FDA ADVISORY
No. 2023-2595

28 DEC 2023

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

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

The Food and Drug Administration (FDA) notifies the public on the WHO Medical Product Alert on five (5) substandard (contaminated) pediatric drug products manufactured (as stated in label) by Pharmix Laboratories (Pvt.) Ltd. that have been identified in the Americas, Eastern Mediterranean, Southeast Asia, and Western Pacific Regions in November 2023:

1. Alergo Syrup

Batch No.	Manufacturing date	Expiry date	Identified in
L126	27/12/2021	26/12/2023	Pakistan
B220	16/02/2022	15/02/2024	Belize, Fiji, Lao PDR, Maldives, Pakistan
G204	05/07/2022	04/08/2024	Maldives
L210	12/12/2022	11/12/2024	Maldives
K222	16/11/2022	15/11/2024	Maldives
J242	26/10/2022	25/10/2024	Maldives

2. Emidone Suspension

Batch No.	Manufacturing date	Expiry date	Identified in
B227	25/02/2022	24/02/2024	Pakistan

3. Mucorid Syrup

Batch No.	Manufacturing date	Expiry date	Identified in
A210	10/01/2022	09/01/2024	Pakistan
A211	19/01/2022	18/01/2024	Pakistan
A212	19/01/2022	18/01/2024	Pakistan
A230	29/01/2022	28/01/2024	Pakistan
B201	03/02/2022	02/02/2024	Pakistan
B224	18/02/2022	17/02/2024	Pakistan
B225	21/02/2022	20/02/2024	Pakistan
C210	08/03/2022	07/03/2024	Pakistan
C227	21/03/2022	20/02/2024	Pakistan

L111	13/12/2021	12/12/2023	Pakistan
L121	20/12/2021	19/12/2023	Pakistan

4. Ulcofin Suspension

Batch No.	Manufacturing date	Expiry date	Identified in
B209	08/02/2022	07/02/2024	Pakistan
C223	17/03/2022	16/03/2024	Pakistan

5. Zincell Syrup

Batch No.	Manufacturing date	Expiry date	Identified in
C218	11/03/2022	10/03/2024	Pakistan

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, there is no reported adverse effects linked to the affected products have been notified to WHO. Furthermore, the Drug Regulatory Authority of Pakistan (DRAP) instructed the manufacturer to stop their production of oral liquid dosage forms, and issued a Recall Alert for these products, as precautionary measures.

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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