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

RAJYA SABHA
UNSTARRED QUESTION NO.923
TO BE ANSWERED ON 03RD DECEMBER, 2024

QUALITY STANDARDS OF MEDICINES

923: SHRI BABUBHAI JESANGBHAI DESAI:
DR. MEDHA VISHRAM KULKARNI:

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

(a) whether it is a fact that more than 15 percent of medicines produced by small companies in the country failed to meet the quality standards compared with the national average standard of about 2 percent;

(b) whether the Central Drugs Standard Control Organization (CDSCO) along with State drug inspectors initiated nationwide crack down on spurious and substandard drugs across the country;

(c) if so, the details thereof State-wise from 2021 to 2024;

(d) whether Government has initiated strict action against these companies to protect the quality standard of medicines; and

(e) if so, the details thereof from 2021 to 2024?

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

(a) to (e): List of drugs of various companies, which are declared Not of Standard Quality/ Spurious/ Misbranded/ Adulterated by the Central Drugs Testing Laboratories is regularly uploaded and available on the website of Central Drugs Standard Control Organization (CDSCO) under the heading of Drug Alert (www.cdsco.gov.in).

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.

Further, in the cases concerning quality or safety of drugs as and when reported, actions are taken by the licensing authorities concerned under the provisions of Drugs and Cosmetics Act 1940 and its Rules including prosecution in the appropriate Court of law.

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