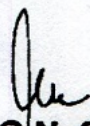
In continuation of this office letter dated 26th June, 2013 wherein you were requested to direct all the manufacturers in your State that as and when the issue related to compliance to GMP and other aspects in manufacturing of drugs are raised and actions like restrictions/alerts are issued by any drug 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 so that its impact in Indian scenario can be assessed and necessary action is taken to ascertain the quality, safety and efficacy of the drugs available in the country.

However, despite several import alerts issued by the international regulatory authorities to the Indian drug manufacturers, no such information has yet been brought to the notice of DCG (I).

The matter is serious in nature. Hence, you are 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 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.

Yours faithfully,

Directorate of Food and Drugs
Administration, Goa.
बिना नामा बरबादा ब्रह्मण्ड विभागाक
Entry No. 12992
नॉद नं.
Date 12/12/13
तारीख


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

Copy to:

1. PS to AS & DG, Ministry of Health and Family Welfare
2. PS to JS, Ministry of Health and Family Welfare
3. All Zonal/Sub-Zonal/Port Offices of CDSCO