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

RAJYA SABHA
UNSTARRED QUESTION NO. 1249#
TO BE ANSWERED ON 10TH FEBRUARY, 2026

LAXITY IN THE PREVENTION OF COUNTERFEIT MEDICINES

1249 # SHRI RAMJI LAL SUMAN:

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

(a) the details of the success achieved in prevention of banned and counterfeit medicines in the country during the last three years, year-wise;

(b) whether any study has been conducted to assess the adverse effects of the use of counterfeit and banned medicines on consumers; and

(c) whether it is a fact that the concerned drug regulatory authorities have been negligent in enforcing inspection and testing standards after granting drug manufacturing licences, leading to the large-scale production of counterfeit medicines?

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

(a): The terminology "Counterfeit Medicines" is not defined under the Drugs and Cosmetics Act, 1940 and Rules made thereunder. However, the Drugs and Cosmetics Act defines spurious, adulterated, misbranded drugs which includes counterfeit drugs.

As per information received from States/UTs Drugs Controllers, the number of drug samples tested in last three years by various States/U.Ts and status regarding number of drug samples declared Not of Standard Quality/spurious/ adulterated including enforcement actions taken 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	Number of prosecution launched for manufacturing, sale and distribution of spurious/adulterated drugs
2022-23	96,713	3,053	424	663
2023-24	1,06,150	2,988	282	604
2024-25	1,16,323	3,104	245	961

(b): Use of any Banned/Spurious/Adulterated/Not of Standard Quality drugs is detrimental and may cause adverse effects on patient's health. Therefore, under the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder, manufacture of Banned/Spurious/Adulterated/ Not of Standard Quality drugs etc. is a punishable offence and concerned licensing authorities are empowered to take appropriate action in such cases.

(c): The manufacture, sale and distribution of drugs are primarily regulated in the country under the provisions of Drugs & Cosmetics Act, 1940 & Rules made thereunder through a system of licensing and inspection by State Licensing Authorities appointed by respective State Governments. Under the Drugs Rules, State licensing authorities shall cause inspection, by the Inspector appointed under the Act, of each premises licensed to verify the compliance with the conditions of license and the provisions of the said Act and Rules, not less than once in three years or as needed as per risk based approach.

Further, in order to assess the regulatory compliance of drug manufacturing premises in the country, CDSCO along with State Drugs Controllers (SDCs) have conducted risk-based inspections of more than 960 premises since December, 2022 and based on findings, more than 860 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses, warning letters etc. have been taken by the State Licensing Authorities as per the provisions of the Drugs Rules 1945.

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