

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

UNSTARRED QUESTION NO:2165

ANSWERED ON:05.12.2014

MANUFACTURING OF GENERIC DRUGS

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

- (a) whether India is the World's largest producer and exporter of generic drugs, and if so, the details thereof;
- (b) whether the Government has laid down uniform procedure for grant of licences to the companies manufacturing generic drugs across the country;
- (c) if so, the details thereof indicating the number of companies given licences for the said purpose, State/UT-wise;
- (d) whether manufacturing and marketing of unsafe and untested generic drugs have been reported in certain parts of the country, if so, the details thereof along with the action taken/proposed to be taken by the Government thereon; and
- (e) the steps taken/proposed to be taken by the Government to protect domestic generic drug manufacturers from the multinational drug companies?

Answer

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

- (a): Data in terms of production of generic and branded drugs is not maintained.
- (b): Yes.
- (c): The License to manufacture drugs for sale is granted by the State Licensing Authorities and no centralized data on the number of licences granted for manufacturing generic drugs is maintained by the Government of India.
- (d): A comprehensive data on the number of cases of Not of Standard Quality and Spurious/ Adulterated drugs reported and number of prosecutions launched thereon is maintained by the Government. A statement for the year 2013-14 and 2014-15 (upto September, 2014), as received from all State Drug Control Authorities and Union Territories and Central Drugs Standard Control Organization (CDSCO) are as follows:

Cases Reported by States/ UTs

S.N.	Year	No. of samples declared not of standard quality	No. of samples declared spurious/ adulterated	No. of prosecutions launched
1.	2013-14	3028	118	237
2.	2014-15	1823	25	65

(Upto
September, 2014)

Cases reported by CDSCO

S.N.	Year	No. of samples declared not of standard quality	No. of samples declared spurious/ adulterated	No. of prosecutions launched
1.	2013-14 and 2014- 15 (Upto June, 2014)	116	04	27

(e): The Drugs & Cosmetics Act, 1940 and Rules made thereunder are applied uniformly to domestic and multinational drug manufacturing companies.