

衛生福利部食品藥物管理署 函

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速別：普通件

密等及解密條件或保密期限：

附件：WHO 111年11月2日第7號藥品警訊 (A21020000I_1111411791_doc2_Attach1.pdf)

主旨：有關世界衛生組織(WHO)發布東南亞地區發現不合格兒科藥品一案，請依說明段辦理，請查照。

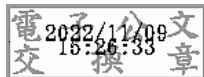
說明：

- 一、依據WHO 111年11月2日第7號藥品警訊辦理(如附件)。
- 二、本署於監控國際藥品警訊發現WHO發布印尼食品藥品監督管理局(Badan POM)於111年10月20日至30日間確認8款兒科藥品檢出含二甘醇 (diethylene glycol)、乙二醇 (ethylene glycol)等污染物，可能導致服用後產生腹痛、嘔吐、腹瀉、無法排尿、頭痛、精神狀態改變及急性腎損傷並可能導致死亡，而該藥品可能已銷往各國。
- 三、經查藥品許可證資料庫，我國未核准案內PT Konimex、PT Yarindo Farmatama、PT Universal Pharmaceutical Industries、PT Afi Farma等4家製造廠藥品，亦未有相關專案進口之藥品，故評估該警訊不影響我國。
- 四、請貴會協助轉知所屬會員於製造及輸入時注意相關藥品品

質，並勿輸入或使用該等藥品。

正本：社團法人中華民國學名藥協會、中華民國基層醫療協會、中華民國藥劑生公會全國聯合會、中華民國西藥商業同業公會全國聯合會、中華民國區域醫院協會、台灣醫學中心協會、台灣社區醫院協會、中華民國藥師公會全國聯合會、中華民國醫師公會全國聯合會、社團法人臺灣臨床藥學會、台灣醫院協會、臺灣製藥工業同業公會、台灣私立醫療院所協會、中華民國製藥發展協會、中華民國西藥代理商商業同業公會、台北市西藥代理商商業同業公會

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Ref. RPQ/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 2022¹. 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-Keselamatan--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				

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

Annex 2 of 2

Product Name	UNIBEBI DEMAM PARACETAMOL SYRUP	PARACETAMOL DROPS	PARACETAMOL SYRUP (<i>mint</i>)	VIPCOL SYRUP
Reported active ingredients	Paracetamol	Paracetamol	Paracetamol	Paracetamol, Guaifenesin, Chlorphenamine Maleate
Stated manufacturer	PT Universal Pharmaceutical Industries	PT Afi Farma	PT Afi Farma	PT Afi Farma
Batch number	All batches	All batches	All batches	All batches
Mfg. date	N/A	N/A	N/A	N/A
Exp. date	N/A	N/A	N/A	N/A
Packaging language	Bahasa Indonesia	Bahasa Indonesia	Bahasa Indonesia	Bahasa Indonesia
Available photograph				

For more information, please visit our [website](https://www.who.int/rapidalert). Email: rapidalert@who.int