

## Press Statement

10 October 2022

### **RE: Substandard (contaminated) paediatric medicines identified in WHO region of Africa**

Harare – The Medicines Control Authority of Zimbabwe (MCAZ), would like to alert Health professionals and members of the public of the existence of substandard paediatric medicines identified in the WHO region of Africa. Like other regulators globally, MCAZ has been notified by the World Health Organization (WHO) through Medical Product Alert Number 6/2022 of the circulation of substandard products identified in The Gambia and reported to WHO in September 2022.

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.

These products are reported to 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.

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 Authority wishes to inform Health professionals and members of the public that these products are not registered in Zimbabwe. Furthermore, the manufacturer is not registered in Zimbabwe and the Authority has not authorized any importation of any products from this manufacturer.

However, through illegal means, these products may find their way into the local market. As a precautionary measure, the Authority will intensify its market surveillance activities through strict premises inspection and public awareness to ensure that these products are not circulated.

In the unlikely event that members of the public are in possession of and/or come across these products, please notify the Authority and/or healthcare provider immediately and desist from administering them to children.

The mandate of the Medicines Control Authority of Zimbabwe (MCAZ) is to protect public health by ensuring that medicines and medical devices on the market are safe, effective, and of good quality and will continue to monitor the situation through the WHO guidelines. The Authority also urges members of the public to access medicines from licenced persons and premises for easier monitoring. The Authority and law enforcement agencies continue to work together to eradicate any substandard and falsified health products.

For further clarification, please do not hesitate to contact the Authority

**MEDICINES CONTROL AUTHORITY OF ZIMBABWE**



.....  
R. Rukwata (Mr.)

**ACTING DIRECTOR-GENERAL**

## Product Details

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