Head Office
Mail: P.O. Box CT 2783, Cantonments-Accra, Ghana
(+233)-302-233200/235100
(+233)-551-112223/4/5 (Hotline)
Email: fda@fda.gov.gh
Digital Address: GA-237-7316

FDA/HPT/SMC/SMD/VGU/22/0449 6th October 2022

Dear Healthcare Professional,

SUBSTANDARD (CONTAMINATED) PAEDIATRIC MEDICINES IDENTIFIED IN WHO REGION OF AFRICA

The Food and Drugs Authority (FDA) wishes to bring to your attention that the World Health Organization (WHO) has identified four substandard medicinal products in The Gambia. The four products are **Promethazine Oral Solution**, **Kofexmalin Baby Cough Syrup**, **Makoff Baby Cough Syrup** and **Magrip N Cold Syrup**.

The products are substandard because laboratory analysis of samples of each of the four products confirms that they contain unacceptable amounts of diethylene glycol and ethylene glycol as contaminants. The manufacturer of these products, Maiden Pharmaceuticals Limited (Haryana, India), has also not provided guarantees to WHO on the safety and quality of these products as of 5th October 2022.

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.

The FDA would like to inform you that these products have **not been registered** by the Authority and are not expected on the Ghanaian market however they may have been distributed illegally.

The FDA wishes to advice all healthcare professionals to report suspected falsified medicinal products to the FDA by completing the Adverse Reaction Reporting Form or online using the link http://adr.fdaghana.gov.gh or call Mobile no: 024431 0297 or send an email to drug.safety@fdaghana.gov.gh.

Meanwhile the FDA has strengthened its post market surveillance activities at the borders and across the country with the view to identify and withdraw any unregistered products on the Ghanaian market.

Please, find attached the Medical Product Alert N°6/2022 from the WHO on substandard (contaminated) paediatric medicines identified in WHO region of Africa.

Additionally, to report and receive the latest safety alerts and recalls, download the Med Safety App from Google Play or the App Store.

Yours faithfully,

DELESE A. A. DARKO (MRS.)
CHIEF EXECUTIVE OFFICER

World Health Organization

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

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

World Health Organization

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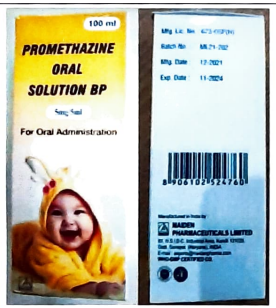
Ref. RPQ/REG/ISF/Alert N°6/2022: PRODUCTS CONTAMINATED WITH DIETHYLENE GLYCOL AND ETHYLENE GLYCOL
The products listed below are manufactured by MAIDEN PHARMACEUTICALS LIMITED (Haryana, India) and were identified to date in The Gambia

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