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

LOK SABHA
UNSTARRED QUESTION NO. 3057
TO BE ANSWERED ON 13TH DECEMBER, 2024

INEFFECTIVE GENERIC MEDICINES FOR DIABETES

3057: DR. MALLU RAVI:

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

(a) whether the Government has received complaints against generic medicines issued by CGHS Doctors, particularly for diabetes, regarding their ineffectiveness, if so, the details thereof;

(b) whether it is a fact that many diabetic patients are refusing to use these medicines due to concerns about their efficacy; and

(c) if so, the details of such complaints along with the steps taken by the Government to address this issue?

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

(a) to (c): Medical Stores organization (MSO) through its 07 Government Medical Stores Depots situated at New Delhi, Karnal, Hyderabad, Guwahati, Kolkata, Mumbai & Chennai only procure and supply generic medicines which are under Rate Contract of MSO to CGHS wellness centres. No such complaints have been received by MSO directly from the CGHS patients.

CGHS procures generic medicines in bulk through Medical Stores Organization (MSO) and also through Jan Aushadhi Pariyojana. Due care is taken to supply good quality generic medicine to CGHS beneficiaries without any discrimination or prejudice as per Government guidelines after following the standard operating procedure for quality control by the each Government agency supplying these drugs. To ensure supply of the standard quality medicines various measures are taken by the Government, as stated below:

(i). Selection of vendor by registration of manufacturing unit only after thorough physical inspection of the manufacturing facility.

(ii). Every batch of drug received from the manufacturer is accompanied by “in-house” test report.

(iii). MSO & GMSDs thereafter tests each and every batch of drug received from the manufacturers through 02 NABL accredited laboratories for quality assurance.

(iv). Only after receipt of “Standard Quality” report from these two labs, the generic drugs are accepted and thereafter dispatched to the CHGS Wellness Centres.

(v). Jan Aushadhi procures medicines after quality checks at laboratories.

(vi). The safety, efficacy and quality of the medicines, whether branded or generic, imported or manufactured for sale, distribution in the country are required to comply to the same standard as specified in the Second Schedule of the Drugs and Cosmetics Act, 1940 and Rules.

(vii). 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. Further, Drugs Inspector under the Act randomly draws drug samples from the supply chain for quality checks. Also, list of drugs of various companies, which are declared Not of Standard Quality/ Spurious/ Misbranded/ Adulterated by the Central Drugs Testing Laboratories are regularly uploaded on the website of Central Drugs Standard Control Organization (CDSCO) under the heading of Drug Alert (www.cdsco.gov.in).

(viii). 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.

(ix). 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.

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