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

RAJYA SABHA
UNSTARRED QUESTION NO. 429
TO BE ANSWERED ON 06TH FEBRUARY, 2024

STEPS TO IMPROVE THE QUALITY OF LOCALLY-MANUFACTURED DRUGS

429: SHRI JAGGESH:

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

(a) whether it is a fact that the Central Drugs Standard Control Organization (CDSCO) along with state drug inspectors initiated nation-wide crackdown on spurious and substandard drugs across the country;

(b) whether medicines produced by small companies in the country has failed to meet the quality standards during the inspections;

(c) whether Government has taken steps to make pharmaceutical companies to adopt good manufacturing practices to improve the quality of locally- manufactured drugs; and

(d) if so, the details thereof?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a): 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) have conducted risk-based inspections of 275 premises. The 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 250 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.

(b) to (d): As per the Drugs Rules, 1945 the manufacturers whether they are small or otherwise, are required to comply with the conditions of license including the Good manufacturing practices (GMP) as prescribed under the Schedule M of the Drugs Rules, 1945. Further, 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.

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