

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

**RAJYA SABHA
UNSTARRED QUESTION NO. 613
TO BE ANSWERED ON 25TH JULY, 2023**

**STANDARDIZATION AND QUALITY IMPROVEMENT IN THE
PHARMACEUTICAL SECTOR**

613: SHRI GHANSHYAM TIWARI:

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

- (a) the details of steps taken by the Government for standardization and quality improvement in the pharmaceuticals sector during last five years;
- (b) the details of actions which can be taken against the concerned company for not meeting the standard; and
- (c) the details of actions taken against such companies/institutions during the last three years ?

ANSWER

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

(a): 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 significantly increased in last 10 years.
- (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.

(b): The manufacturing, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945. The regulatory control over the manufacture, sale and distribution of drug in the country is exercised through a system of licensing and inspection by the State Licensing Authorities (SLAs) appointed by the respective State Governments. Manufacturers are required to comply with the conditions of license granted under the said Act and Rules to manufacture any drugs for sale and distribution in the country. The cases concerning quality or safety of drugs are taken up with the concerned State Licensing Authority in order to take necessary action under the provisions of Drugs and Cosmetics Act 1940 and its Rules. The SLAs are legally empowered to take action of violation of any conditions of such licenses including prosecution in appropriate Court of law.

(c): As per information received from various States/UT's Drugs Controllers, number of drug samples tested, number of drug samples reported spurious/adulterated, sub-standard drugs and action taken against the offenders during last three years i.e. 2019-2022 is as below.

Year (1 st April of preceding year to 31 st 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	81,329	2497	199	421
2020-21	84,874	2652	263	236
2021-22	88,844	2545	379	592
