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

RAJYA SABHA
UNSTARRED QUESTION NO.3466
TO BE ANSWERED ON 01ST APRIL, 2025

SUB-STANDARD INDIAN GENERIC DRUGS

3466: SHRI S NIRANJAN REDDY:

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

(a) whether it is a fact that Indian-made generic drugs have been linked to a higher rate of severe adverse effects, if so, the details thereof;

(b) the measures taken by Government to improve the monitoring and reporting of adverse drug reactions (ADRs) in the country;

(c) whether it is a fact that Indian pharmaceutical companies have faced regulatory actions and export bans due to non-compliance with global Good Manufacturing Practices, if so, the details thereof; and

(d) the steps Government is taking to ensure that Indian-made generics meet international safety standards?

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

(a) to (d): There is no definition of 'generic medicines' provided under Drugs & Cosmetics Act. Drugs 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.

Reports regarding quality concerns appear from time to time in sections of the media. However, Central Drugs Standard Control Organization (CDSCO) has not received any such report linking Indian-made generic drugs to a higher incidence of severe adverse effects.

For export of drugs, the manufacturers are required to obtained license for manufacturing of the drugs from the concerned State licensing Authority (SLA) under the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder. Further, for export of drugs, the Indian Pharmaceutical companies are also required to comply with the requirements of the importing country.

Manufacturing of drug is regulated under the provision of Drugs and Cosmetics Act 1940, and Rules thereunder, through a system of inspection and licensing by the state licensing authorities appointed by the state government As per the revised good manufacturing practices requirements under Schedule M to the drug Rules 1945, "*the licensee shall have a pharmacovigilance system in place for collecting, processing and*

forwarding the reports to the licensing authorities for information on the adverse drug reactions emerging from the use of drugs manufactured or marketed by the licensee".

Further, to enhance the monitoring and reporting of adverse drug reactions (ADRs) in India, the Government is implementing the Pharmacovigilance Programme of India (PvPI), a flagship drug safety monitoring program that collects, collates, and analyzes adverse events reported with the use of medical products marketed in India. So far a total of 1025 Adverse Drug Reaction Monitoring Centres (AMCs) have been enrolled across the country for monitoring and reporting of adverse drug reactions on voluntary basis.

(i). PvPI is the 8th largest reporter of Individual Case Safety Reports (ICSRs) in VigiBase at global level.

(ii). As a part of capacity building programme in pharmacovigilance, PvPI is organizing continuously the Skill Development Programmes (SDPs). Continuing Medical Education (CME), Advanced Level Training Programmes (ALTs), Induction-cum Training programmes, hand holding meetings for newly recognized AMCs under PvPl for the sensitization of Healthcare Professionals (HCPs), Patients/Consumers etc. about reporting of Adverse Events with the use of medical products. In the F.Y 2024-25, so far 1,932 trainings have been organized imparting training to 1,62,105 participants.

(iii). The National Coordination Centre-PvPI at Indian Pharmacopoeia Commission has initiated the celebration of National Pharmacovigilance Week from 17th to 23rd September 2021 onwards to raise awareness among stakeholders for reporting adverse drug reaction to Pharmacovigilance Programme of India. This is celebrated annually.

(iv). Indigenously developed ADRMS software of Pharmacovigilance Programme of India has been launched on 19.08.2024.

(v). The PvPI publishes various resource materials, including periodic newsletters, annual performance reports, awareness posters and pamphlets, and pharmacovigilance comics, to inform stakeholders about its nationwide activities. Additionally, the PvPI has released the *Pharmacovigilance Guidance Document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products, Version 2.0*, which became effective on 01.02.2025, to enhance pharmacovigilance systems within MAH organizations. Regional training sessions are also conducted to help MAHs implement this guidance document effectively.

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