### GOVERNMENT OF INDIA MINISTRY OF CHEMICALS AND FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

#### RAJYA SABHA STARRED QUESTION No. 287 TO BE ANSWERED ON THE 28<sup>TH</sup> MARCH, 2023

#### Toxins found in cough syrups manufactured in the country

### 287 Shri Binoy Viswam:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) whether Government has taken cognizance of reports of toxins found in cough syrups manufactured and exported by Indian companies to Uzbekistan and Gambia;

(b) whether Government intends to launch an investigation into the manufacturing standards of the Indian companies involved;

(c) whether Government has found the said cough syrups to be in circulation in Indian markets; and

(d) whether Government intends to issue a global alert on the cough syrups manufactured and exported by the Indian companies involved?

## ANSWER

# MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS (DR. MANSUKH MANDAVIYA)

(a) to (d): A statement is laid on the Table of the House.

# STATEMENT REFERRED TO IN REPLY TO PARTS (a) TO (d) OF STARRED QUESTION NO. 287 FOR REPLY ON 28.03.2023

(a) & (b): The subject matter pertains to the Department of Health and Family Welfare. In the matter of deaths reported in Gambia, a joint investigation was carried out by CDSCO in coordination with State Drug Controller, Haryana at M/s Maiden Pharmaceuticals Limited 81, HSIDC Industrial Area, Kundli 131028, Dist. Sonepat (Haryana) and control samples of the drugs were drawn and sent for test and analysis to Regional Drug Testing Laboratory, (RDTL) Chandigarh. As per report of the Government Analyst of RDTL Chandigarh, the samples were declared to be of standard quality. The said samples were also found negative for both Diethylene Glycol (DEG) and Ethylene Glycol (EG).

However, based on violations observed in Good Manufacturing Practices, State Drugs Controller, Haryana issued show cause notice to M/s Maiden Pharma on 7.10.2022. Further, an order has been issued to M/s Maiden Pharmaceuticals Limited, Sonepat, Haryana on 11.10.2022 stopping all the manufacturing activities of M/s Maiden Pharmaceuticals at Sonepat with immediate effect in public interest.

Similarly, in case of Uzbekistan, CDSCO in coordination with State Drugs Controller, Uttar Pradesh conducted a joint investigation at M/s. Marion Biotech Pvt. Ltd. B-49, Sector 67, Gautam Budh Nagar, Noida-201301 (U.P.) and during the investigation, drug samples were drawn from the manufacturing premises and sent to Regional Drug Testing Laboratory (RDTL) Chandigarh for test and 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. An FIR has been lodged on 02.03.2023 in the concerned police station and three persons have been arrested.

(c): The State Drug Controller, Haryana and Uttar Pradesh had given licenses to the said company for manufacture of these drugs, for export purpose only.

(d): In view of the above, the question does not arise.

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