檔　　號:
保存年限:

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密等及解密條件或保密期限：
附件：WHO 111年10月5日第6號藥品警訊 (A21020000I_1111410682_doc2_Attach1.pdf)

主旨：有關世界衛生組織(WHO)發布非洲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10月5日第6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表示印度製造廠Maiden Pharmaceuticals Limited所生產4款兒科藥品檢出含二甘醇 (diethylene glycol)、乙二醇(ethylene glycol)，有不符規格情事，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Maiden Pharmaceuticals Limited生產藥品，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，並勿輸入或使用該款藥品。

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

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Ref. RPQ/REG/ISF/Alert N°6/2022 5 October 2022

Medical Product Alert N°6/2022

Substandard (contaminated) paediatric medicines identified in WHO region of Africa

Alert Summary

This WHO Medical Product Alert refers to four substandard products, identified in The Gambia and reported to WHO in September 2022. Substandard medical products are products that fail to meet either their quality standards or specifications and are therefore "out of specification"[1].

The four products are *Promethazine Oral Solution, Kofexmalin Baby Cough Syrup*, *Makoff Baby Cough Syrup* and *Magrip N Cold Syrup*. The stated manufacturer of these products is Maiden Pharmaceuticals Limited (Haryana, India). To date, the stated manufacturer has not provided guarantees to WHO on the safety and quality of these products.

Laboratory analysis of samples of each of the four products confirm that they contain unacceptable amounts of diethylene glycol and ethylene glycol as contaminants. To date, these four products have been identified in The Gambia, but may have been distributed, through informal markets, to other countries or regions.

Risks

Diethylene glycol and ethylene glycol are toxic to humans when consumed and can prove fatal

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.

All batches of these products should be considered unsafe until they can be analyzed by the relevant National Regulatory Authorities.

The substandard products referenced in this alert are unsafe and their use, especially in children, may result in serious injury or death.

Advice to regulatory authorities 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.

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 these products, 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.

National regulatory/health authorities are advised to immediately notify WHO if these substandard products are discovered in their respective country. If you have any information concerning the manufacture or supply of these products, please contact WHO via **rapidalert@who.int.**

Please see annex for details of the substandard products referenced in Alert N°6/2022.
Alert n°6/2022 may be updated at a later stage as and when necessary.

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

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Ref. RPQ/REG/ISF/Alert N°6/2022: PRODUCTS CONTAMINATED WITH DIETHYLENE GLYCOL AND ETHYLENE GLYCOL
The products listed below are manufactured by MAIDEN PHARMACEUTICALS LIMITED (Haryana, India) and were identified to date in The Gambia

Product Name	PROMETHAZINE ORAL SOLUTION BP	KOFEXMALIN BABY COUGH SYRUP	MAKOFF BABY COUGH SYRUP	MAGRIP N COLD SYRUP
Reported active ingredients	Promethazine	Pheniramine Maleate, Ammonium chloride, Menthol	Chlorphenamine Maleate, Phenylephrine HBR, Dextromethorphan syrup	Paracetamol Phenylephrine HCL, Chlorphenamine Maleate
Stated manufacturer	MAIDEN PHARMACEUTICALS LIMITED (Haryana, India)	MAIDEN PHARMACEUTICALS LIMITED (Haryana, India)	MAIDEN PHARMACEUTICALS LIMITED (Haryana, India)	MAIDEN PHARMACEUTICALS LIMITED (Haryana, India)
Lot number	ML21-202	ML21-199	ML21-203	ML21-198
Mfg. date	Dec-21	Dec-21	Dec-21	Dec-21
Exp. date	Nov-24	Nov-24	Nov-24	Nov-24
Packaging language	English	English	English	English
Available photograph				

WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products
For more information, please visit our website. Email: rapidalert@who.int