

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

**LOK SABHA
UNSTARRED QUESTION NO. 5711
TO BE ANSWERED ON 27TH MARCH, 2026**

REGULATION OF DRUG QUALITY AND SAFETY

5711. SHRI BHASKAR MURLIDHAR BHAGARE:

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

- (a) whether the Government is aware of the circulation of fake, spurious and substandard medicines and vaccines in various parts of the country, if so, the details thereof;
- (b) whether there is any proposal to strengthen public drug testing laboratories under State authorities and enable citizens to voluntarily submit medicine samples for verification;
- (c) whether the Government proposes to introduce consumer-friendly verification mechanisms such as QR-code based tracking and other authentication systems for medicines, if so, the details thereof;
- (d) the number of drug samples tested by the Central Drugs Standard Control Organization and State Food and Drug Administrations during the last three years, year-wise and State-wise along with the number found Not of Standard Quality or spurious; and
- (e) whether any random sampling drives have been conducted and against manufacturers or distributors found involved in the sale of fake or substandard medicines and if so, the details thereof?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY
WELFARE**

(SMT. ANUPRIYA PATEL)

(a) to (e): Complaints regarding Manufacture/ sales/distribution of not of standard quality/ spurious/adulterated drugs/vaccine, as and when received, action is initiated by the licensing authority as per the provisions of Drugs & Cosmetics Act, 1940 and rules thereunder.

To strengthen the drug testing infrastructure and enhance laboratory capacity across the country, Ministry of Health and Family Welfare has implemented a Centrally Sponsored Scheme 'Strengthening of States' Drug Regulatory System (SSDRS). The scheme envisages upgrading existing State laboratories, setting up of new drug testing laboratories and upgradation of existing State drug control offices in the country. Under the SSDRS Scheme,

funds totalling Rs. 756 Crore has been released to States/UTs as part of the Central Share and 19 New Drug Testing Labs have been constructed and 28 existing labs have been up-graded in various States/UTs. Further, Section 26 of the Drugs and Cosmetics Act, 1940, specifically empowers individual citizens and consumer associations to have medicines tested.

The Drugs Rules, 1945 have been amended in year 2023 to mandate that manufacturers of the top 300 drug formulation brands listed in Schedule H2 shall print or affix a Bar Code or QR Code on the primary packaging label, or on the secondary label where space is insufficient, to store data readable through software applications for authentication. Similarly, the Rules have also been amended to require that every Active Pharmaceutical Ingredient (bulk drug), whether manufactured or imported, shall bear a QR Code on each level of packaging containing data readable through software applications to facilitate tracking and tracing.

Central Drugs Standard Control Organization (CDSCO) has made the said requirements regarding QR Codes available to the general public by publishing the notification in this regard on its website (<https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications>) and has also advised industry stakeholders for public awareness campaigns in this regard.

Under the Drug and Cosmetics Act 1940, drugs inspector randomly draws drug samples from the supply chain for quality checks. List of drugs of various companies, which are declared Not of Standard Quality/ Spurious/ Misbranded/ Adulterated by the Central Drugs Testing Laboratories are regularly uploaded on the website of Central Drugs Standard Control Organization (CDSCO) under the heading of Drug Alert (www.cdsco.gov.in). In case of drug samples failing in quality check, regulatory, actions are taken by the concerned licensing authorities under the provisions of Drugs & Cosmetics Act & Rules thereunder.

As per information received from States/UTs Drugs Controllers, the number of drug samples tested by various States/U.Ts in last three years and their status is as under:

Financial Year	No. of drugs samples tested	No. of drugs samples declared Not of Standard Quality	No. of drugs samples declared Spurious/ Adulterated
2022-23	96,713	3,053	424
2023-24	1,06,150	2,988	282
2024-25	1,16,323	3,104	245
