

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

**LOK SABHA
UNSTARRED QUESTION NO. 3101
TO BE ANSWERED ON 09TH AUGUST, 2024**

CASES OF SPURIOUS AND SUBSTANDARD DRUGS

3101. SHRI ANAND BHADAURIA:

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

- (a) whether the Government is aware that market is flooded with spurious and substandard drugs;
- (b) if so, the details of instances reported during the last three years and current year, year-wise and State-wise;
- (c) whether the Government has granted approvals to those substandard drugs which had failed in test also during the last five years in the country, year-wise; and
- (d) if so, the details thereof and reasons therefor?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SMT. ANUPRIYA PATEL)**

(a) to (d): Isolated complaints regarding quality of drugs as and when received are referred to State Licensing Authorities for taking action as per the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945.

As per information received from various States/U.Ts Drugs Controllers, the details of number of drugs sample tested and declared Not of Standard Quality/ spurious/ adulterated drugs during the last five years is as under.

Year (April to March)	Number of drugs samples tested	Number of drugs samples declared Not of Standard Quality	Number of drugs samples declared Spurious/ Adulterated
2018-2019	79,604	2,549	205
2019-2020	81,329	2,497	199
2020-2021	84,874	2,652	263
2021-2022	88,844	2,545	379
2022-2023	96,713	3,053	424

Under the Drugs and Cosmetics Act, 1940 and Rules thereunder the license for manufacture of drugs are granted by the State Licensing Authority appointed by the respective State Government. Licensee is required to comply with all the conditions of license including

Good manufacturing practices (GMP) as prescribed under Drugs Rules, 1945 to ensure quality of drugs. State Licensing Authorities are empowered to take action on violation of any conditions of such licenses including prosecution in appropriate Court of law.
