GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 1451
TO BE ANSWERED ON THE 14th March, 2023

Deaths of children in Gambia and Uzbekistan due to adulterated cough syrups

1451 Shri Elamaram Kareem:

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

(a) the details regarding the findings and recommendations of the panel set up by Government to investigate the deaths of children in Gambia and Uzbekistan due to adulterated cough syrups supplied by an Indian pharmaceutical company;
(b) whether Government is aware that the company used the same batch of contaminated excipients to manufacture different brands that are sold in the country;
(c) whether Government is aware that the company failed in quality control tests in Gujarat and Kerala and has previously been blacklisted in Bihar and Vietnam; and
(d) if so, the action taken thereon?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a): The subject matter pertains to Central Drugs Standard Control Organization (CDSCO) under the Department of Health and Family Welfare.

As per the information received from CDSCO, the Committee set up by the Department of Health and Family Welfare has submitted its report; The committee observed that several important information is not available for establishing the causality; The limited information provided by WHO was analysed by the committee and found to be inadequate. As part of the summary of the adverse events, WHO has classified the event as Acute Kidney Injury (AKI) secondary to E. coli infection compounded by medication associated poisoning and it was mentioned to be a working hypothesis. The committee, however, observed that the test results from Regional Drugs Testing Laboratory (RDTL), Chandigarh have demonstrated that the four samples in question were of standard quality and negative for Diethylene Glycol (DEG) and Ethylene Glycol (EG). On overall perspective taking into view all the information as available from WHO and CDSCO, the committee opined that there is no causal relationship that could be established between the deaths in Gambia and the products manufactured by M/s Maiden Pharmaceuticals Limited, Haryana.

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., 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, which can cause grievous hurt to patients. An FIR has been lodged on 02.03.2023 in the concerned police station and three persons have been arrested.

(b): In case of Gambia, joint investigation was undertaken by CDSCO and State Drug Controller, Haryana during which it was revealed that the State Drug Controller, Haryana had given licenses to the said company for manufacture of these four drugs namely Promethazine Oral Solution BP, KOFEXMALIN Baby Cough Syrup, MaKOFF Baby Cough syrup and MaGrip n Cold Syrup, for export purpose only. The control samples of the aforementioned drugs were drawn and sent for test and analysis to Regional Drug Testing Laboratory, (RDTL) Chandigarh by the investigating team. As per report of the Government Analyst, the samples have been declared to be of standard quality. The said samples were also found negative for both Diethylene Glycol (DEG) and Ethylene Glycol (EG) meaning thereby that the excipients used was not contaminated with DEG & EG.

Based on investigations conducted, State Drugs Controller, Haryana issued show cause notice to M/s Maiden Pharma on 7.10.2022 under Rule 85(2) of the Drugs Rules, 1945. Further, an order under section 22(1) (d) of the Drugs and Cosmetics Act, 1940 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.

In the case of Uzbekistan, joint investigation was undertaken by CDSCO and State Drug Controller, Uttar Pradesh during which it was revealed that the firm M/s Marion Biotech has obtained permissions for the product DOK 1 Max syrup (Paracetamol, Guaiphenesin and Phenylephrine Hydrochloride Cough syrup), DOK 1 Max tablets (Paracetamol, Guaiphenesin and Phenylephrine Hydrochloride tablet) and Ambronol Syrup (Ambroxol Syrup) for export purpose only.

The sample of excipient ‘Propylene Glycol’ was declared NSQ by Government Analyst Chandigarh and was found not conforming to claim as per IP 2018, Addendum 2021 in respect to Identification. The sample was found to contain Ethylene Glycol (EG). Further, during joint investigation, it was observed that M/s Maya Chemtech India Private Limited, 558, ground floor, village siraspur, landmark near ganesh dharam kanta, delhi-110042 (Registered office address: 158, 159, Block-B, Sainik Nagar, Uttam Nagar, West Delhi, Delhi-110059) was mainly the supplier of Propylene Glycol which has been used in the impugned batches.

Accordingly, an alert has been issued on 07-03-2023 to all State/UT’s Licensing Authorities for issuing directions to manufacturers, not to use Propylene Glycol supplied by M/s Maya Chemtech India Private Limited, Delhi in public interest

(c) & (d**):** As per information received from State Drug Controller, Kerala, five drug formulations of M/s Maiden Pharmaceuticals Limited, Sonepat, Haryana were reported as Not of Standard Quality and necessary steps were taken to prevent the sale of balance portion of drugs available in the market.

As per information received from Commissioner, FDCA Gujarat, one formulation manufactured by M/s Maiden Pharmaceuticals Limited, Himachal Pradesh failed in quality test and the matter was referred to Drugs Controller, Himachal Pradesh for investigation and necessary action.

As per information received from State Drug Controller Bihar, the State Health Society, Bihar had blacklisted the firm M/s Maiden Pharmaceuticals Limited, 81, HSIDC, Industrial Area, Kundli, Distt- Sonepat (Haryana) on 10/02/2011.

Earlier in 2013, CDSCO had received information from Drug Administration of Vietnam regarding Blacklisting of Indian Pharma Companies for alleged quality violations, in which one of the manufacturers was M/s Maiden Pharmaceuticals Limited, India for Drug Omeprazole 20 mg (Omepro) manufactured and exported to Vietnam.

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