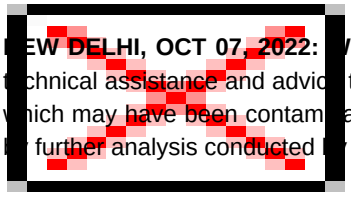
WHO product alert on cough syrup - Probe rolled out

By TIOL News Service



NEW DELHI, OCT 07, 2022: WHO on 29.09.2022 informed DCGI, the National Drug Regulator of India, that WHO it is currently providing technical assistance and advice to Gambia, where children have died and where a contributing factor, is suspected to be the use of medicines which may have been contaminated with Diethylene glycol or Ethylene glycol (in some of the samples it was claimed to have been confirmed by further analysis conducted by WHO).

CDSCO took up the matter immediately with Haryana State Regulatory Authority, under whose jurisdiction the drug manufacturing unit of M/s Maiden Pharmaceutical Limited, Sonepat is located. Further, a detailed investigation was launched to ascertain the facts/ details in the matter in collaboration with State Drugs Controller, Haryana.

From the preliminary enquiry of CDSCO, it has been made out that M/s Maiden Pharmaceutical Limited, Sonepat, Haryana is a manufacturer licensed by the State Drug Controller for the products Promethazine Oral Solution BP, Kofexnalin Baby Cough Syrup, MaKoff Baby Cough Syrup and MaGrip n Cold Syrup under reference, and holds manufacturing permission for these products for export only. The company has manufactured and exported these products only to Gambia.

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

As per the tentative results received by WHO, out of the 23 samples of the products under reference which were tested, 04 samples have been found to contain Diethylene Glycol/ Ethylene Glycol. 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 the Indian Regulator which is yet to be done. The exact one to one causal relation of death has not yet been provided by WHO to CDSCO.

As a robust National Regulatory Authority, CDSCO has requested WHO to share at the earliest with CDSCO the report on establishment of causal relation to death with the medical products in question etc.

The State Drug Controller had given licenses to the said Company only for export of these four drugs namely Promethazine Oral Solution BP, Kofexnalin Baby Cough Syrup, MaKoff Baby Cough Syrup and MaGrip n Cold Syrup. Further all these 04 drugs manufactured only for exports by M/s. Maiden Pharmaceuticals Limited are not licensed for manufacture and sale in India. In effect, none of these four drugs of M/s. Maiden Pharmaceuticals is sold domestically in India.

The samples (controlled samples of the same batch manufactured by M/s. Maiden Pharmaceuticals Limited for all the four drugs in question) have been taken and sent for testing to Regional Drug Testing Lab, Chandigarh by CDSCO, the results of which will guide further course of action as well as bring clarity on the inputs received/ to be received from WHO.