

DCGI/MISC/2014 (31)
Directorate General of Health Services
Office of Drugs Controller General India
FDA Bhawan, Kotla Road, New Delhi

Dated: 05th March, 2014

OFFICE MEMORANDUM

This is to bring to the notice of all concerned that Central Drug Standard Control Organization is celebrating the year 2014 as "Patient & Animal Safety" year. In this context, it has become imperative to ensure that the drugs, cosmetics and medical devices manufactured, marketed, imported or exported meet the quality parameters and safety provisions prescribed under the Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945.

It has come to the notice of the undersigned that certain issues relating to quality of drugs have been highlighted by the Press/Associations/civil societies/others which need to be seriously attended. It is desired that any violation wherever being observed on quality, safety and efficacy parameters, strict measures be taken to stop such violations and provisions of the said Act and Rules enforced against the culprits.

Further in regard to the issues related to quality of medicines exported from India when referred for investigation at your end, are required to be investigated on top priority and an interim report be submitted within 15 days and complete information be made available to the office of DCGI within three months so that requisite information is flashed to embassies or Govt. agencies of those countries in time. This will help in allaying doubts and misinformation about the quality of drugs exported from India.

You are also requested to submit compliance report to the office of DCGI on quarterly basis so that the Ministry, international regulatory bodies and other concerned could be informed suitably.


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

To

1. All State/UT Drugs Controller
2. All Officers of CDSCO HQ/Zonal/Sub-Zonal Offices/Port Offices of CDSCO

Copy forwarded to:

1. Joint Secretary (R), Ministry of Health & Family Welfare
2. Shri Sudhanshu Pandey, Joint Secretary, Department of Commerce
3. Director General, Pharmexcil, Hyderabad
4. PPS to DGHS/PS to AS&DG, Ministry of Health & Family Welfare.