Steps taken for Testing and Surveillance of Drugs

Strengthened Drug Quality Monitoring: Nearly 5 Lakh Samples Tested in Five Years to Ensure Safe Medicines

Intensified Regulatory Vigilance: 960+ Drug Manufacturing Units Inspected Since Dec 2022; 860+ Actions Taken to Enforce Quality Standards

Major Boost to Drug Safety Infrastructure: ₹756 Crore Central Share Released for Expansion of Drug Testing Laboratories

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The manufacture, sale and distribution of drugs are regulated in the country under the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder through a system of licensing and inspection.

As per information received from various States/Union Territories Drugs Controllers (SDCs), number of drug samples reported Not of Standard Quality/spurious/adulterated by the States/UTs Drugs Controller during the last five years is as follows:

Financial Year	No. of drugs samples tested	No. of drugs samples declared Not of Standard Quality	No. of drugs samples declared Spurious/ Adulterated
2020-21	84,874	2,652	263
2021-22	88,844	2,545	379
2022-23	96,713	3,053	424
2023-24	1,06,150	2,988	282
2024-25	1,16,323	3,104	245

As a part of quality monitoring and 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. Firms have been identified based on risk criteria like number of drugs declared as not of standard quality, complaints, criticality of the products etc. As of now, CDSCO along with SDCs have conducted risk-based inspections of more than 960 premises since December, 2022 and based on findings, more than 860 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses, warning letters have been taken by the States/UTs as per the provisions of the Drugs Rules 1945.

Also, more than 1100 cough syrup manufacturers and 380 blood centres have been subjected to intense audit in coordination with State authorities. Increased market surveillance sampling of syrup formulations by Central and State drugs regulators has also been done.

Further, Food Safety Standard Authority of India (FSSAI) and its regional offices through the State/UT Food Safety Departments, carry out regular surveillance, monitoring, inspections, and random sampling of food to ensure compliance with the quality & safety standards established under the Food Safety and Standards Act (FSS), 2006, and the Rules and Regulations made thereunder.

To strengthen the drug testing infrastructure and enhance laboratory capacity across the country, Ministry of Health and Family Welfare has implemented a Centrally Sponsored Scheme 'Strengthening of States' Drug Regulatory System (SSDRS). 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. Under the SSDRS Scheme, funds totalling Rs. 756 Crore has been released to States/UTs as part of the Central Share and 19 New Drug Testing Labs have been constructed and 28 existing labs have been up-graded in various States/UTs.

The Union Minister of State for Health and Family Welfare, Smt. Anupriya Patel stated this in a written reply in the Rajya Sabha today.

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