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

LOK SABHA
UNSTARRED QUESTION NO. 5650
TO BE ANSWERED ON 04TH APRIL, 2025

ACTION AGAINST NORRIS MEDICINES

5650 SHRI RAJA RAM SINGH:

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

(a) whether the Government has taken any action against Norris Medicines Limited company that was accused of manufacturing cough syrups containing toxins, if so, the details thereof;

(b) the current status of enquiry, penal action taken and any other relevant information in this regard;

(c) whether the Government has drafted any procedures/regulations to identify and punish companies producing toxic medicines for children post Norris incident and if so, the details thereof;

(d) the list of the companies that have been identified by Central Drugs Standard Control Organisation (CDSCO) for producing fraudulent medicines especially for children since 2020; and

(e) the details of the punishments recommended and the steps taken by the Government for cancellation of licenses of companies responsible for malpractices stated above?

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

(a) & (b): The manufacture, sale and distribution of drugs are primarily regulated in the country under the provisions of Drugs & Cosmetics Act, 1940 & its Rules through a system of licensing and inspection by State Licensing Authorities appointed by respective State Governments. Licensee is required to comply with all the conditions of license as prescribed under Drugs & Cosmetics Rules and the State Licensing Authorities are empowered to take stringent action against violation of provisions of the Act and Rules.

Based on the test results indicating that the drug sample manufactured by M/s. Norris Medicines Limited, Ankleshwar, was not of standard quality, a joint inspection was carried out by Drugs Inspectors from the State and Central Drugs Standard Control Organization (CDSCO). Consequently, following the recommendations of the inspection team, the State

Licensing Authority of Gujarat issued a Show Cause Notice to the firm, followed by stop production order to the firm.

(c) to (e): The provisions under the Drugs and Cosmetics Act, 1940 defines standards of quality drugs including spurious and adulterated drugs.

Manufacture of Spurious/Adulterated/Not of Standard Quality drugs etc. is a punishable offence under the provisions of Drugs & Cosmetics Act, 1940 and licensing authorities concerned are empowered to take action in such cases.

A list of drugs of various companies, which are declared Not of Standard Quality/ Spurious/ Misbranded/ Adulterated by the Central Drugs Testing Laboratories are regularly uploaded on the website of Central Drugs Standard Control Organization (CDSCO) under the heading of Drug Alert (www.cdsco.gov.in).

Further, in order to assess the regulatory compliance of drug manufacturing premises and the quality of drugs being manufactured in the country, the Central Drugs Standard Control Organization (CDSCO), in collaboration with state regulators, initiated risk-based inspections of drug manufacturing and testing firms in December 2022. As of now, 905 units have been inspected, resulting in 694 actions being taken. These actions include Stop Production Orders (SPO), Stop Testing Orders (STO), license suspensions/cancellations, warning letters, and showcause notices, depending on the severity of non-compliance.

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