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

LOK SABHA
UNSTARRED QUESTION NO. †4723
TO BE ANSWERED ON 28TH MARCH, 2025

PREVENTION OF SPURIOUS DRUGS

†4723 SHRI MURARI LAL MEENA:

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

(a) the number of drug investigation laboratories that are functioning in Rajasthan to check the trade of spurious drugs;

(b) the number of samples tested by these laboratories during the last three years along with the number of spurious or substandard drugs detected out of these samples tested;

(c) the number of officers deployed in the drug control department of Rajasthan to check the spurious drugs along with the details of these officers;

(d) whether the Government is contemplating to bring a new legislation to award strict punishment (like life term imprisonment or heavy fines) on people who are involved in the manufacturing and sale of spurious drugs and if so, the details thereof;

(e) the special steps taken/proposed to be taken by the Government to supply only authentic and safe medicine to people residing in remote and rural areas of Rajasthan; and

(f) the manner in which the system is checking supply of spurious medicines when medicines are being supplied online now a days along with the details thereof?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a): As per information received from Food Safety and Drugs Control Commissionerate, Government of Rajasthan, there are four Drug Testing Laboratories in the state located in Jaipur, Bikaner, Udaipur and Jodhpur.

(b): As informed by the Food Safety and Drugs Control Commissionerate, Government of Rajasthan, the number of drug samples tested and reported Not of Standard Quality/spurious during last three years by State Drugs Testing Laboratories is as under:

Year (01st Jan to 31st Dec)	Number of drugs samples tested	Number of drugs samples declared Spurious	Number of drugs samples declared Not of Standard Quality
01st Jan 2022-31st Dec 2022	7,778	01	205
01st Jan 2023-31st Dec 2023	8,571	16	133
01st Jan 2024-31st Dec 2024	7,639	38	191

(c): As per information received from Food Safety and Drugs Control department, Government of Rajasthan, currently, 02 Drugs Controller, 35 Assistant Drugs Controller & 100 Drugs Control Officer are been posted in Drug Control Department while 02 Drugs Analyst and 09 Assistant Drugs Analyst are posted in Drug Testing Laboratories of Rajasthan.

(d): The manufacture, sale and distribution of drugs are primarily regulated in the country under the provisions of Drugs & Cosmetics Act, 1940 & its Rules through a system of licensing and inspection by State Licensing Authorities appointed by respective State Governments. Licensee is required to comply with all the conditions of license as prescribed under Drugs & Cosmetics Rules and the State Licensing Authorities are empowered to take stringent action against violation of provisions of the Act and Rules.

The Drugs and Cosmetics Act, 1940 has provisions for penalties in case of contraventions to various provisions of the said Act and Rules. The Act was amended by way of Drugs & Cosmetics (Amendment) Act 2008 to provide for more stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non bailable.

(e): Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken several measures to ensure quality, safety and efficacy of medicines throughout the country, as stated below:

(i) In order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO), in collaboration with state regulators, initiated risk-based inspections of drug manufacturing and testing firms in December 2022. As of now, 905 units have been inspected, resulting in 694 actions being taken. These actions include Stop Production Orders (SPO), Stop Testing Orders (STO), license suspensions/cancellations, warning letters, and showcase notices, depending on the severity of non-compliance. This initiative has provided valuable insights into the ground reality of manufacturing practices and has led to relevant corrective actions, resulting in noticeable improvements in the regulatory framework.

(ii) Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. Revised Schedule M has become effective for the drug manufacturers with turnover > Rs. 250 crores from 29.06.2024. However, for manufacturers having turnover of less than Rs. 250 Cr, extension of the timeline for implementation have been granted till 31st December, 2025 vide G.S.R. 127(E) dated 11.02.2025.

(iii) On 17.11.2022, the Drugs Rules, 1945 were amended vide G.S.R. 823(E) which has come into force from 1st of August, 2023 providing that the manufacturers of top 300 brands of drug formulation products, as specified in Schedule H2, shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.

(iv) On 18.01.2022, the Drugs Rules, 1945 were amended vide G.S.R. 20 (E) providing that every Active Pharmaceutical Ingredient (bulk drug) manufactured or imported in India shall bear Quick Response Code on its label at each level of packaging that store data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the minimum particulars including unique product identification code, Batch Number, Manufacturing date, Expiry Date etc.

(v) On 11.02.2020, the Drugs Rules, 1945 were amended vide G.S.R. 101 (E), providing that with effect from 01.03.2021, any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these Rules.

(vi) The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act, 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.

(vii) States/ UTs have set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.

(viii) To ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of some drugs.

(ix) The Drugs and Cosmetics Rules, 1945 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 manufacturing license by the Authority.

(x) The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been significantly increased in last 10 years.

(xi) Central regulator coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee (DCC) meetings held with State Drugs Controllers for uniformity in administration of the Drugs and Cosmetics Act.

(xii) Central government is providing regular residential, regional training and workshops to officials of CDSCO and State Drug Regulatory Authorities on Good Manufacturing Practices. In the Financial Year 2023-24 CDSCO has trained 22854 persons while in Financial Year 2024-25, so far 13007 persons have been trained.

(f): As and when complaints regarding spurious drugs are received in Central Drugs Standard Control Organisation (CDSCO), 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