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

LOK SABHA
UNSTARRED QUESTION NO.377
TO BE ANSWERED ON 03RD FEBRUARY, 2023

DEATHS DUE TO COUGH SYRUP

377: ADV. ADOOR PRAKASH:

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

(a) whether the Government has conducted any probe into death of children in Gambia and Uzbekistan after consuming cough syrup made in the Country;
(b) if so, the details thereof;
(c) whether the Government has taken any action in this regard;
(d) whether the Government received any communication from the concerned countries in this matter; and
(e) if so, the details thereof?

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

(a) to (b): Subsequent to reports of deaths of children in Gambia, Central Drugs Standard Control Organisation (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 that allegedly led to the death of children in Gambia.

Joint investigation was conducted by CDSCO and State Drug Controller during which it was revealed that the State Drug Controller had given licenses to the said company for manufacture of four drugs, for export purpose only. These drugs were not licensed for manufacture and sale in India, and the said drugs are not marketed or distributed in India.

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.

As per report of the Government Analyst, the samples have been declared to be of standard quality. The said samples were found to be negative for both Diethylene Glycol (DEG) and Ethylene Glycol (EG).

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., Noida, Uttar Pradesh 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.

(c): 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 have been issued for stopping all the manufacturing activities of M/s Maiden Pharmaceuticals at Sonipat with immediate effect for violation of GMP.

Similary, based on investigations conducted by State Drugs Controller, Uttar Pradesh manufacturing license of M/s. Marion Biotech Pvt. Ltd., Noida, Uttar Pradesh has been suspended with immediate effect for violation of GMP.

(d) & (e): As informed by CDSCO, no communication has been received from Government of Gambia that use of the products manufactured by M/s Maiden Pharmaceuticals Limited, Sonipat has led to the death of children in their Country.

However, a communication has been received in Ministry of Health and Family Welfare from the Ministry of Health of the Republic of Uzbekistan informing that the use of the drug ‘Doc-1 Max’ Syrup manufactured by M/s. Marion Biotech Pvt. Ltd, Noida resulted in severe side effects that led to the death of children and upon testing the said drug has revealed presence of Ethylene Glycol and/or Diethylene Glycol.

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