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

RAJYA SABHA
STARRED QUESTION NO. 203
TO BE ANSWERED ON THE 8TH AUGUST, 2023

QUALITY OF COUGH-SYRUPS

203 SHRI VIVEK K. TANKHA:

Will the Minister of Health and Family Welfare be pleased to state:

(a) the steps being taken in the aftermath of hundreds of deaths of infants reported worldwide linked to cough-syrups manufactured in the country;

(b) whether any form of testing/reporting by the Central Drugs Standard Control Organisation (CDSCO) is mandatory for pharmaceuticals manufactured in the country, before they are permitted for use or to be exported; and

(c) if so, the details of the drugs which have been tested and if not, the reasons therefor?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR MANSUKH MANDAVIYA)

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

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA STARRED QUESTION NO. 203 * FOR 8TH AUGUST, 2023

(a) to (c) The manufacturing, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945. The regulatory control over the manufacture, sale and distribution of drug in the country is exercised through a system of licensing and inspection by the State Licensing Authorities (SLAs) appointed by the respective State Governments. Manufacturers are required to comply with the conditions of Licence granted under the said Act and Rules to manufacture any drugs for sale and distribution in the country. The cases concerning quality or safety of drugs when reported, the matter is taken up with the concerned State Licensing Authority (SLA) in order to take necessary action under the provisions of Drugs and Cosmetics Act 1940 and its Rules. The SLAs are legally empowered to take action of violation of any conditions of such licenses including prosecution in appropriate Court of law.

Central Drugs Standard Control Organization (CDSCO) along with SLAs have conducted risk-based inspections of 162 pharmaceutical firms and based on findings, show cause notices have been issued in 143 cases. So far, stop production order has been issued in 40 cases, cancellation & suspension of product/section Licenses in 66 cases, issuance of warning letter in 21 cases and in 1 case, FIR has been lodged and three persons have been arrested as per the provisions of the Drugs Rules, 1945.

Further, the Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce & Industry has issued a notification (No. 06/2023) dated 22.05.2023 for amendment in export policy of cough syrups, making it compulsory for cough syrup manufactures to get certificate of analysis from a government-approved laboratory before exporting their products with effect from 01.06.2023.

Accordingly, more than 900 such cough syrup samples have been analysed and Certificate of Analysis (CoA) released as on date.

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