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

LOK SABHA
UNSTARRED QUESTION NO.402
TO BE ANSWERED ON 21ST JULY, 2023

COUGH SYRUPS MANUFACTURED BY INDIAN COMPANIES

402: SHRI T.R.V.S. RAMESH:

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

(a) whether the Government has taken cognizance of the reports of the toxins found in cough syrups manufactured and exported by Indian companies to Uzbekistan and Gambia and if so, the details thereof;
(b) whether the Government intends to launch an investigation into the manufacturing standards of the Indian companies involved therein and if so, the the details thereof;
(c) whether the Government has found the said cough syrups to be in circulation in Indian markets; and
(d) whether the Government intends to issue a global alert on the cough syrups manufactured and exported by the involved Indian companies?

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

(a) to (d): Subsequent to reports of deaths of children in Gambia, CDSCO in coordination with State Drug Controller, Haryana carried out investigation at the manufacturing unit of M/s Maiden Pharmaceuticals Limited, to ascertain the facts. Control samples of the aforementioned drugs from the manufacturing unit were drawn and sent for test and analysis to Regional Drug Testing Laboratory, (RDTL) of CDSCO by the investigating team. The said samples were found to be negative for both Diethylene Glycol (DEG) and Ethylene Glycol (EG).

Based on investigations conducted which revealed violation of Good Manufacturing Practices (GMP), State Drugs Controller, Haryana issued show cause notice to M/s Maiden Pharma under Rule 85(2) of the Drugs Rules, 1945 and order has been issued for stopping all the manufacturing activities of M/s Maiden Pharmaceuticals at Sonipat with immediate effect.

In case of Uzbekistan, CDSCO in coordination with State Drugs Controller, Uttar Pradesh conducted a joint investigation at M/s. Marion Biotech Pvt. Ltd., Gautam Budh Nagar, Noida-201301 (U.P.), India to ascertain the facts that allegedly led to the death of children in Uzbekistan. Drug samples were drawn from the manufacturing premises under the provisions of Drugs & Cosmetics Act, 1940 for test & analysis.

Further, manufacturing license of the firm has been suspended by State Licensing Authority, Uttar Pradesh on 09.01.2023. RDTL, Chandigarh has forwarded the test reports of 30 drug samples so far, wherein 24 samples of drugs/raw material were declared as "Not of Standard Quality". Out of these 24 samples declared as "Not of Standard Quality", 22 samples fall under the category of adulterated/spurious under Section 17A and 17B of the Drugs and Cosmetics Act, 1940. An FIR has been lodged on 02.03.2023 in the concerned police station and three persons have been arrested.

Following the suspension of manufacturing license, all the manufacturing and export activities of the said companies are halted.

The joint investigation conducted by CDSCO and State Drugs Controller revealed that the State Drugs Controller had given license to the said companies for manufacture of the drugs, for export purpose only. These drugs were not licensed for manufacture and sale in India.

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 manufacturers to get certificate of analysis from a government-approved laboratory before exporting their products with effect from 01.06.2023.

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