

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

**RAJYA SABHA  
STARRED QUESTION NO.\*149  
TO BE ANSWERED ON 14<sup>TH</sup> MARCH, 2023**

**QUALITY OF GENERIC MEDICINES**

**\*149: DR. ASHOK BAJPAI:**

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

(a) whether Government is aware that there is a general public notion that the generic medicines have poor quality;

(b) whether the quality of the generic medicines is being checked by the concerned departments to ensure the correct quantity of its contents; and

(c) the total production, sales and export of generic medicines during the last three years?

**ANSWER  
THE MINISTER FOR HEALTH AND FAMILY WELFARE  
(DR. MANSUKH MANDAVIYA)**

(a) to (c): A Statement is laid on the Table of the House.

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**STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA  
STARRED QUESTION NO.\*149 FOR 14<sup>TH</sup> MARCH, 2023**

(a) to (c): Isolated complaints regarding quality of drugs are received from time to time. As and when such complaints are received, the matter is referred to State Licensing Authorities (SLAs) for taking action as per the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945, as the SLAs are empowered to take action in case of any violation to the provisions of the said Act and Rules.

Drugs imported, manufactured and sold in the country are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder. 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.

The Drugs inspectors appointed under the said Act are authorized to take samples of any drug which is being manufactured or being sold or is stocked or exhibited or offered for sale or is being distributed and these samples are sent to Govt. Analyst for testing/ analysis to ascertain the quality of drugs. In case the sample is found to be Not of Standard Quality (NSQ)/ Spurious/Adulterated/Misbranded, actions are initiated, based on merit, as per provisions of said Acts & Rules.

As per information received from Medical Stores Organization (MSO), they procure generic medicines under Rate Contract for approximately 1100 registered indenters pan India including CGHS, para-military forces, State & Central prisons, civil institutions etc. All the batches of generic medicines received are subjected to double quality checks before they are supplied to the indenters. Each and every batch of generic medicine received is sent to two NABL accredited registered laboratories for quality check. MSO also ensures that each & every batch of medicine received is also accompanied with an "In House" test report from the manufacturers.

As per information provided by Directorate General of Commercial Intelligence & Statistics under Ministry of Commerce & Industry, the export of pharmaceutical products in last three financial years has shown a year-on-year increase. It was USD 20703.46 million in FY 2019-20, USD 24444.03 million in FY 2020-21 & USD 24618.78 million in FY 2021-22. There is no separate code for 'Generic Medicine' under the 'Principal Commodity Groups' of India's export.

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