

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

**LOK SABHA
UNSTARRED QUESTION NO. †1157
TO BE ANSWERED ON 09TH FEBRUARY, 2024**

CURB ON SPURIOUS DRUGS

†1157. SHRI DULAL CHANDRA GOSWAMI:

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

- (a) whether the Government intends to amend the existing rules and guidelines for the manufacturers and suppliers to curb the spurious medicines in the country;
- (b) if so, the details thereof and if not, the reasons therefor; and
- (c) the steps taken/proposed to be taken by the Government to control the production of medicines in the country during the last three years, year-wise?

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

(a) to (c): Manufacturing, sale and distribution of drugs in the country are regulated by the State Licensing Authorities appointed by the respective State Government under Drugs and Cosmetics Act 1945 and Rules. State Licensing Authorities (SLAs) are empowered to take the action in case of violation of any condition of licenses.

Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken following regulatory measures to ensure the quality of medicines in the country:-

- i. 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.
- ii. States/ UTs have set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.
- iii. The number of sanctioned posts in CDSCO has been increased from 111 in 2008 to 931 till date.
- iv. 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.

- v. 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.
- vi. 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.
- vii. 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.
- viii. 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.
- ix. In order to ensure the quality of drugs and to assess the regulatory compliance of drug manufacturing premises in the country, the CDSCO along with State Drugs Controllers (SDCs) have conducted risk-based inspections of 275 premises. The 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 250 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.

CDSCO, Ministry of Health and Family Welfare regulates quality, safety and efficacy of Drugs, Medical Device and Cosmetics in the country under the provisions of Drugs & Cosmetics Act, 1940 and its Rules.
