

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

UNSTARRED QUESTION NO:2077

ANSWERED ON:05.12.2014

QUALITY OF DRUGS

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

- (a) whether a number of essential and life-saving drugs have been found to be substandard or of poor quality in the recent past, if so, the details thereof along with the facts in this regard;
- (b) whether any complaint has also been received regarding the poor quality of certain cancer drugs in the country, and if so, the details thereof;
- (c) the corrective measures taken/ proposed to be taken by the Government in this regard;
- (d) the steps taken/proposed to be taken by the Government to strengthen the monitoring mechanism to ensure quality, efficacy and standards of drugs in the country; and
- (e) whether misuse of certain essential and life- saving drugs has been reported in the country, if so, the details thereof along with the action taken/proposed to be taken by the Government to check this trend?

**Answer**

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

(a): The essential or life-saving drugs are not defined in the Drugs and Cosmetics Act, 1940 and Rules made thereunder. The number of cases of Not of Standard Quality and Spurious/ Adulterated drugs reported and the number of prosecutions launched thereon, during 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 standard quality	No. of samples declared 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 standard quality	No. of samples declared spurious/ adulterated	No. of prosecutions launched
1.	2013-14 and 2014-15 (Upto June, 2014)	116	04	27

(b): No.

(c): Does not arise.

(d): Measures taken for ensuring the safety, quality and efficacy of drugs in the country include provision of stringent penalties including making certain offences cognizable and non-bailable; establishment of special designated Courts for trial of offences under the Drugs and Cosmetics Act for the speedy disposal of cases; announcement of a Whistle Blower Scheme to encourage vigilant public participation in the detection of movement of spurious drugs in the country; issuance of guidelines to the State Drugs Controllers for taking action on samples of drugs declared spurious or not of standard quality and regular instructions to inspectorate staff to keep a vigil and draw samples of drugs for test and analysis to monitor the quality of drugs moving in the country.

(e): Misuse of oxytocin, certain antibiotics, Anti-TB and certain habit forming drugs have been reported in the country. In order to check the misuse of Oxytocin, the Government has regulated and restricted the manufacture, sale and distribution of Oxytocin in the country vide Notification GSR 29 (E) dated 17th January, 2014. Further, a new Schedule, namely, Schedule H1 has been incorporated in the Rules to restrict the sale of certain antibiotics, Anti-TB drugs and habit forming drugs vide Notification G.S.R. 588(E) dated 30th August, 2013. This Notification has become effective from 1st March, 2014.