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

RAJYA SABHA
UNSTARRED QUESTION NO. 1893
TO BE ANSWERED ON 05TH AUGUST, 2025

NATIONAL-LEVEL POLICY AND ENFORCEMENT MEASURES AGAINST FAKE DRUG TRADE

1893: SHRI SANT BALBIR SINGH:

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

(a) the concrete steps the Central Government has taken in the last five years to prevent the smuggling and distribution of counterfeit or substandard medicines in the Indian market;

(b) whether there have been any new laws, amendments, or policy frameworks introduced specifically targeting the fake drug trade; and

(c) whether the Ministry has launched any national awareness campaigns to educate the public and medical professionals about the dangers of counterfeit medicines?

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

(a) to (c): 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.

Various major steps have been taken in the last five years by Central Drugs Standard Control Organisation (CDSCO) and Ministry of Health to ensure the production of quality medicines across the country as under: -

(i) In order to assess the regulatory compliance of drug manufacturing premises in the country, the 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.

(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.

The 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.

Further, the guidance for identification and verification of spurious drugs have also been provided on the website of CDSCO describing the process flow for verifying the authenticity of the drugs by reading the bar code or quick response code.

(iv) As part of quality monitoring, the samples failing in quality check, as received by CDSCO are uploaded on the website of CDSCO as part of the monthly drug alerts to make it available publicly. Details of these drugs are available on the CDSCO website under the heading of Drug Alert (www.cdsco.gov.in).

In case of drug samples declared as NSQ by the Drugs Testing laboratories under CDSCO, the respective manufacturing firms are asked for immediate recall and stop further distribution of the not of standard quality drugs in the market. Further, based on investigation outcome, actions are taken by the licensing authorities concerned under the provisions of Drugs & Cosmetics Act & Rules made thereunder such as stop production orders, stop testing orders, license suspensions/cancellations, warning letters and showcause notices.

(v) 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.

(vi) In February, 2024 CDSCO published regulatory guidelines for the sampling of drugs, cosmetics, and medical devices by drugs inspectors of Central and State Drug Authorities in the Country. The guidelines provides a structured approach to ensure the quality and efficacy of products available in the market through uniform drug sampling methodology for drugs inspectors under state and central drug regulatory authorities in India. It covers various aspects of sampling, including sampling plans, selection, locations, number and quantity of samples, timelines, and role of testing laboratories. It stresses the importance of a structured sampling plan, risk-based sample selection, and covering diverse locations, including rural areas.

(vii) An online portal, SUGAM labs is in place since September 2023 for integrating the drug testing labs of the CDSCO. It automates the entire workflow for testing of Medical Products (Drugs, Vaccine, Cosmetics & Medical devices) to meet the quality specification and tracing the testing status in the laboratories.

(viii) 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.

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

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

(xi) 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.

(xii) The Drugs and Cosmetics Rules, 1945 have been amended making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government.

(xiii) 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.

(xiv) 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.

(xv) 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.

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