

No.DCG(I)/MISC/2013(87)
Directorate General of Health Services
O/o Drugs Controller General India
FDA Bhawan, Kotla Road, New Delhi

Dated: 26th June, 2013.

To

All States/UTs Drugs Controller

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.

India is exporting drugs to more than 200 countries. Recently some concerns have been flagged in some countries with regard to the issues related to compliance to GMP and other aspects in manufacturing of certain drugs by some Indian drug manufacturers and exported to these countries. Restrictions like import alerts have also been issued in certain cases. Such actions have been taken by the Drug Regulatory authorities abroad in light of the regulatory requirements in those countries. Such Indian drug manufacturers are also involved in manufacturing and supplying the similar drugs to the Indian market.

In view of above, it has been considered necessary that such issues, as and when raised, be brought to the notice of regulatory authorities in India so that necessary action is taken to ensure the quality, safety and efficacy of the drugs marketed in the country.

You are, therefore, requested to direct all the manufacturers in your State that, as and when such issues 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 immediately to the notice of the office of DCG (I) as well as the State Drug Control Authority concerned 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.

Yours faithfully,



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

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IDMA/OPPI/IPA/BDMA/Others