FOOD AND DRUGS AUTHORITY
FDA
GHANA
Your Well-being, Our Priority

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FDA/HPT/VVC/SMD/VGU/23/0263

9th August 2023

SAFETY ALERT:
SUBSTANDARD (CONTAMINATED) SYRUP MEDICINE IDENTIFIED IN WHO REGION OF THE EASTERN MEDITERRANEAN

The Food and Drugs Authority (FDA) wishes to bring to your attention that the World Health Organization (WHO) has identified a substandard batch of medicinal products in The Republic of Iraq. The identified product is **COLD OUT SYRUP** which contains Paracetamol and Chlorpheniramine maleate. The details of the product is shown on page 3 as Annex I.

Paracetamol and Chlorpheniramine maleate combination syrups are used to treat and relieve symptoms of common cold and allergy.

The product is considered substandard because laboratory analysis showed that the samples contain unacceptable amounts of diethylene glycol (0.25%) and ethylene glycol (2.1%) as contaminants. The acceptable safety limit for both ethylene glycol and diethylene glycol is **not more than 0.10%**.

The stated manufacturer of the affected batch of the product is **FOURRTS (INDIA) LABORATORIES PVT. LTD**, and the product is stated to be manufactured for **DABILIFE PHARMA PVT. LTD (INDIA)**. As of 7th August 2023, the stated manufacturer and the marketer have not provided guarantees to WHO on the safety and quality of the affected batch of this product.

Diethylene glycol and ethylene glycol are toxic to humans when consumed and can prove fatal. Toxic effects can include abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state and acute kidney injury which may lead to death.

The FDA would like to inform you that these products have **not** been registered by the Authority and are not expected on the Ghanaian market however they may have been distributed illegally.

The FDA wishes to advise all healthcare professionals to report suspected falsified medicinal products to the FDA by completing the Adverse Reaction Reporting Form or online using the link http://adr.fdaghana.gov.gh or call Mobile no: 024431 0297 or send an email to drug.safetv@fdaghana.gov.gh.

Meanwhile, the FDA has strengthened its post-market surveillance activities at the borders and across the country with the view to identify and withdraw any unregistered products on the Ghanaian market.

Please, find attached the Medical Product Alert No.6/2023 from the WHO on Substandard (contaminated) syrup medicines identified in the WHO Region of the Eastern Mediterranean.

Additionally, to report and receive the latest safety alerts and recalls, download the MedSafety App from Google Play or the App Store.

Yours faithfully,

DR. MRS. AKUA O. AMARTEY
DCEO, TECHNICAL OPERATIONS DIVISION
FOR: CHIEF EXECUTIVE OFFICER

Annex I: Image of Implicated product.

Annex: Batch of Product subject of WHO Medical Product Alert No.6/2023

Product name	COLD OUT syrup
Stated manufacturer	FOURRTS (INDIA) LABORATORIES PVT. LTD
Stated marketer	DABILIFE PHARMA PVT. LTD. - INDIA
Batch	SF001A02
Expiry date	DEC.2024
Identified in	Republic of Iraq
Available photos