Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

21 SEP 2023

FDA ADVISORY
No. 2023-2071

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning on Substandard (Contaminated) Paracetamol + Chlorpheniramine Maleate Syrup Confirmed by the World Health Organization (WHO)**

The Food and Drug Administration (FDA) notifies the public on the WHO Medical Product Alert on a substandard (contaminated) Paracetamol + Chlorpheniramine Maleate 2 mg/5 mL syrup [Cold Out Syrup] that have been identified in the Eastern Mediterranean region in July 2023:

PRODUCT NAME	Paracetamol + Chlorpheniramine Maleate 2 mg/5 mL Syrup [Cold Out]
STATED MANUFACTURER	Fourrts (India) Laboratories Pvt. Ltd. – Tamil Nadu, India
STATED MARKETER	Dabilife Pharma Pvt. Ltd. – India
BATCH NO.	SF001A02
EXP. DATE	DEC.2024
PACKAGING LANGUAGE	English

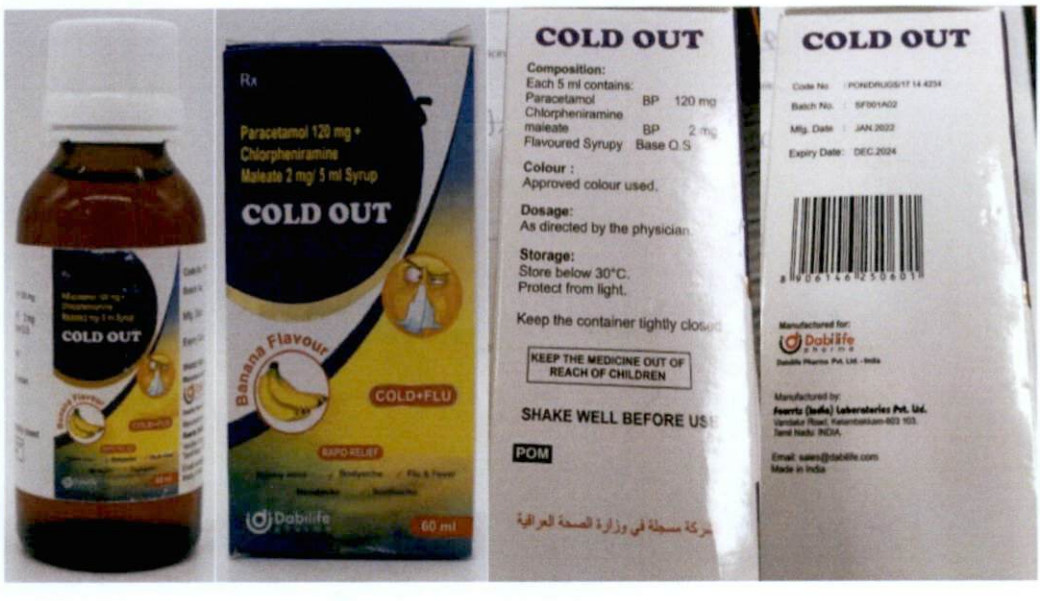

Figure 1. Paracetamol + Chlorpheniramine Maleate 2 mg/5 mL Syrup [Cold Out] detected in Iraq

The FDA strongly advises the public to be vigilant on the circulation of these substandard drug products since its contaminants, Diethylene Glycol and Ethylene Glycol, are toxic to humans when consumed above the acceptable limit and may result to abdominal pain, vomiting, diarrhea, inability to pass urine, headache, altered mental state and acute kidney injury which may lead to death. Substandard drug products are products that fail to meet either their quality standards or specifications. To date, the stated manufacturer and marketer have yet to provide guarantees to WHO on the safety and quality of this product.

This is to emphasize that the abovementioned drug product is not registered with FDA. However, it is important to detect and remove this product from circulation to prevent harm to patients.

Therefore, all Local Government Units (LGU) and Law Enforcement Agencies (LEAs), after the issuance of this advisory, are requested to ensure that this substandard drug product is not sold or not administered to patients in their localities or areas of jurisdiction. Furthermore, manufacturers of liquid dosage forms, especially syrups that contain excipients such as propylene glycol, polyethylene glycol, sorbitol, and/or glycerin/glycerol, are urged to test for the presence of the stated contaminants before use in production of pharmaceutical products.

For more information and inquiries, please e-mail us at **cdrr_postmarketsurveillance@fda.gov.ph**. To report unauthorized sale, or distribution of the abovementioned, kindly e-mail us via **cdrr.od@fda.gov.ph**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**.

Dissemination of the information to all concerned is highly requested.

DR. SAMUEL A. ZACATE
Director General

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