

2200

MOST IMMEDIATE  
**Enforc-11014(12)/4/2025-eoffice**  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(Enforcement Division)

FDA Bhawan, Kotla Road,  
New Delhi 110002.

Dated

To,  
All State/UTs Drugs Controllers

12 SEP 2025

Subject: Action to be taken against the marketer of drugs -reg-Reg.

Sir,

As you are aware that Risk Based Inspections are being carried out in the country to assess the status of compliance of the manufacturing units, as per the Drugs & Cosmetics Act, 1940 and Rules thereunder as per risk based approach.

Based on the market data, names of few of the marketers of drug were obtained and RBI of the associated manufacturers was carried out. It was observed that in most of the cases, several critical observations were reported by the inspecting team and based on the recommendation of the inspecting team the concerned State Licensing Authority (SLA) has taken action like issuance of Stop manufacturing activity, cancellation of manufacturing section, suspension of product permission and issuance of warning letters.

It is pertinent to note that as per Rule 84(E) of the Drug Rules 1945, the marketer of drugs is also responsible for quality of drugs as well as other regulatory compliances along with the manufacturer. Accordingly, the associated marketers, in the cases where manufacturers have been found to be violating the norms of GMP, are also responsible for poor quality of drugs being manufactured by these manufacturers. In two such specific cases, State Drugs Controllers of Gujarat and Delhi have been requested to initiate action against the marketers of drugs. Further, the marketers addresses mentioned on the labels of the drugs have also found to be non-existing in few cases.

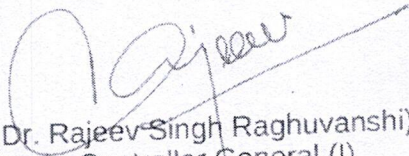
In view of the above, you are requested to sensitize the marketers of drugs under your jurisdiction against such violations and take action in cases warranted, for effective implementation of the said Rules under the Drug Rules 1945, in the interest of public health at large.

Any action taken in the matter may be informed to the undersigned at the earliest.

This may be accorded TOP PRIORITY.

C219

Yours faithfully

  
(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (I)

Copy to: All CDSCO Zonal and subzonal offices