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

LOK SABHA
UNSTARRED QUESTION NO.294
TO BE ANSWERED ON 21ST JULY, 2023

DRUGS PRODUCTION OF SUB-STANDARD

294: SHRI RAMESH CHAND BIND:

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

(a) whether the Government intend to amend the existing rules and guidelines for manufacturer and suppliers to stop adulterated drugs;
(b) if so, the details thereof and if not, the reasons therefor; and
(c) the details of the steps taken by the Government to control sub-standard drugs production in the country during the last three years?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (c): Isolated complaints regarding spurious drugs are received in Central Drugs Standard Control Organisation (CDSCO). As and when such complaints are received, based on merit, the matter is taken up by the CDSCO in coordination with State/UT Drugs Controller for action as per the provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945.

As per information received from various States/U.Ts Drugs Controllers, the number of drug samples tested, number of drug samples reported Not of Standard Quality/spurious/adulterated by the States/UTs Drugs Controller and such information in respect of CDSCO during last three years is enclosed as **Annexure-I**

The manufacture, sale and distribution of drugs are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and Rules there under. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by the respective State Governments and SLAs are empowered to take the action in case of violation of any condition of licenses.

CDSCO and Ministry of Health and Family Welfare have taken following regulatory measures to ensure the quality of medicines in the country:-

1) 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.

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

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

4) 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.

5) 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.

6) 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.

7) CDSCO 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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Annexure-I

Number of samples tested and enforcement action taken, no. of drug samples reported Not of Standard Quality/spurious/adulterated and enforcement action taken by the States/UTs Drugs Controller and such information in respect of CDSCO during last three years is as below:

Year (1st April of preceding year to 31st March of following year)	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/adulterated	No. of prosecution launched for manufacturing, sale and distribution of spurious/adulterated drugs
2019-20	81329	2497	199	421
2020-21	84874	2652	263	236
2021-22	88844	2545	379	592

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