GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. **4612**
TO BE ANSWERED ON THE **20TH MARCH 2026**

Variations in Generic Medicines

4612. Dr. Amol Ramsing Kolhe:
Shri Sanjay Dina Patil:
Prof. Varsha Eknath Gaikwad:
Shri Mohite Patil Dhairyasheel Rajsinh:
Shri Bhaskar Murlidhar Bhagare:
Smt. Supriya Sule:

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

(a) whether the Government is aware that patients and healthcare practitioners in public hospitals have raised concerns regarding perceived variations in quality, therapeutic effectiveness and onset time of certain generic medicines across the country, if so, the details thereof;
(b) whether any scientific or regulatory assessment has been conducted to evaluate the bioequivalence, absorption rates and clinical effectiveness of generic medicines supplied through public procurement systems in the country, if so, the details thereof including Maharashtra, Statewise;
(c) whether the Government has received feedback from doctors regarding differences observed between branded and generic medicines in treatment outcomes, even as generic prescribing is being promoted to improve affordability in Maharashtra, if so, the details thereof;
(d) the quality control mechanisms, batch-wise testing and post-marketing surveillance measures put in place to ensure the safety and efficacy of generic medicines supplied in Maharashtra; and
(e) whether the Government proposes to strengthen regulatory oversight, testing infrastructure and transparency to ensure sustained public confidence in generic medicines in the said State, if so, the details thereof?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a): As per the information provided by Ministry of Health and Family Welfare there is no definition of 'generic medicines' under Drugs & Cosmetics Act, 1940 and Rules made there under and Central Drugs Standard Control Organization (CDSCO) has not received any such reports regarding variations in quality, therapeutic effectiveness and onset time of certain generic medicines.

The manufacture, sale and distribution of drugs are primarily regulated in the country under the provisions of Drugs & Cosmetics Act & Rules 1945 made thereunder through a system of licensing and inspection by State Licensing Authorities appointed by respective State Governments. Licensee is required to comply with all the condition of license as prescribed under Drugs & Cosmetics Rules, 1945. As per one of the conditions of license, licensee is required to test each batch or lot of the raw material used by him for the manufacture of his product and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests.

Further, Drugs manufactured in the country, irrespective of whether generic medicines or branded medicines or for domestic or international market are required to comply with the same standards as prescribed in the Drugs and Cosmetics Act, 1940 and Rules made thereunder for their quality.

(b): Ministry of Health and Family Welfare has informed that CDSCO approves new drugs in accordance with the provisions of the New Drugs and Clinical Trials (NDCT) Rules, 2019, based on a comprehensive evaluation of their quality, safety, and efficacy in consultation with Subject Expert Committee (SEC) experts.

Further, to ensure efficacy of drugs, the Drugs Rules 1945 amended vide G.S.R. 327(E) dated 3rd April, 2017, wherein requirement of bio-equivalence study results was placed to the concerned State/UTs Drugs Authorities for grant of manufacturing license for oral dosage form of drugs falling under the Category II and Category IV of the Bio-pharmaceutical Classification System.

(c): Ministry of Health and Family Welfare has informed that no such feedback has been received.

(d) & (e): Ministry of Health and Family Welfare has informed that CDSCO and Ministry of Health and Family Welfare have taken following regulatory measures to ensure the production of quality medicines across the country: -

(i). In order to assess the regulatory compliance of drug manufacturing premises in the country, the CDSCO along with State Drugs Controllers (SDCs) have conducted Risk-Based Inspections of more than 960 premises since December, 2022 and based on findings, more than 860 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses, warning letters have been taken by the State Licensing Authorities.

(ii). More than 1100 cough syrup manufacturers and 380 blood centres have been subjected to intense audit in coordination with State authorities. Increased market surveillance sampling of syrup formulations by Central and State drugs regulators has also been done.

(iii). Advisory has been issued on 03.10.2025 to all State/UT Health Departments and healthcare facilities to ensure rational use of paediatric cough syrups. Further, the Drugs Controller (India) directed all State/UT Drug Controllers on 07.10.2025 to ensure strict compliance with testing requirements under the Drugs Rules, 1945, and on 27.10.2025 instructed them to maintain heightened vigilance against spurious and substandard drugs and take prompt action under the Drugs & Cosmetics Act, 1940.

(iv). In addition to the existing requirements of testing the raw materials, the Indian Pharmacopoeia Commission, Ghaziabad has issued an amendment to Indian Pharmacopoeia (IP) 2022, to also mandate the testing for DEG and Ethylene Glycol (EG) in oral liquids at finished product stage before market release.

(v). List of drugs of various companies, which are declared Not of Standard Quality/ Spurious/ Misbranded/ Adulterated by the Central Drugs Testing Laboratories is uploaded and available on the website of CDSCO under the heading of Drug Alert (www.cdsco.gov.in) and actions initiated.

(vi). The Drugs Rules, 1945 have been amended in year 2023 to mandate that manufacturers of the top 300 drug formulation brands listed in Schedule H2 shall print or affix a Bar Code or QR Code on the primary packaging label, or on the secondary label where space is insufficient, to store data readable through software applications for authentication. Similarly, the Rules have also been amended to require that every Active Pharmaceutical Ingredient (bulk drug), whether manufactured or imported, shall bear a QR Code on each level of packaging containing data readable through software application to facilitate tracking and tracing.

(vii). The Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. Revised Schedule M has become effective for the drug manufacturers with turnover > Rs. 250 crores from 29.06.2024 and for manufacturers having turnover of less than Rs. 250 Cr from 01.01.2026.

(viii). In February 2024, CDSCO published regulatory guidelines for the sampling of drugs, cosmetics, and medical devices by Central and State Drugs Inspectors. These guidelines provide a structured approach to ensure the quality and efficacy of products available in the market through uniform drug sampling methodology.

(ix). An online portal, SUGAM labs is in place since September 2023 for integrating the drug testing labs of the CDSCO. It automates the entire workflow for testing of Medical Products (Drugs, Vaccine, Cosmetics & Medical devices) to meet the quality specification and tracing the testing status in the laboratories.

(x). The 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.

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