গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
ঔষধ প্রশাসন অধিদপ্তর
ঔষধ ভবন, মহাখালী, ঢাকা-১২১২
www.dgda.gov.bd

নং-ডিজিডিএ/এলার্ট-নোটিশ/এমসি-১৬/২০১৯/ ১৯৭০৭ তারিখঃ ০২/১১/২০২২খ্রিঃ
বরাবর

1. DG, Directorate General of Health Services Director,
2. CMSD,Tejgoan,Dhaka.
3. Secretary General, Bangladesh Medical Association (BMA), BMA Vaban, 15/2 Topkhana Road, Dhaka.
4. Secretary General, BAPI.
5. President, Bangladesh Importers Association.
6. Bangladesh Chemist & Drugist Somity (BCDS)

বিষয়ঃ বিশ্ব স্বাস্থ্য সংস্থা (WHO) এর Rapid Alert team এর email প্রসঙ্গে।

WHO Rapid Alert team নিম্নলিখিত ৩টি উৎপাদনকারী প্রতিষ্ঠান PT Konimex, PT Yarindo Farmatama, Universal Pharmaceutical Industries এর ৫টি পদের সিরাপের বিষয়ে Indonesia এর ড্রাগ রেগুলেটরি অথোরিটি Bandan, POM (National Agency of Drug and Food Control, Indonesia) দেশটিতে এলার্ট জারি করেছে বলে ঔষধ প্রশাসন অধিদপ্তরকে জানিয়েছে।উক্ত সিরাপগুলোতে মাত্রাতিরিক্ত পরিমানে ইথিলিন গ্লাইকল এবং ডাই ইথিলিনগ্লাইকল পাওয়া যচ্ছে বলে WHO Rapid Alert team অবগত করেছে।

মেডিকেল প্রোডাক্টগুলোর বর্ণনাঃ

PRODUCT	TERMOREX SYRUP	FLURIN DMP SYRUP	UNIBEBI COUGH SYRUP	UNIBEBI DEMAM PARACETAMOL SYRUP	UNIBEBI FEVER DROPS
Active Ingredient	Paracetamol 160mg	Paracetamol 120 mg, Chlorpheniramine maleate 0.5 mg, Pseudoephedrine HCl 7.5 mg, Dextromethorphan HBr 5 mg	Paracetamol 120 mg, Guaifenesin 25mg, Chlorpheniramine maleate 1mg	Paracetamol 120 mg	Paracetamol 100mg
MANUFACTURER	PT Konimex	PT Yarindo Farmatama	Universal Pharmaceutical Industries	Universal Pharmaceutical Industries	Universal Pharmaceutical Industries
PACKAGING LANGUAGE	Indonesian	Indonesian	Indonesian	Indonesian	Indonesian

এমতাবস্থায়, উপরোল্লিখিত ঔষধটি ব্যবহার থেকে বিরত থাকার জন্য এবং এতদ্বসংক্রান্ত বিষয়ে সতর্ক থাকার জন্য অনুরোধ করা হল।

০২/১১/২২
মোঃ আসরাফ হোসেন
পরিচালক
ঔষধ প্রশাসন অধিদপ্তর, ঢাকা।
ফোনঃ ০২২২২২-৮০৮০৩

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Q/REG/ISF/Alert N°7/2022

2 November 2022

Medical Product Alert N°7/2022

Substandard (contaminated) paediatric liquid dosage medicines identified in WHO region of South-East Asia

Alert Summary

This WHO Medical Product Alert refers to eight substandard products, identified in the WHO Region of South-East Asia. These products were identified in Indonesia and publicly reported by the national regulatory authority (Badan POM) on 20 and 30 October 2022[1]. Substandard medical products are products that fail to meet either their quality standards or specifications and are therefore "out of specification"[2].

The eight products are *Termorex syrup, Flurin DMP syrup, Unibebi Cough Syrup, Unibebi Demam Paracetamol Drops, Unibebi Demam Paracetamol Syrup, Paracetamol Drops, Paracetamol Syrup (mint) and Vipcol Syrup.* Please see the annex for further details.

These products contain unacceptable amounts of ethylene glycol and/or diethylene glycol as contaminants: this has been confirmed by laboratory analysis of samples by the authorities in Indonesia. To date, these products have been identified in Indonesia. They may however have marketing authorizations in other countries. These products may have been distributed, through informal markets, to other countries or regions.

Risks

Ethylene glycol and diethylene glycol are toxic to humans when consumed and can prove fatal.

The substandard products referenced in the annex of 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, manufacturers and the public

It is important to detect and remove these substandard products from circulation to prevent harm to patients.
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/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 including propylene glycol, polyethylene glycol, sorbitol, and/or glycerin/glycerol, are urged to test for the presence of contaminants such as ethylene glycol and diethylene glycol before use in medicines.

All medical products must be approved and obtained from authorized/licensed suppliers. The products' authenticity and physical condition should be carefully checked. Seek advice from a healthcare professional when in doubt.
If you have these substandard products, **please DO NOT use them**. If you, or someone you know, have used them or suffered any adverse reaction/event after use, you are advised to seek immediate medical advice from a qualified healthcare professional and report the incident to the National Regulatory Authority or National Pharmacovigilance Centre.

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

Please see annex 1 and 2 for details of the substandard products referenced in Alert N°7/2022.
Alert n°7/2022 may be updated if further relevant information becomes available.

---

[1] Badan POM Press Release: https://www.pom.go.id/new/view/more/klarifikasi/158/INFORMASI-KEEMPAT-HASIL-PENGAWASAN-BPOM-TERHADAP-SIRUP-OBAT-YANG-DIDUGA-MENGANDUNG-CEMARAN-ETILEN-GLIKOL--EG--DAN-DIETILEN-GLIKOL--DEG-.html and https://www.pom.go.id/new/view/more/pers/664/Tindakan-Tegas-BPOM-dan-Bareskrim-Polri-Terhadap-Industri-Farmasi--Produsen-Sirup-Obat-yang-Tidak-Memenuhi-Standar-dan-atau-Persyaratan-Keamanan--Khasiat--dan-Mutu.html

[2] WHO definitions : https://www.who.int/teams/regulation-prequalification/incidents-and-SF/background/definitions

Ref. RPQ/REG/ISF/Alert N°7/2022: products contaminated with ethylene glycol and/or diethylene glycol
Annex 1 of 2

Product Name	TERMOREX	FLURIN DMP	UNIBEBI COUGH SYRUP	UNIBEBI DEMAM PARACETAMOL DROPS
Reported active ingredients	Paracetamol	Paracetamol, Pseudoephedrine HCl, Dextromethorphan HBr, Chlorpheniramine Maleate	Paracetamol, Guaifenesin, Chlorphenamine Maleate	Paracetamol
Stated manufacturer	PT Konimex	PT Yarindo Farmatama	PT Universal Pharmaceutical Industries	PT Universal Pharmaceutical Industries
Batch number	AUG22A06	All batches	All batches	All batches
Mfg. date	AUG 2022	N/A	N/A	N/A
Exp. date	AUG 2025	N/A	N/A	N/A
Packaging language	Bahasa Indonesia	Bahasa Indonesia	Bahasa Indonesia	Bahasa Indonesia
Available photograph