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INDIAN FIRM'S COUGH SYRUPS MAY BE TIED TO 66 DEATHS IN GAMBIA: WHO

Relevant for: Science & Technology | Topic: Biotechnology, Genetics & Health related developments

A building of the World Health Organization (WHO). File. | Photo Credit: Reuters

The World Health Organization (WHO) on Wednesday issued a medical product alert over four cough and cold syrups made by Maiden Pharmaceuticals in India, warning that they could be linked to acute kidney injuries and deaths of 66 children in The Gambia.

According to reports, the global health body said it was conducting further investigation with the company and regulatory authorities in India.

"Laboratory analysis of samples of each of the four products confirms that they contain unacceptable amounts of diethylene glycol and ethylene glycol as contaminants," the WHO said and warned that while the contested products had so far been found in the West African nation, the same could have been distributed to other countries.

A senior Health Ministry official confirmed to *The Hindu* that the WHO on September 29 informed the Drugs Controller General of India (DCGI) that it was providing technical assistance and advice to The Gambia where children were suspected to have died, and a significant contributing factor was suspected to be the use of medicines which may have been contaminated with diethylene glycol or ethylene glycol (this has been confirmed in some of the samples by further analysis conducted by the WHO).

Urgent investigation in the matter had been taken up by the drug regulator with the State regulatory authorities immediately after receiving communication from the WHO based on the available information, the official said.

The official added that while all required steps would be taken in the matter, “as a robust National Regulatory Authority, WHO has been requested to share at the earliest with Central Drugs Standard Control Organisation (CDSCO) the report on establishment of causal relation to death with the medical products in question, photographs of labels/ products etc. which is awaited”.

“The drug regulator took up the matter immediately with the concerned State Regulatory Authority under whose jurisdiction the drug manufacturing unit is located. Further, a detailed investigation was launched to ascertain the facts/ details in the matter in collaboration with the State Drugs Controller, Haryana (the concerned State Drug Control Authority),’’ the official said.

From the preliminary inquiry, it has been found that Maiden Pharmaceutical Ltd., Sonepat, Haryana is a manufacturer licensed by the State Drug Controller for the products under reference, and holds manufacturing permission for these products. The company has manufactured and exported these products only to The Gambia so far.

It is a practice that the importing country tests these products on quality parameters, and satisfies itself as to the quality of the products before their release for usage in the country.

The Health Ministry official further added that as per the tentative results received by the WHO, out of the 23 samples tested, four were found to contain diethylene glycol/ ethylene glycol as

indicated.

“It has also been informed by WHO that the certificate of analysis will be made available to WHO in near future and WHO will share it with India. At the same time, the exact one-to-one causal relation of death has not yet been provided by WHO, nor have the details of labels/ products been shared by WHO with Indian drug regulators enabling it to confirm the identity/ source of the manufacturing of the products,” he said.

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