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

LOK SABHA
UNSTARRED QUESTION NO.1895
TO BE ANSWERED ON 06TH DECEMBER, 2024

STRENGTHENING DRUG REGULATORY SYSTEM

1895: SHRI BASTIPATI NAGARAJU:

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

(a) the total amount of funds allocated under the Centrally Sponsored Scheme Strengthening of States Drug Regulatory System (SSDRS), State-wise especially in the State of Andhra Pradesh;

(b) whether the Government has conducted any training programmes for Central Drugs Standard Control Organization (CDSCO) and State Drug Control officials in the country and if so, the details thereof especially in the State of Andhra Pradesh;

(c) the current status of the physical progress of the State Government laboratories identified in the State of Andhra Pradesh;

(d) the time by which the said project is likely to be completed and the amount of funds allocated for the same; and

(e) whether the Government has any data regarding the cases registered on manufacturing of spurious and adulterated drugs and if so, the details thereof along with the measures taken/proposed to be taken by the Government to address the same?

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

(a): For strengthening the Drug Regulatory System in the country, Government has approved Rs. 850 Crore for the Centrally Sponsored Scheme 'Strengthening of States' Drug Regulatory System (SSDRS) which envisages to upgrade 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, Rs. 33.57 Crore has been allocated to State of Andhra Pradesh.

(b): Central government is providing regular Residential, regional training and workshops to officials of CDSCO and State Drug Regulatory Authorities including Andhra Pradesh on Good Manufacturing Practices. In the training Financial Year 2023-24 CDSCO has trained 22,854 persons while in F.Y 2024-25, so far 13,007 persons have been trained.

(c) & (d): So far under the SSDRS Scheme, funds of Rs.31.93 Crore has been released to the State of Andhra Pradesh as Central Share against total allocation of Rs. 33.57 Crore for construction of two Regional Drugs Testing Laboratories at Visakhapatnam & Kurnool, construction of a new building for the State Drug Testing Laboratory at Vijayawada and for

upgradation of existing State Drugs Testing Laboratory cum Assistant Director (Drugs) office at Siddhartha Medical College Campus, Gundala, Vijayawada.

(e): As per information received from various States/U.Ts Drugs Controllers, number of drug samples reported Not of Standard Quality/spurious/adulterated and enforcement action taken by the States/UTs Drugs Controller during 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
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

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 and to improve the functioning and capacity of CDSCO, 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.

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