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

LOK SABHA
UNSTARRED QUESTION NO. 2226
TO BE ANSWERED ON 01ST AUGUST, 2025

COUNTERFEIT DRUGS AND ILLEGAL PHARMACEUTICAL NETWORKS

2226. SHRI P C MOHAN:

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

(a) whether the Government is aware of the growing menace of counterfeit and substandard drugs being sold across the country, including in urban and peri-urban markets, if so, the details thereof;

(b) the estimated number of drug samples found to be spurious, substandard or misbranded in inspections during the last three years, year-wise with respect to Karnataka and Bengaluru;

(c) whether the Government has identified any inter-state or international networks involved in the manufacture and distribution of counterfeit drugs, if so, the details thereof;

(d) the steps taken by the Union Government to strengthen regulatory mechanisms, inter-agency coordination and digital tracking of pharmaceutical supply chains to prevent counterfeiting; and

(e) whether the Government is planning to implement or expand Track and Trace systems and modernise drug testing laboratories under the Central Drugs Standard Control Organisation (CDSCO), if so, the details thereof?

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.

Isolated complaints regarding sale of not of standard quality and spurious drugs have been received. As and when such complaints are received, action is initiated as per the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945.

(b): 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 showcause 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.

Out of aforementioned units, 06 firms are situated in Karnataka state and during inspection, 29 numbers of drug sample were collected for test and analysis. Out of these 29 drugs samples, analysis reports of 22 samples have been received and no samples are declared as spurious, substandard or misbranded.

(c): Information of such networks has not been received by CDSCO.

(d) & (e): Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken several measures to strengthen the drug regulatory system in the country.

(i). 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, conditional extension up to 31.12.2025 is currently operational for those who submitted their upgradation plan for the extended compliance period.

(ii). 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.

(iii). 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.

(iv). 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.

(v). 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.

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

(vii). 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.

(viii). 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.

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

(x). 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.

(xi). 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, 20551 persons have been trained.

(xii). Further, for strengthening the drug regulatory system in the country, Ministry of Health and Family Welfare is implementing a Centrally Sponsored Scheme 'Strengthening of States' Drug Regulatory System (SSDRS) with an approved outlay of Rs. 850 Crore. 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. So far under the SSDRS Scheme, funds totalling Rs. 756.00 Crore has been released to States/UT's as part of the Central Share and 17 New Drug Testing Labs have been constructed and 24 existing labs have been up-graded in various States/U.T's.

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