

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION No. 3697
TO BE ANSWERED ON THE 11th August, 2023

Production of Generic Medicines

**3697. DR. PRITAM GOPINATHRAO MUNDE:
SHRI CHANDRA SEKHAR SAHU:
SHRI RAHUL RAMESH SHEWALE:**

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

- (a) the percentage increase in the production of generic medicines in the country during the last three years, year-wise;
- (b) whether the Government is aware that the manufacturers of generic medicines have been supplying empty wrappers or half-filled wrappers of generic medicines to the bulk buyers, if so, the details thereof along with the action taken/proposed to be taken by the Government in this regard;
- (c) whether the Government has received complaint(s) about the quality of generic medicines and if so, the details thereof;
- (d) whether the Government has conducted any study on the quality of generic medicines in the country and if so, the details and outcome/findings thereof and if not, the reasons therefor; and
- (e) the steps taken/proposed to be taken by the Government to maintain public confidence in generic medicines in the country?

ANSWER

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

(a): Indian Pharmaceuticals Industry is 3rd largest by volume and 13th largest by value in the world producing more than 60,000 generic drugs across 60 therapeutic categories. The annual turnover of the pharmaceutical sector during the last 3 years is estimated as under:

Financial Year	Turnover (Rs. in Crore)	Percentage increase
2019-2020	2,89,998	-
2020-2021	3,28,054	13.12%
2021-2022	3,44,125	4.90%

No separate data regarding production of generic medicines in the country is, however, maintained.

(b): Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health & Family Welfare (MoHFW) has informed that it has no information in this regard.

(c) and (d): Drugs, whether branded or generic, imported or manufactured for sale, distribution in the country are required to comply to the same standards as specified in the Second Schedule

of the Drugs and Cosmetics Act, 1940 and rules thereunder. CDSCO has received isolated complaints regarding quality of drugs. Action thereon are taken, based on merit, by the CDSCO in coordination with State/UT Drugs Controller as per provisions of the Drugs & Cosmetics Act, 1940 and the Drugs Rules, 1945. A nation-wide survey (2014-16) was conducted by CDSCO to assess the extent of Not of Standard Quality (NSQ)/Spurious drugs.

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

- (i) 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) States/ UTs have set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.
 - (iii) The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been significantly increased during the last 10 years.
 - (iv) 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 some drugs.
 - (v) 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.
 - (vi) 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.
 - (vii) Central regulator coordinates activities of State Drug Control Organisations 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.
- (e): In order to make quality generic drugs available to citizens of the country at affordable prices, the department of Pharmaceuticals has launched *Pradhan Mantri Bhartiya Janaushadhi Pariyojana* (PMBJP) wherein about 9,668 Kendras have been opened all across the country till 31.07.2023. The quality of drugs dispensed at these Kendras is ensured by procuring medicines only from World Health Organization – Good Manufacturing Practices (WHO-GMP) certified suppliers and getting each batch of drug at the warehouses tested at laboratories accredited by ‘National Accreditation Board for Testing and Calibration Laboratories’ (NABL) before their dispatch to Kendras. Citizens are made aware of the scheme through advertisements in Print Media, Radio, TV, cinema, outdoor publicity as well as through social media. Further, *Jan Aushadhi Diwas* is celebrated every year on 7th March for further dissemination and spreading awareness about generic medicines.
