

**Ref: CCC/CP/CA/5/2022
7 October 2022**

CONSUMER ALERT

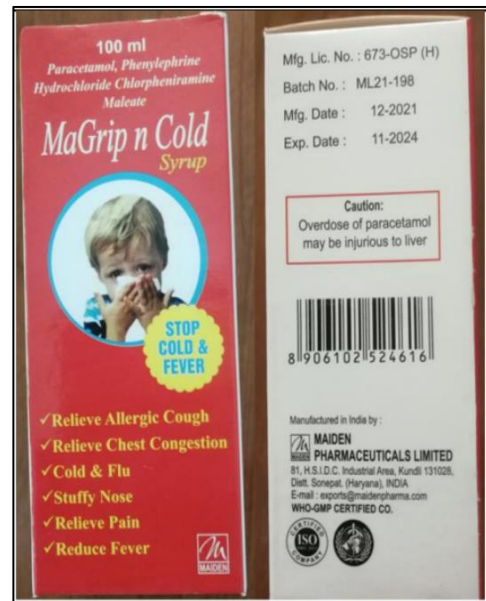
SUBSTANDARD/CONTAMINATED PAEDIATRIC MEDICINES BY MAIDEN PHARMACEUTICALS LIMITED (HARYANA, INDIA)

The COMESA Competition Commission (“the Commission”) has become aware that on 5th October 2022, the World Health Organization (WHO) issued a Medical Product Alert, Ref: RPQ/REG/ISF/Alert N°6/2022, with regard to four substandard medicines manufactured by **Maiden Pharmaceuticals Limited (Haryana, India)**, for failing to meet either their quality standards or specifications.

According to WHO, laboratory analysis on samples of the four products confirmed that they contain unacceptable amounts of diethylene glycol and ethylene glycol, which are toxic to humans and can prove fatal when consumed. WHO further reported that 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 affected products have been identified in Gambia, but it is believed that they may be distributed to other countries or regions through informal markets.

The affected products are indicated below:

	Product Name	Manufacture and Expiry Dates	Lot number	Reported ingredient	active
1.	Promethazine Oral Solution	Mfg: Dec-21 Exp: Nov -24	ML21-202	Promethazine	
2.	Kofexmalin Baby Cough Syrup	Mfg: Dec-21 Exp: Nov -24	ML21-199	Pheniramine Ammonium Menthol	Maleate, Chloride,
3.	Makoff Baby Cough Syrup	Mfg Dec-21 Exp: Nov -24	ML21-203	Chlorphenamine Phenylephrine Dextromethorphan syrup	Maleate, HBR,
4.	Magrip N Cold Syrup	Mfg: Dec-21 Exp: Nov -24	ML21-198	Paracetamol Phenylephrine Chlorphenamine	HCL, Maleate



In line with the WHO advise, the Commission wishes to appeal to the public not to use the above products, and in cases where the product has been consumed, and one has suffered from adverse reaction, they are advised to seek immediate medical advice from a qualified healthcare professional and the case be reported to the National Regulatory Authority or National Pharmacovigilance Centre, or reported to the WHO via rapidalert@who.int. Further details regarding the alert by WHO can be accessed through the following link: [World Health Organization Medical Product Alert-Ref. RPQ/REG/ISF/Alert N°6/2022](https://www.who.int/alerts/World-Health-Organization-Medical-Product-Alert-Ref.-RPQ/REG/ISF/Alert-N-6/2022)

The Commission pursuant to Article 30(1)(b) of the COMESA Competition Regulations (“the Regulations”), wishes to request any person who establishes that these products are being sold in the COMESA Region to report the matter to the Commission on +265 (0) 1 772466 or contact the undersigned on mdisasa@comesa.int; or Mr. Steven

Kamukama, Manager Consumer Welfare and Advocacy Division on skamukama@comesa.int .

In addition, any person within the Common Market who purchased or is affected by the above medicines may also contact their national consumer institutions or any other body with the mandate on consumer protection in their countries.



Meti Demissie Disasa
Registrar
COMESA Competition Commission
5th Floor, Kang'ombe House
P.O. Box 30742, Lilongwe 3, Malawi
Office Phone: +265 (0) 1 772466
Email: compcom@comesa.int