

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

**LOK SABHA
UNSTARRED QUESTION NO.5008
TO BE ANSWERED ON 31ST MARCH, 2023**

SUPPLY OF SUBSTANDARD MEDICINES

5008: SHRI KIRTI VARDHAN SINGH:

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

- (a) whether the Ministry is aware of the fact that 67 medicine batches have failed to qualify a random drug sample test in which the products of several prominent pharmaceutical companies like Sun Pharma and Alkem are listed;
- (b) if so, the details thereof;
- (c) the various measures/steps taken by the Government to control such substandard supply of medicines in the market; and
- (d) the various penal actions the Government has taken against such pharmaceutical companies during the last three years, State/UT-wise?

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

(a) to (c): The list of Not of Standard Quality (NSQ) drugs declared by Drug Testing Laboratory under Central Drugs Standard Control Organisation (CDSCO) is available on official website of CDSCO i.e. www.cdsc.gov.in. The list of such drugs for the month of January, 2023 contains the products of various companies including M/s Sun Pharma and M/s Alkem and may be seen at link given below:

https://cdsc.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTg4OQ==

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

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. Serious 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 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.

(d): 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 enclosed as **Annexure-I**.

Annexure-I

Number of samples tested and enforcement actions taken, no. of drug samples reported Not of Standard Quality /spurious /adulterated and enforcement action taken by States/UTs Drugs Controller since last three years 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	81329	2497	199	421
2020-21	84874	2652	263	236
2021-22	88844	2545	379	592