

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:7024

ANSWERED ON:08.05.2015

GENERIC DRUGS

Birla Shri Om;Hemamalini Smt. ;Roy Prof. Saugata;Singh Shri Raj Kumar

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether instances of manufacturing and distribution of generic drugs by nonregistered companies without any license have been reported in the country in the recent past;
- (b) if so, the details thereof along with the action taken/proposed to be taken by the Government thereon indicating the rules and procedure laid down by the Government in this regard, State/UT-wise;
- (c) the steps taken/proposed to be taken by the Government to ensure the safety and quality of generic drugs and make them widely available in the country;
- (d) whether the Government proposes to take action against online companies selling prescription drugs without proper license in the country; and
- (e) if so, the details thereof and if not, the reasons therefor?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

- (a): As per the Drugs and Cosmetic Act, 1940 and Rules there under, licence for manufacture and distribution of drugs is granted by the State Governments and information in this regard, is not centrally maintained. Further, CDSCO has not received any information in this regard from any State.
- (b): No company can manufacture or distribute drugs without a valid licence under the Drugs and Cosmetics Act, 1940 and Rules there under.
- (c): The manufacture for sale of drugs is regulated through a system of inspection and licensing and regular inspections thereafter. The drug manufacturers are required to comply with the conditions of license and follow Good Manufacturing Practices to ensure that the drugs manufactured by them are safe and of standard quality. One of the conditions of the license is that licensee shall either in his own lab, or in any other laboratory approved by the Licensing Authority, test each batch of the raw material used by him for manufacturing products and also each batch of the final product and shall maintain records showing the particulars in respect of such tests.
- (d) & (e): Action as per the provisions of Drugs and Cosmetics Act, 1940 and Rules there under will be taken against any one selling prescription drugs without proper licence and prescription.