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

RAJYA SABHA
UNSTARRED QUESTION NO. 2491
TO BE ANSWERED ON 17TH DECEMBER, 2024

DETECTION OF SUBSTANDARD MEDICINES BY CDSCO

2491: DR. ASHOK KUMAR MITTAL:

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

(a) the specific findings of the Central Drugs Standard Control Organisation (CDSCO) on the 50 substandard drugs, including detailed data on deficiencies;

(b) the budget allocated for drug quality monitoring and enforcement in the past five years and the projected funding required to ensure drug safety and efficacy;

(c) the current criteria and testing procedures used by CDSCO to identify substandard drugs and any planned enhancements;

(d) the quantitative data on regulatory actions taken against manufacturers, including recalls and penalties in the past five years; and

(e) the new policy measures to improve regulatory oversight and prevent sub-standard drug production, including timelines and expected outcomes?

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

(a): List of drugs of various companies, which are declared Not of Standard Quality/ Spurious/ Misbranded/ Adulterated by the Central Drugs Testing Laboratories is regularly uploaded and available on the website of Central Drugs Standard Control Organization (CDSCO) under the heading of Drug Alert (www.cdsco.gov.in).

(b): For strengthening the drug regulatory system in the country both at the Central and State level, the Government had approved Rs.1750 Crore. Out of this, Rs. 900 Crore is for strengthening the central drug regulatory structures and Rs. 850 Crore is for the Centrally Sponsored Scheme 'Strengthening of States' Drug Regulatory System (SSDRS) which envisages to strengthen the laboratory infrastructure and up-gradation of existing State Drug Controller offices in States.

(c): As a part of surveillance and monitoring activities, the Drugs Inspectors draw drug samples from the supply chain at regular frequency for quality checks. These drug samples are then forwarded for testing to the Government Drug testing Laboratories for Quality checks. The Laboratories test these drugs as per the standards prescribed in accordance with Drugs and Cosmetics Act 1940 and its Rules. In case the sample is found to be Not of Standard Quality (NSQ)/ Spurious/Adulterated/Misbranded, actions are initiated as per provisions of the Drugs and Cosmetics Act, 1940 and rules thereunder.

(d): As per information received from various States/Union Territories Drugs Controllers, number of drug samples reported Not of Standard Quality/spurious/adulterated and enforcement action taken by the States/UTs Drugs Controller during the last three years is as under:

Year (April to March)	Number of drugs samples tested	Number of drugs samples declared Not of Standard Quality	Number of drugs samples declared Spurious/ Adulterated	Number of prosecution launched for manufacturing, sale and distribution of spurious/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

The data regarding drugs recalled after failing quality tests is not maintained centrally by CDSCO. However, as per information received from various States/U.Ts Drugs Controllers, the details of number of batches recalled during the last five years are as under.

Year (April to March)	Number of Batches Recalled
2019-2020	950
2020-2021	1091
2021-2022	1153
2022-2023	1171
2023-2024*	1394

* Provisional figure

(e): Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken several measures to ensure that the drugs produced in the country meet the required safety and efficacy standards, as stated below:

(i). In order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO) along with State Drugs Controllers (SDCs) had initiated risk-based inspections of Drug manufacturing firms from Dec 2022. Risk-based inspections of more than 500 premises have been conducted so far. Drug manufacturing firms have been identified based on risk criteria like number of drugs declared as Not of Standard Quality, complaints, criticality of the products etc. Based on findings of inspections, more than 400 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses etc., have been taken by the State Licensing Authorities as per the provisions of the Drugs Rules 1945.

(ii). 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>250 crores from 29.06.2024.

(iii). 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.

(iv). 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.

(v). 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.

(vi). 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.

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

(viii). 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.

(ix). 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.

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

(xi). 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.

(xii). 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 so far 13007 persons have been trained.

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