



NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL

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NAFDAC/DG/12/LTTI/AHNCRMAH.CLMDGAEG/22.12

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LETTER TO THE INDUSTRY

TO ALL HOLDERS OF NAFDAC CERTIFICATE OF REGISTRATION/ MARKET
AUTHORIZATION HOLDERS

RE: CONTAMINATION OF LIQUID MEDICINES BY DIETHYLENE GLYCOL AND
ETHYLENE GLYCOL

The World Health Organization (WHO) has notified NAFDAC about the incident of five (5) contaminated syrup and suspension medicines initially detected in the **Maldives** and **Pakistan** and notified to WHO on 8 November 2023. Some affected products have also been detected in **Belize, Fiji**, and the **Lao People's Democratic Republic**.

The quality control laboratory of the Maldives Food and Drug Authority (MFDA) detected potentially unacceptable amounts of diethylene glycol and ethylene glycol as contaminants in five batches of Alergo Syrup during a routine screening using Thin Layer Chromatography (TLC) with reference to The International Pharmacopoeia. Laboratory testing conducted by the Therapeutic Goods Administration (TGA) 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.

The Drug Regulatory Authority of Pakistan (DRAP) follow-on inspection report of PHARMIX LABORATORIES (PVT.) LTD, a 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. As a precautionary measure, PHARMIX LABORATORIES has been instructed by DRAP to stop production of all oral liquid dosage medicines and issued a Recall Alert for five different syrup medicines manufactured by PHARMIX LABORATORIES.

Below is the list of the affected products as captured on the WHO website.

S/N	PRODUCT	MANUFACTURER
1	ALERGO SYRUP	Pharmix Laboratories (PVT) LTD, Pakistan
2	EMIDONE SUSPENSION	Pharmix Laboratories (PVT) LTD, Pakistan
3	MUCORID SYRUP	Pharmix Laboratories (PVT) LTD, Pakistan
4	ULCOFIN SUSPENSION	Pharmix Laboratories (PVT) LTD, Pakistan
5	ZINCELL SYRUP	Pharmix Laboratories (PVT) LTD, Pakistan

Note that none of the above-listed products are registered in Nigeria by NAFDAC.

Other WHO similar alert notices on product contamination with diethylene glycol/ethylene glycol are:

S/N	PRODUCT	MANUFACTURER
1	Promethazine Oral Solution	Maiden Pharmaceuticals Limited (Haryana, India).
2	Kofexmalin Baby Cough Syrup	Maiden Pharmaceuticals Limited (Haryana, India).
3	Makoff Baby Cough Syrup	Maiden Pharmaceuticals Limited (Haryana, India).
4	Magrip N Cold Syrup	Maiden Pharmaceuticals Limited (Haryana, India).
5	Termorex Syrup (batch AUG 22A06 only)	PT Afi Farma, Indonesia
6	<i>Flurin DMP syrup</i>	PT Afi Farma, Indonesia
7	<i>Unibebi Cough Syrup</i>	PT Afi Farma, Indonesia
8	<i>Unibebi Demam Paracetamol Drops</i>	PT Afi Farma, Indonesia
9	<i>Unibebi Demam Paracetamol Syrup</i>	PT Afi Farma, Indonesia
10	<i>Paracetamol Drops</i>	PT Afi Farma, Indonesia
11	<i>Paracetamol Syrup (mint)</i>	PT Afi Farma, Indonesia
12	<i>Vipcol Syrup</i>	PT Afi Farma, Indonesia
13	AMBRONOL syrup	Marion Biotech Pvt. Ltd, (Uttar Pradesh, India).
14	DOK-1 Max syrup	Marion Biotech Pvt. Ltd, (Uttar Pradesh, India).
15	Guaifenesin syrup TG syrup	QP PHARMACHEM LTD (Punjab, India)

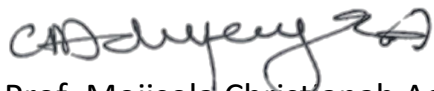
16	NATURCOLD syrup	FRAKEN INTERNATIONAL, England (Not confirmed)
17	COLD OUT syrup	FOURRTS (INDIA) LABORATORIES PVT. LTD

Note: Diethylene glycol and ethylene glycol are toxic to humans, especially in children, and may result in serious injury or death. Toxic effects can include abdominal pain, vomiting, diarrhea, inability to pass urine, headache, altered mental state, and acute kidney injury which may lead to death.

Manufacturers of liquid dosage forms, especially syrups that contain excipients including propylene glycol, polyethylene glycol, sorbitol, and glycerine/glycerol, **are urged to test for the presence of contaminants** such as ethylene glycol and diethylene glycol before use in the manufacture of medicines.

In response, NAFDAC is also surveying liquid medicines to determine contamination with Diethylene glycol and ethylene glycol.

Thank you for your anticipated cooperation.



Prof. Mojisola Christianah Adeyeye, PhD, FAS
Director-General