

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>

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](https://www.who.int/rapidalert). Email: rapidalert@who.int