GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 2331
TO BE ANSWERED ON THE 3rd AUGUST, 2021

Spurious Drugs

†2331. SHRIMATI RANJANBEN DHANANJAY BHATT:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether there is excess of spurious drugs in different parts of the country;
(b) if so, whether the Government will consider taking concrete and effective steps to check it;
(c) if so, the details thereof along with the time by which the said steps are likely to be taken; and
(d) if not, the reasons therefor?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI MANSUKH MANDAVIYA)

(a) to (d): As per Central Drugs Standard Control Organisation (CDSCO), isolated complaints regarding spurious drugs are received in CDSCO. As and when such complaints are received, based on merit, the matter is taken up by the CDSCO in coordination with State/UT Drugs Controller for action as per the provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945. The information received from Drugs Controllers of various States/UTs during last three years and current year in this context is as under:

Financial Year	No. of drug samples tested	No. of drug samples declared spurious/ adulterated	Percentage of drug samples declared spurious/ adulterated
2017-18	82599	236	0.28
2018-19	79604	205	0.27
2019-20	81329	199	0.24
2020-21*	69272	139	0.20

Corresponding information received from various Zonal/Sub-zonal offices of CDSCO is as under:

Financial Year	No. of drug samples tested	No. of drug samples declared spurious/ adulterated	Percentage of drug samples declared spurious/ adulterated
2017-18	7088	2	0.028
2018-19	10382	5	0.048
2019-20	9299	12	0.12
2020-21*	4237	1	0.02

*The information of FY 2020-21 is upto 31st January, 2021 only.

Further, amidst reports received of fake & spurious Covid-19 management drugs, CDSCO has requested all States/UTs Drugs Controllers through several advisories to instruct their enforcement staff to keep strict vigil especially at sensitive places and to take stringent action against the offenders by conducting special drive of monitoring and investigation.

As per information available from various State Licensing Authorities, in cases of fake & spurious Covid management drugs, various enforcement actions like Drug seizure, Arrests of accused persons / registration of FIR etc. have been carried out by the States/UTs Drugs Controllers. CDSCO and Ministry of Health and Family Welfare have taken various regulatory measures to ensure the quality of medicines distributed in the country which are as under:

(i) The Drugs and Cosmetics Act, 1940 was amended under the 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) The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 33 States have already set up designated special Courts.

(iii) Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were forwarded to the State Drugs Controllers for uniform implementation.

(iv) The number of sanctioned posts in the Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 492 (in Jan, 2021).

(v) The testing capacities of Central Drugs Testing Laboratories under the CDSCO are being constantly strengthened to expedite testing of drug samples in the country.

(vi) On 3.4.2017, in order 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 drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.

(vii) On 27.10.2017, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 1337 (E) 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.

Joint inspection of the licensed manufacturing premises by the Drugs Inspectors of Central Government and State Government to verify the compliance with the conditions of license and the provisions of the Drugs & Cosmetics Act and Rules for not less than once in three years or as needed as per risk based approach is also provided for.

On 10.04.2018, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 360 (E), making it mandatory for all drugs, that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of product manufacturing license by the Authority.

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