GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 41
TO BE ANSWERED ON 2nd February, 2024

Sale of Generic Medicines

†41. SHRIMATI KESHARI DEVI PATEL:

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

(a) whether generic medicines manufactured by some of the Pharmaceutical companies are being sold in the markets that failed during the testing;
(b) if so, the details thereof along with the total number of the said generic medicines sold in the market;
(c) the number and names of the Pharmaceutical companies which have manufactured the said medicines in the country; and
(d) the steps taken/proposed to be taken by the Government in this regard?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a) to (c): As per information received from Ministry of Health & Family Welfare (M/o H&FW), Govt. of India, various States/UTs Drugs Controllers have forwarded data regarding 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. The details are enclosed as **Annexure.**

(d): M/o H&FW and Central Drugs Standard Control Organisation (CDSCO) have taken following regulatory measures to ensure the quality of medicines in the country: -

1. On 17-11-2022, the Drugs Rules, 1945 were amended vide G.S.R. 823(E) which has come into force on 1st of August, 2023 providing that the manufacturers of top 300 brands of drug formulation products, as specified in Schedule H2, shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.

The stored data shall include the following particulars, namely: -

(i) unique product identification code;
(ii) proper and generic name of the drug;
(iii) brand name;
(iv) name and address of the manufacturer;
(v) batch number;
(vi) date of manufacturing;

(vii) date of expiry; and
(viii) Manufacturing licence number.

2. On 18.01.2022, the Drugs Rules, 1945 were amended vide G.S.R. 20 (E) providing that every Active Pharmaceutical Ingredient (bulk drug) manufactured or imported in India shall bear Quick Response Code on its label at each level of packaging that store data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the minimum particulars including Unique product identification code, Batch No, MFG date, Exp. Date etc.

3. 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.

4. States/ UTs have set up Special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.

5. The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been significantly increased over the last 10 years.

6. To ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bio-equivalence study along with the application for grant of manufacturing license of oral dosage form of some drugs.

7. 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.

8. 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. Central regulator coordinates activities of State Drug Control Organizations 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.

Annexure

Statement referred to in reply to part (a to c) of the LOK SABHA UNSTARRED Q. NO. 41 for answer on 02.02.2024 raised by SHRIMATI KESHARI DEVI PATEL regarding Sale of Generic Medicines

Details of No. of drug samples tested, no. of drug samples reported spurious/adulterated, sub-standard drugs and action taken against the offenders during last three years			
Year	Number of drugs sample tested	Number of drugs samples declared not of standard quality	Number of drugs samples declared spurious/ adulterated
2020-21	84874	2652	263
2021-22	88844	2545	379
2022-23	96713	3053	424

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