GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

RAJYA SABHA
UNSTARRED QUESTION NO.293
TO BE ANSWERED ON 04TH FEBRUARY, 2025

QUALITY OF DRUGS

293: MS. SUSHMITA DEV:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government has taken note of the concerns regarding the substandard quality of generic medicines sold in the country, if so, the steps taken thereafter;

(b) the details of the new Good Manufacturing Practices (GMP) for pharmaceutical products and the timeline for compliance, and how it ensures the quality of drugs;

(c) whether Government has initiated any measures to establish a centralised drug testing system to ensure uniform quality across States, if so, the details thereof; and

(d) the funds provided and utilised by the Seven National Laboratories for drug testing in the past five years?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a) to (c): There is no definition of 'generic medicines' provided under Drugs & Cosmetics Act. Drug manufactured in the country, irrespective of whether generic medicines or branded medicines, are required to comply with the same standards of quality and safety as prescribed in the Act. As and when such cases are received, these are investigated by the licensing authorities concerned for taking action under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945, as the licensing authorities are empowered to take action in case of any violation to the provisions of the said Act and Rules.

Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken several measures to ensure quality, safety and efficacy of medicines in the country, as stated below:

(i). In order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO) along with State Drugs Controllers (SDCs) had initiated risk-based inspections of Drug manufacturing firms from Dec 2022. Risk-based inspections of more than 500 premises have been conducted so far. Drug manufacturing firms have been identified based on risk criteria like number of drugs declared as Not of Standard Quality, complaints, criticality of the products etc. Based on findings of inspections, more than 400 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses etc., have been taken by the State Licensing Authorities as per the provisions of the Drugs Rules 1945.

(ii). 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>250 crores from 29.06.2024. However, for manufacturers having turnover of less than 250 Cr, draft rules have been published vide GSR 10(E) dated 04.01.2025 regarding extension of timelines till 31st December, 2025.

(iii). On 17.11.2022, the Drugs Rules, 1945 were amended vide G.S.R. 823(E) which has come into force from 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.

(iv). 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 Number, Manufacturing date, Expiry Date etc.

(v). On 11.02.2020, the Drugs Rules, 1945 were amended vide G.S.R. 101 (E), providing that with effect from 01.03.2021, any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these Rules.

(vi). 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.

(vii). States/ UTs have set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.

(viii). 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.

(ix). 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.

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

(xi). 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.

(xii). Central government is providing regular residential, regional training and workshops to officials of CDSCO and State Drug Regulatory Authorities on Good

Manufacturing Practices. In the Financial Year 2023-24 CDSCO has trained 22854 persons while in Financial Year 2024-25, so far 13007 persons have been trained.

(xiii). Further, Department of Pharmaceuticals is implementing a Scheme, viz., 'Revamped Pharmaceuticals Technology Upgradation Scheme' (RPTUAS), with a view to facilitate existing Pharma units to upgrade to 'Revised Schedule M' and 'WHO-GMP' standards, enhancing the quality and safety of pharmaceutical products manufactured in our country. The tenure of the scheme is from F.Y 2021-22 to 2025-26 with the total outlay of Rs. 300.10 crores.

(d): There is no separate head of account for the Seven National Laboratories for drug testing. However, funds are released by CDSCO to the labs as per their requirement.

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