Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No: 2023-0945

09 MAY 2023

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

SUBJECT: **Public Health Warning on Substandard (Contaminated) Guaifenesin 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) Guaifenesin syrup [TG Syrup] that have been identified in the Western Pacific region in April 2023:

PRODUCT NAME	Guaifenesin Syrup [TG Syrup]
STATED MANUFACTURER	QP Pharmachem Ltd. – Punjab, India
STATED MARKETER	Trillium Pharma – Haryana, India
BATCH NO.	SL-429
EXP. DATE	10/2023
PACKAGING LANGUAGE	English

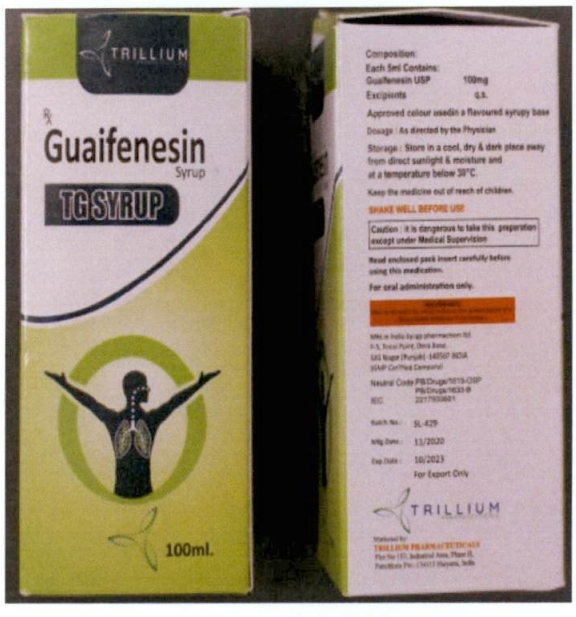

Figure 1. Guaifenesin Syrup [TG Syrup] detected in Marshall Islands, Micronesia (Federated States of)

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, neither the stated manufacturer nor the marketer have provided 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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