

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
STARRED QUESTION NO. 37
TO BE ANSWERED ON THE 3RD FEBRUARY, 2023**

SPURIOUS DRUGS

**†*37. SHRI RAJIV RANJAN SINGH ALIAS LALAN SINGH:
SHRI SANTOSH KUMAR:**

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

- (a) whether the sale of spurious drugs in the market has become rampant these days, if so the details thereof;
- (b) whether spurious/fake drugs are being sold/ made available in the market even for serious diseases like cancer;
- (c) if so, the details thereof and the reaction of the Government thereon; and
- (d) the steps taken/being taken by the Government to put a complete ban on availability and sale of such spurious drugs?

**ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR MANSUKH MANDAVIYA)**

(a) to (d) A Statement is laid on the Table of the House.

**STATEMENT REFERRED TO IN REPLY TO LOK SABHA
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(a) to (d): Isolated complaints regarding spurious drugs are received in Central Drugs Standard Control Organisation (CDSCO). As and when such complaints are received, based on merit, the matter is taken up by the CDSCO in coordination with State/UT Drugs Controller for action as per the provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945. As per information received from CDSCO, the details of drugs sample tested and declared Not of Standard Quality/ spurious/ adulterated drugs during the last three years is **annexed**.

Upon receipt of complaints regarding quality of medicines, CDSCO in coordination with State Licensing Authority takes action as per the provisions of Drugs & Cosmetics Act and Rules.

The Government has taken various regulatory measures to ensure the quality of medicines in the country. These includes notification for affixing Bar Code or Quick Response Code in Active Pharmaceutical Ingredients (APIs) and some drug formulations, increase in sanctioned regulatory posts of CDSCO and notification providing marketers of any drug to be responsible for its quality.

Further, testing capacities of Central Drugs Testing Laboratories under CDSCO have been strengthened, and Drugs and Cosmetics Rules, have been amended making it mandatory that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of product manufacturing license by the Authority, and that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.

The Central Government has provided Rs. 651.97 crores for strengthening the drug regulatory system including upgradation of existing State laboratories, setting up of new drug testing laboratories and upgradation of existing State drug control offices as part of “Strengthening of State Drug Regulatory System”.

Annexure

Number of samples tested and no. of drug samples reported Not of Standard Quality /spurious /adulterated by States/UTs Drugs Controller during last three years is as below:

	By States/UTs Drugs Controller			By Zonal/Sub-zonal offices of CDSCO		
Year	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated
2019-20	81329	2497	199	9299	307	12
2020-21	84874	2652	263	5460	170	3
2021-22	88844	2545	379	7036	287	2
