World Health Organization

7 December 2023

Medical Product Alert No. 8/2023
Substandard (contaminated) syrup and suspension medicines identified in the WHO Regions of the Americas, Eastern Mediterranean, South-East Asia and Western Pacific

Alert Summary

This WHO Medical Product Alert refers to five different syrup and suspension medicines initially detected in the Maldives and Pakistan and notified to WHO on 8 November 2023. Some of the affected products have also been detected in Belize, Fiji and Lao People's Democratic Republic.

The five products are ALERGO Syrup, EMIDONE Suspension, MUCORID Syrup, ULCOFIN Suspension and ZINCELL Syrup. A total of 23 batches of these products are affected. The stated manufacturer of all the affected products is PHARMIX LABORATORIES (PVT.) LTD (Pakistan).

In November 2023, samples of five different batches of ALERGO syrup were screened for non-compliance by the quality control laboratory of the Maldives Food and Drug Authority (MFDA) in accordance with the thin layer chromatography (TLC) test for Diethylene Glycol and Ethylene Glycol for inclusion in The International Pharmacopoeia. The routine screening detected potentially unacceptable amounts of diethylene glycol and ethylene glycol as contaminants. Laboratory testing conducted by the Therapeutic Goods Administration of Australia confirmed that all five batches were contaminated with ethylene glycol at levels ranging from 0.62 to 0.82% w/w relative to the accepted limit of not more than 0.10% w/w.

A follow-on inspection of PHARMIX LABORATORIES (PVT.) LTD was conducted by the Drug Regulatory Authority of Pakistan (DRAP). DRAP's review of the manufacturing facility and manufacturing records suggests that diethylene glycol/ethylene glycol as contaminants may be present in other products and batches manufactured by PHARMIX LABORATORIES (PVT.) LTD. The safety and quality of these products can, therefore, not be guaranteed.

As a precautionary measure PHARMIX LABORATORIES has been instructed by DRAP to stop production of all oral liquid dosage medicines and on 16 November 2023, DRAP issued a Recall Alert for five different syrup medicines manufactured by PHARMIX LABORATORIES. See DRAP Alert No I/S/11-23-40.

The products referenced in this Medical Product Alert No. 8/2023 may have been distributed, through formal and informal markets, to other countries or regions.

To date, no reports of adverse effects linked to the affected products have been notified to WHO. However, while this Medical Product Alert specifically relates to products referenced in the Annex, out of an abundance of caution, WHO recommends increased vigilance and testing in respect of oral liquid dosage medicines produced by PHARMIX LABORATORIES (PVT.) between December 2021 and December 2022.

Please refer to the Annex 1 of this Alert for full details of the affected products.

WHO has previously published six Alerts on other contaminated liquid dosage medicines. Please see Medical Product Alert No.6/2022, Medical Product Alert No.7/2022, Medical Product Alert No.1/2023, Medical Product Alert No.4/2023, Medical Product Alert No.5/2023 and Medical Product Alert No.6/2023.

Risks

Diethylene glycol and ethylene glycol are toxic to humans when consumed and can prove fatal.
The substandard products referenced in this alert are unsafe and their use, especially in children, may result in serious injury or death. 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.

Advice to regulatory authorities and the public

WHO recommends that you do not use any of the affected products.. If you, or someone you know, have used these products, or suffered an adverse reaction or unexpected side-effect after use, you are advised to seek immediate medical advice from a healthcare professional.

WHO requests increased surveillance and diligence within the supply chains of countries and regions likely to be affected by these products. Increased surveillance of the informal/unregulated market is also advised. National regulatory authorities/health authorities are advised to immediately notify WHO if these substandard products are discovered in their respective country.

Manufacturers of liquid dosage forms, especially syrups that contain excipients at risk for contamination with EG/DEG, e.g. glycol, sorbitol, and/or glycerin/glycerol, are urged to follow GMP requirements and to test each container of each incoming batch for ethylene glycol and diethylene glycol before using the excipients in the production of medicines.

Healthcare professionals should report any cases of adverse events suspected to be linked to the use of these contaminated medicines to the National Regulatory Authorities/National Pharmacovigilance Centre.

If you have any information about the manufacture or supply of these products or excipients, please contact WHO via rapidalert@who.int.

Click to access Annex 1: Products subject of WHO Medical Product Alert No. 8/2023.

Annex: Products subject of WHO Medical Product Alert No. 8/2023

Annex 1 of WHO Medical Product Alert No. 8/2023				
Stated Manufacturer: Pharmix Laboratories (Pvt.) Ltd.				
Product Name	**Batch**	**Manufacture date**	**Expiry date**	**Identified In**
Alergo syrup	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	04/07/2024	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
Emidone Suspension	B227	25/02/2022	24/02/2024	Pakistan
Mucorid Syrup	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
	A230	29/01/2022	28/01/2024	Pakistan
	B201	03/02/2022	02/02/2024	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
Ulcofin Suspension	B209	08/02/2022	07/02/2024	Pakistan
	C223	17/03/2022	16/03/2024	Pakistan
Zincell Syrup	C218	11/03/2022	10/03/2024	Pakistan