Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration PHILIPPINES

FDA ADVISORY
No: 2023-0088

18 JAN 2023

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

SUBJECT: **Public Health Warning on Substandard (Contaminated) Pediatric Drug Products in Syrup Dosage Form Confirmed by the World Health Organization (WHO)**

The Food and Drug Administration (FDA) notifies the public on the WHO Medical Product Alert on two (2) substandard (contaminated) pediatric drug products that have been identified in the European Region in December 2022:

PRODUCT NAME	Ambroxol HCl Cough Syrup [Ambronol]	Paracetamol + Guaifenesin + Phenylephrine Hydrochloride Syrup [Dok-1 Max]
STATED MANUFACTURER	Marion Biotech Pvt. Ltd. – Uttar Pradesh, India	
BATCH NO.	See attached Annex	
EXP. DATE		
PACKAGING LANGUAGE	Russian	

Figure 1. Ambronol Cough Syrup and Dok-1 Max Syrup detected in Uzbekistan

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 has not provided guarantees to WHO on the safety and quality of these products.

This is to emphasize that the abovementioned drug products are not registered with FDA. However, it is important to detect and remove these products 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 these substandard drug products are 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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