Production of Generic Medicines

प्रविष्टि तिथि: 12 DEC 2025 4:21PM by PIB Delhi

While generic medicines constitute the predominant proportion of medicines produced in India, separate data on its production is unavailable. Based on the sales turnover data of Pharmarack, a company that provides commercial intelligence on medicines sold in the country and the data of exports maintained by the Directorate General of Commercial Intelligence and Statistics, the total sales value of medicines produced in the country increased by 26%, from ₹3,22,116 crore in the financial year (FY) 2022-23 to ₹4,06,047 crore in FY2024-25.

The Department of Pharmaceuticals is not in receipt of any report regarding manufacturers of generic medicines supplying empty or half-filled wrappers to bulk buyers. The Ministry of Health and Family Welfare has informed that drugs manufactured in the country, irrespective of whether they are generic or branded, are required to comply with the same standards for quality that have been provided under the Drugs and Cosmetics Act, 1940 and the rules made thereunder. Based on quality testing of drugs in government drug testing laboratories, cases of not of standard quality (NSQ) drugs are reported from time to time and as and when reports regarding such cases are received, the same are investigated by the licensing authorities concerned for taking action under the provisions of the said Act and rules, including prosecution in a court of law.

The Ministry of Health and Family Welfare has informed that Government has not conducted any specific study on the quality of generic medicines. However, a nation-wide survey (2014-16) was conducted to assess the extent of NSQ/spurious drugs, in which a total of 47,012 drug samples were drawn from various sources and the percentage of NSQ and spurious drugs from retail outlets was 3% and 0.023% respectively.

Further, the Central Drugs Standard Control Organisation (CDSCO) and the Ministry of Health and Family Welfare have taken the following measures to ensure production of quality medicines across the country:

(i) The Drugs Rules, 1945 as amended on 17.11.2022 require with effect from 1.8.2023 that manufacturers of top-300 brands of drug formulation products, as specified in Schedule H2 to the said rules, 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 stores data or information legible with software application to facilitate authentication. Such stored data shall include particulars regarding unique product identification code, proper and generic name of the drug, brand name, name and address of the manufacturer, batch number, date of manufacturing, date of expiry and manufacturing licence number.

(ii) The said rules were amended on 18.1.2022 to provide 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., manufacturing date, expiry date etc.

(iii) The said rules were amended on 28.12.2023 to revise the good manufacturing practices and requirements of premises, plant and equipment for pharmaceutical products under Schedule M to the said rules. The revised Schedule M specifies pharmaceutical quality system, quality risk management, good manufacturing practices for pharmaceutical products, qualification and validation etc. The revised Schedule M is already in effect in respect of manufacturers having turnover of over ₹250 crore. For manufacturers with turnover of up to ₹250 crore, the timeframe for compliance has been extended up to 31.12.2025 vide notification dated 11.2.2025.

(iv) The Drugs and Cosmetics Act, 1940 was amended in 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs, and certain offences were made cognizable and non-bailable.

(v) States and Union territories have set up special courts for trial of offences under the said Act, with a view to facilitate speedy disposal.

(vi) The number of sanctioned posts in CDSCO has increased significantly over the last 10 years.

(vii) To ensure efficacy of drugs, the Drugs Rules, 1945 have been amended to provide that applicants shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of some drugs.

(viii) The said rules have been amended to make it mandatory that before grant of manufacturing license, the manufacturing establishment is inspected jointly by the drugs inspectors of the Central Government and the State Government concerned.

(ix) The said rules have been amended to make it mandatory that applicant shall submit evidence of stability, safety of excipients, etc. to the State Licensing Authority concerned before manufacturing license is granted by such authority.

(x) CDSCO coordinates activities of State drugs control organisations and provides expert advice through meeting of the Drugs Consultative Committee, held with the State Drugs Controllers, with a view to ensure uniformity in the administration of the Drugs and Cosmetics Act, 1940.

Further, regulatory provisions under the said Act and the rules made thereunder are considered from time to time for appropriate amendment, with a view to ensure quality, safety and the efficacy of drugs manufactured in or imported into the country.

The government has also launched Pradhan Mantri Bhartiya Janaushadhi Pariyojana to make quality generic medicines available at affordable prices to all. Under this scheme, dedicated outlets known as Jan Aushadhi Kendras (JAKs) are opened across the country to provide medicines at 50%-80% cheaper rates than branded medicines. A total of 17,610 JAKs have been opened across the country till 30.11.2025. Under PMBJP, 2,110 types of medicines are part of the product basket covering all major therapeutic groups such as cardiovascular, anti-cancers, anti-diabetics, anti-infectives, anti-allergic, gastro-intestinal medicines, nutraceuticals, etc. With a view to ensure supply of quality medicines sold from JAKs, the following measures are in place:

(i) Medicines are procured only from suppliers certified for World Health Organization – Good Manufacturing Practices (WHO-GMP).

(ii) Each batch of drugs supplied under the scheme is tested at laboratories accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL) and only after passing quality tests, medicines are dispatched to Jan Aushadhi Kendras.

(iii) Quality audit of the facilities of vendors is routinely done by the Pharmaceuticals and Medical Devices Bureau of India.

This information was given by Union Minister of State in the Ministry of Chemicals and Fertilizers, Smt. Anupriya Patel, in a written reply in the Lok Sabha today.

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