Kids’ death in Gambia: Question of Drug Regulation

Published On: 16-12-2022

In News: WHO drew an early link between kids' deaths in Gambia, Haryana Firm's syrups: DCGI; The WHO medical alert in October linked four syrups manufactured by Haryana-based Maiden Pharmaceuticals — Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup and Magrip N Cold Syrup — with the death of 70 children due to Acute Kidney Injury in the Gambia.

What is the Issue?

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.

What is the Role of WHO in Drug Regulation?

Established in 1968, the WHO Programme for International Drug Monitoring (PIDM) provides a global platform for Member States to exchange safety and regulatory information on all medicines and vaccines. Vigibase is the WHO global database of individual case safety reports (ICSR), a repository of safety data maintained by the WHO Collaborating Centre, the Uppsala Monitoring Centre (UMC), on behalf of WHO and its Member States. Vigibase holds over 28 million case safety reports shared by 148 countries. The data are routinely analyzed by UMC for new signals and to study trends with known signals using a Bayesian method of disproportionality analysis and adverse event-drug pair pattern detection.

What is Pharmacovigilance?

Medicines and vaccines have transformed the prevention and treatment of diseases. In addition to their benefits, medicinal products may also have side effects, some of which may be undesirable and / or unexpected. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.

All medicines and vaccines undergo rigorous testing for safety and efficacy through clinical trials before they are authorized for use. However, the clinical trial process involves studying these products in a relatively small number of selected individuals for a short period of time. Certain side effects may only emerge once these products have been used by a heterogenous population, including people with other concurrent diseases, and over a long period of time.

Why DCGI make a critical statement?

An independent investigation by DCGI found that the control samples — samples from the same batch exported to the Gambia maintained by the company for quality control purposes — did not contain di-ethylene glycol or ethylene glycol.

The drug regulator also tested the propylene glycol and glycerine — both used as solvents in manufacturing of syrups — available at the manufacturing facility at the time of inspection and found that they did not contain di-ethylene glycol or ethylene glycol over the permissible limit, the report stated. The propylene glycol had been sourced from a South Korean company and the glycerine from Adani Wilmar via a Delhi-based firm. The solvents were thought to be the most likely source of di-ethylene glycol or ethylene glycol contamination, which is known to cause acute kidney injury.