



SAFETY ALERT

DRAP ALERT NO. N° I/S/10-22-26

WHO GLOBAL ALERT ON CONTAMINATED PEDIATRICS COUGH SYRUPS IDENTIFIED IN GAMBIA-WEST AFRICA

Date: 12th October 2022

Target Audience:

- Healthcare Professionals- Physicians, Pharmacists, and Nurses.
- Manufacturers and Importers of Glycerine containing formulations to control level of Diethylene glycol and Ethylene glycol
- General Public

Problem or Issue:

World Health Organization (WHO) has issued [Medical Product Alert No. N°6/2022](#) dated 05th October 2022 which refers to four substandard products, identified in Gambia. These four products are ***Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup and Magrip N Cold Syrup***. Laboratory analysis of samples of each of the four products confirm that they contain **unacceptable amounts of diethylene glycol and ethylene glycol as contaminants**.

DRAP has never authorized sale of any products from **Maiden Pharmaceuticals Limited (Haryana, India)** and these four products referred in WHO medical product alert are neither registered nor available on Pakistan market, however these may have been carried for personal use while visiting other countries. Please do not use any of these products as these are substandard products and their use may result in serious injury.

Potential Hazards linked to Diethylene glycol (DEG) and Ethylene glycol (EG):

Toxic effects can include abdominal pain, diarrhea, inability to pass urine, headache, altered mental state, vomiting and acute kidney injury which may lead to death especially in children.

Advice for Healthcare Professionals: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities to detect any substandard / falsified product in the market. Adverse reactions or quality problems experienced with the use of any product shall be reported to the National Pharmacovigilance Centre(NPC), DRAP using [Adverse Event Reporting Form](#) or online through this [link](#). Further information of reporting problems to DRAP is available on this [link](#).





Advice for Manufacturer's and Importers of Products containing Glycerin Solvent:

Unacceptable amounts of Diethylene glycol (DEG) and Ethylene glycol (EG) as contaminants may lead to severe injury or death. You are therefore advised to strictly follow the pharmacopoeia guidelines for excipients and ensure testing of all those products where diethylene glycol and ethylene glycol can appear as impurity, to ensure specifications limits are being comply for all those products where glycerin is used especially cough syrups and other oral products.

Advice for General Public: -

All therapeutic goods must be obtained from the licensed pharmacies, and other authorized retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professional in case of any doubt.



PRODUCTS CONTAMINATED WITH DIETHYLENE GLYCOL AND ETHYLENE GLYCOL manufactured by MAIDEN PHARMACEUTICALS LIMITED (Haryana, India) and identified to date in The Gambia with following specifications

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				

