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

LOK SABHA
UNSTARRED QUESTION NO.†1783
TO BE ANSWERED ON 16th DECEMBER, 2022

CONTAMINATED MEDICINE

†1783: SHRI TIRATH SINGH RAWAT:

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

(a) whether the Government has taken/proposes to take any concrete steps to investigate the contaminated medicine/deficiencies of syrup as reported by WHO which led to the death of infants;
(b) if so, the details thereof and if not, the reasons therefor;
(c) whether the Government is aware that the pharmaceutical company violated the norms prescribed by the Drug Controller for the manufacturing of medicines/syrups; and
(d) if so, the details thereof?

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

(a) to (d): Central Drugs Standard Control Organisation (CDSCO) in coordination with State Drug Controller has carried out investigation at the concerned manufacturing unit, to ascertain the facts of the matter reported by WHO.

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).

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.

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