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

RAJYA SABHA
UNSTARRED QUESTION NO. 2648
TO BE ANSWERED ON 11TH AUGUST, 2026

FAKE AND SUB-STANDARD QUALITY MEDICINES

2648. SHRI PARTH AJIT PAWAR:

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

(a) whether fake and Not of Standard Quality (NSQ) medicines, including CDSCO-flagged antibiotics and blood-pressure formulations, continue to be found in the market;

(b) the number of manufacturing units inspected, fake drug consignments seized, and prosecutions launched in the last two years, State-wise;

(c) the impact of mandatory QR codes on APIs and top 300 medicine brands, and whether QR-code tracking will be extended to more medicines;

(d) the implementation progress of revised Good Manufacturing Practices (Schedule M), including by small manufacturers; and

(e) whether Government proposes to further strengthen Centre–State coordination and build a common national database for tracking fake and NSQ drugs?

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

(a) to (e): The terminology "fake" is not defined under the Drugs and Cosmetics Act, 1940 and Rules made thereunder. However, the Drugs and Cosmetics Act defines spurious, adulterated and misbranded drugs which includes fake drugs. From time to time, certain drug samples are identified as Not of Standard Quality (NSQ)/Spurious during routine quality surveillance undertaken by the Central Drugs Standard Control Organisation (CDSCO) and State Drug Regulatory Authorities. The details of such drug samples are uploaded every month on the CDSCO website under the heading of Drug Alerts (https://cdsco.gov.in/opencms/opencms/en/Alerts/) and includes the name of the drug, their batch no., manufacturer, manufacturing and expiry date, test result and name of the testing lab.

Whenever, a drug is declared Spurious or NSQ by the Government Analyst, the Licensing Authority concerned is empowered to take actions under the provisions of the said Act. Based on the outcome of the investigation, appropriate action such as suspension or

cancellation of licences, prosecution, product recall and other penal action as provided under the Act is initiated against the erring manufacturers, suppliers and other persons.

As per the information received from various States/Union Territories Drugs Controllers (SDCs), number of drug samples reported Not of Standard Quality/spurious/adulterated by the States/UTs Drugs Controller during the last two years is as follows:

Financial Year	No. of drugs samples tested	No. of drugs samples declared Not of Standard Quality	No. of drugs samples declared Spurious/ Adulterated	Number of prosecution cases for manufacturing, sale and distribution of spurious/adulterated drugs
2024-25	1,16,323	3,104	245	961
2025-26	1,41,322	3,012	283	779*

* Provisional figure

To strengthen traceability, enable authentication by stakeholders, and curb the circulation of spurious drugs in the country, the Government has amended the Drugs Rules in the year 2023 to mandate the manufacturers of the top 300 drug formulation brands listed in Schedule H2 to 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.

Further, the Central Government vide G.S.R. 506 (E) dated 22.06.2026, has also extended the provision of QR code to all vaccine, all antimicrobials, all narcotic & psychotropic substance, listed under the Narcotic Drugs and Psychotropic Substance Act, 1985 and rules made thereunder and all anticancer drugs by bringing them under Scheduled H2. The provisions relating to vaccines, narcotic and psychotropic drugs, and anti-cancer medicines shall come into force from 1st July 2027, while the provisions relating to antimicrobials shall become effective from 1st July 2028.

The 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 and for manufacturers having turnover of less than Rs. 250 Cr from 01.01.2026. The implementation of the revised Schedule M has been carried out in a phased manner, balancing strict quality compliance with adequate support and transition time for small manufacturers. CDSCO and State Licensing Authorities are carrying out risk-based inspections to ensure compliance with the revised GMP requirements. Non-compliant manufacturing units are subject to regulatory action, including suspension or cancellation of licences, as per the provisions of the Drugs and Cosmetics Act and Rules thereunder.

The Government has taken several measures to strengthen Centre-State coordination in drug regulation. These include risk-based joint inspections by CDSCO and State Drug Controllers, issuance of uniform drug sampling guidelines, integration of CDSCO laboratories through the SUGAM lab portal, publication of monthly NSQ Drug Alerts, and regular coordination with State Drug Regulatory Authorities for surveillance and enforcement. CDSCO also 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.

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