

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 4285
TO BE ANSWERED ON THE 20th DECEMBER, 2024

Production of Medicine

†4285. Smt. Sanjna Jatav:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

- (a) whether the Government is aware of the news item published in Dainik Jagran Delhi news dated 23.07.2024 pointing out that five medicines manufactured in Uttarakhand failed the sample test;
- (b) if so, the details thereof;
- (c) the names of the medicines of various pharmaceutical companies which have been tested in different States by the Government through Central Drugs Standards Control Organisation (CDSCO) during the last three years;
- (d) the names of the medicines along with the details of their manufacturing companies which have failed the sample tests; and
- (e) the action taken/Licenses of pharmaceutical companies cancelled by the Government in this regard?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SMT. ANUPRIYA PATEL)

(a) to (e): List of drugs of various companies, which are declared Not of Standard Quality(NSQ)/ Spurious/ Misbranded/ Adulterated by the Central Drugs Testing Laboratories is regularly uploaded and is available on the website of Central Drugs Standard Control Organization (CDSCO) under the heading of Drug Alert (www.cdsco.gov.in). These drug alerts contain complete information regarding the name of the drug, its batch number, manufacturing and expiry date, name of manufacturer, NSQ results from CDSCO lab etc.

With regard to quality and safety of drugs, action is taken as and when the cases of relating to quality or safety are reported, by the state licensing authorities concerned against the manufacturer/producer of Not of Standard Quality (NSQ)/ Spurious/ Misbranded/ Adulterated medicines as per the provisions of Drugs and Cosmetics Act 1940 and its Rules including prosecution in the appropriate Court of law.

Further, 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 December, 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.
