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

**LOK SABHA**
**UNSTARRED QUESTION NO. 3373**
**TO BE ANSWERED ON 08TH AUGUST, 2025**

# SUB-STANDARD AND FALSIFIED DRUGS

**3373. SHRI ESWARASAMY K:**

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

(a) whether the World Health Organization (WHO) in a study has identified India as one of the countries which manufactures and supplies sub-standard and falsified drugs;

(b) if so, the details thereof;

(c) whether the Government has any plan to take a serious call on the outcome of the study; and

(d) if so, the details thereof?

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

(a) & (b): The Director General of the World Health Organization (WHO), Geneva, launched two key documents in 2018 concerning the issue of substandard and falsified medical products, namely: (i) A study on the public health and socioeconomic impact of substandard and falsified medical products, and (ii) WHO Global Surveillance and Monitoring System for substandard and falsified medical products.

These documents are the outcome of collaborative efforts and data reported by various Member States over a period of time. The study includes data from quality surveys conducted between 2007 and 2016, covering over 48,000 samples from 88 countries, including India.

As per the aggregated data reported in these surveys, the observed failure rate of sampled medicines in low- and middle-income countries was estimated at approximately 10.5%. These figures represent a consolidated average across participating countries and are not specific to any individual country.

(c) & (d): Further, Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken following regulatory measures to ensure the manufacture, distribution and sale of quality medicines across the country:

(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). 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 provide 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.

(iii). Apart from complaints from various sources, the inspectorate staff of CDSCO and SLA keeps strong vigil and draw drug samples regularly for identification of spurious /adulterated/ misbranded drugs in the distribution chain.

(iv). 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.

(v). 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.

(vi). 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.

(vii). 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.

(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). 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.

(xi). 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.

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

(xiii). 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.

(xiv). 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.

(xv). 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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