GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 3393
TO BE ANSWERED ON 01ST APRIL 2025

Spurious medicines in the country

3393 # Dr. Laxmikant Bajpayee:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) the quantity of spurious medicines being manufactured at present in the country;
(b) the measures taken by Government along with the law enacted to prevent and control the manufacturing of such medicines;
(c) the number of unlicensed institutions caught for manufacturing spurious medicines in the country in the last five years and the action taken against them; and
(d) the details of spurious medicines seized during the last five years?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a) to (d): The Ministry of Health and Family Welfare has informed that manufacture, sale and distribution of spurious drugs is a punishable offence under the Drugs and Cosmetics Act, 1940. Isolated complaints regarding spurious drugs are received in the Central Drugs Standard Control Organisation (CDSCO). As and when such complaints are received, based on merit, the matter is taken up by CDSCO in coordination with the Drugs Controllers of the States and Union Territories (UTs) concerned, for action as per the provisions of the said Act and the rules made thereunder. Further, as per information received from various State/UT Drugs Controllers, the number of drug samples reported Not of Standard Quality, spurious or adulterated, and the enforcement action taken by the State/UT Drugs Controller concerned, during the last five financial years, is at Annexure.

CDSCO and the Ministry of Health and Family Welfare have taken several measures to ensure the quality, safety and efficacy of medicines, as described below:

(a) In order to assess the regulatory compliance of drug manufacturing premises in the country, CDSCO, in collaboration with State regulators, initiated risk-based inspections of drug manufacturing and testing firms in December 2022. 905 units have been inspected, resulting in 694 actions being taken. Depending on the severity of non-compliance, the actions taken include orders to stop production, orders to stop testing, suspension or cancellation of licence and issuance of warning or notice to show cause. Risk-based inspections have provided valuable insights into manufacturing practices being followed, led to corrective actions and resulted in discernable improvements in the regulatory framework.

(b) The Central Government, *vide* its notification dated 28.12.2023, amended the Drugs Rules, 1945 to revise Schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. From 29.6.2024, the revised schedule has become effective for drug manufacturers with turnover of over ₹ 250 crore. For manufacturers having a turnover of up to ₹ 250 crore, *vide* notification dated 11.2.2025, time for implementation has been granted till 31.12.2025.

(c) To require manufacturers to print or affix on packaging labels of top 300 brands of drug formulation products bar code or Quick Response (QR) code that stores data or information legible with software application to facilitate authentication, the Drugs Rules, 1945 were amended through notification dated 17.11.2022, which came into force from 1.8.2023, to provide for such printing or affixation in respect of the drug formulation products specified in Schedule H2 to the said rules.

(d) On 18.1.2022, the Drugs Rules, 1945 were amended to provide that every active pharmaceutical ingredient (bulk drug) manufactured or imported in India shall bear QR code on its label at each level of packaging, that stores data or information readable with software application to facilitate tracking and tracing. Such stored data or information shall include the minimum particulars, including unique product identification code, batch number, manufacturing date, expiry date, etc.

(e) On 11.2.2020, the Drugs Rules, 1945 were amended to provide with effect from 1.3.2021 that, along with the manufacturer, any marketer who sells or distributes any drug shall be responsible for the quality of that drug as well as other regulatory compliances under these rules.

(f) The Drugs and Cosmetics Act, 1940 was amended through an amending Act of 2008 to provide for stringent penalties for manufacture of spurious and adulterated drugs. Certain offences were also made cognizable and non-bailable.

(g) For speedy disposal of cases relating to offences under the Drugs and Cosmetics Act, 1940, State and Union Territory Governments have set up special courts.

(h) To ensure efficacy of drugs, the Drugs Rules, 1945 have been amended to provide that applicants for grant of manufacturing license shall submit along with their application the result of bioequivalence study of oral dosage form of some drugs.

(i) The Drugs Rules, 1945 have been amended to make it mandatory that applicants submit to the State Licensing Authority evidence of stability, safety of excipients, etc. before manufacturing license is granted by such authority.

(j) The number of sanctioned posts in CDSCO has been increased significantly over the last 10 years.

(k) For uniformity in the administration of the Drugs and Cosmetics Act, 1940, the Central regulator coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee meetings held with the State Drugs Controllers.

(l) The Central Government is providing regular residential and regional training and workshops to officials of CDSCO and State Drug Regulatory Authorities on Good Manufacturing Practices. Since April 2023, CDSCO has trained over 35,000 persons.

Annexure

Annexure referred to in the reply to Rajya Sabha Unstarred Q. No. 3393 for answer on 1.4.2025, raised by Dr. Laxmikant Bajpayee, regarding spurious medicines in the country

Drug samples reported Not of Standard Quality, spurious or adulterated, and the enforcement action taken by the State/UT Drugs Controller concerned

Financial year	Number of drug samples tested	Number of drug samples declared Not of Standard Quality	Number of drug samples declared spurious/adulterated	Number of prosecutions launched for manufacturing, sale or distribution of spurious or adulterated drugs
2019-20	81,329	2,497	199	421
2020-21	84,874	2,652	263	236
2021-22	88,844	2,545	379	592
2022-23	96,713	3,053	424	663
2023-24	1,06,150	2,988	282	604

*****