GOVERNMENT OF INDIA
MINISTRY OF COMMERCE & INDUSTRY
(DEPARTMENT OF COMMERCE)

LOK SABHA
UNSTARRED QUESTION NO. 5424
TO BE ANSWERED ON 05th APRIL, 2023

PHARMA EXPORT

5424. SHRIMATI MALA ROY:

Will the Minister of **COMMERCE & INDUSTRY (**वाणिज्य एवं उद्योग मंत्री**)** be pleased to state:

(a) whether the Government has undertaken any survey to assess the impact of incidents of cough syrup adulteration/sub-standard items found in products imported from India in the global market in Indian pharma products;

(b) if so, the steps that are being taken to restore confidence of importers; and

(c) the action taken/being taken against these companies?

ANSWER

वाणिज्य एवं उद्योग मंत्रालय में राज्य मंत्री (श्रीमती अनुप्रिया पटेल)

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY
(SMT. ANUPRIYA PATEL)

(a) & (b): Indian Missions abroad are having regular interactions with the authorities to retain the confidence within the drug regulatory agencies. To build confidence and also to ensure continuity of the trade, Pharmaceuticals Export Promotion Council of India (Pharmexcil) has led business delegations to African and Commonwealth of Independent States (CIS) countries and had one-to-one discussions with drug regulating agencies and Pharma trade associations assuring them of the quality of Indian generic products. Pharmexcil is also conducting workshops/training programmes to sensitize the exporters on quality management and to apprize them of the international standards and their compliances.

(c): In the two recent incidents of alleged cough syrup adulteration/sub-standard items found in products exported to Gambia and Uzbekistan, following actions have been taken:

(i) In the case of Gambia, a joint investigation was carried out by Central Drugs Standard Control Organization (CDSCO) in coordination with State Drug Controller, Haryana against M/s Maiden Pharmaceuticals Limited, Sonepat (Haryana) and control samples of the drugs were drawn for test and analysis by Regional Drug Testing Laboratory (RDTL), Chandigarh. RDTL Chandigarh has declared the samples to be of standard quality and negative for both Diethylene Glycol (DEG) and Ethylene

Glycol (EG). However, based on violations observed in Good manufacturing Practices, State Drugs Controller, Haryana has issued an order to M/s Maiden Pharmaceuticals Limited on 11.10.2022 stopping all the manufacturing activities at Sonepat with immediate effect in public interest.

(ii) In the case of Uzbekistan, CDSCO in coordination with State Drugs Controller, Uttar Pradesh conducted a joint investigation at M/s Marion Biotech Pvt. Ltd., Noida (U.P.) and collected drug samples from the manufacturing premises for test and analysis by RDTL, Chandigarh. The manufacturing license of the firm was 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 which 22 samples fall under the category of adulterated/ spurious.

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