

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

**RAJYA SABHA
UNSTARRED QUESTION NO.1882
TO BE ANSWERED ON 02nd AUGUST, 2022**

SUBSTANDARD DRUGS

1882: #SHRI SAMIR ORAON:

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

- (a) whether the Central Drugs Standard Control Organisation (CDSCO) had recently collected samples of drugs from many States of the country;
- (b) if so, the number of the samples taken, State-wise ;
- (c) the number of drugs found to be substandard during testing of the samples;
- (d) whether effective action has been taken against the pharmaceutical companies manufacturing these substandard drugs;
- (e) if so, the details thereof; and
- (f) the steps being taken by Government to prevent its recurrence in future?

ANSWER

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

(a) to (e): During the period from 01.04.2022 to 25.07.2022, various zonal and sub-zonal offices of Central Drugs Standard Control Organisation (CDSCO) have drawn more than 1400 samples from various States. Details in respect of States/UTs where drug samples have been drawn and tested are enclosed as **Annexure-I**.

In case of sample found Not of Standard Quality (NSQ), based on investigation etc., action is taken as per the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder.

(f): 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. 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.

| Number of samples tested by various Zonal/ Sub-Zonal offices of CDSCO during 01.04.2022 to 25.07.2022 (2022-2023) | | | | |
|--|-------------------|-----------------------------|------------------------------------|--|
| S. No. | States/UTs | No. of Samples drawn | No. of drugs samples tested | No. of drugs samples declared Not of Standard Quality |
| 1. | Andhra Pradesh | 5 | 1 | 1 |
| 2. | Arunachal Pradesh | 8 | 2 | 0 |
| 3. | Assam | 12 | 1 | 1 |
| 4. | Goa | 36 | 31 | 0 |
| 5. | Gujarat | 212 | 45 | 3 |
| 6. | Himachal Pradesh | 64 | 40 | 3 |
| 7. | Jammu & Kashmir | 28 | 24 | 0 |
| 8. | Karnataka | 197 | 161 | 2 |
| 9. | Madhya Pradesh | 32 | 8 | 0 |
| 10. | Maharashtra | 222 | 63 | 0 |
| 11. | Odisha | 27 | 14 | 5 |
| 12. | Punjab | 6 | 1 | 0 |
| 13. | Tamilnadu | 212 | 101 | 2 |
| 14. | Telangana | 116 | 33 | 1 |
| 15. | West Bengal | 230 | 131 | 6 |
| 16. | Puducherry | 18 | 18 | 0 |
| 17. | Chandigarh | 4 | 2 | 0 |
