All correspondence should be addressed to the Director General

LET_LSE/PMS/0007/08/23

In reply, please quote .....

ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

Date: 9th August 2023

To: Distributors, Wholesalers, Retailers, Healthcare Professionals, Parents, General Public

MEDICAL PRODUCT ALERT: SUBSTANDARD (CONTAMINATED) SYRUP MEDICINES IDENTIFIED IN WHO REGION OF THE EASTERN MEDITERRANEAN

The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia. The main mandate of ZAMRA is to regulate and control the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances for human and animal health protection.

ZAMRA wishes to alert healthcare professionals and the general public that it has been notified by the World Health Organisation (WHO) about a batch of substandard (contaminated) **COLD OUT Syrup** (Paracetamol and Chlorpheniramine) identified in the Republic of Iraq.

Paracetamol and Chlorpheniramine combination syrups are used to treat and relieve symptoms of the common cold and allergy symptoms.

Quality analysis tests of the product indicated that the product contains unacceptable amounts of diethylene glycol (0.25%) and ethylene glycol (2.1%) as contaminants. The acceptable safety limit for both diethylene and ethylene glycol is **no more than 0.10%.**

Diethylene glycol and ethylene glycol are toxic to humans when consumed and can result in serious injury or death, especially in children. Toxic effects following use of this product may include but not limited to abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state and acute kidney injury which may lead to death.

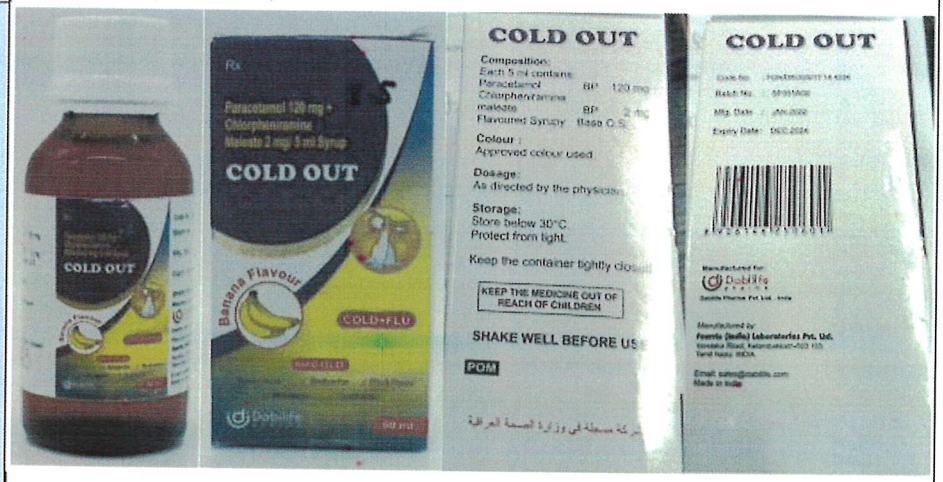
While the stated manufacturer, **FOURRTS (INDIA) Laboratories Private Limited** has registered some products with the Authority, we wish to state that **COLD OUT Syrup** has never been marketed or registered in Zambia; and it has never been authorised for importation into the country.

Considering the possibility that this product could have been distributed through informal (illegal) markets, the Authority has intensified countrywide vigilance for these products through public notification and inspection of pharmaceutical outlets. Further,

the Authority wishes to caution members of the public to also be vigilant and only buy medicines from authorised entities.

PRODUCT DETAILS

Annex: Batch of Product subject of WHO Medical Product Alert No.6/2023

Product name	COLD OUT syrup
Stated manufacturer	FOURRTS (INDIA) LABORATORIES PVT. LTD
Stated marketer	DABILIFE PHARMA PVT. LTD. - INDIA
Batch	SF001A02
Expiry date	DEC.2024
Identified in	Republic of Iraq
Available photos	

In the unlikely event that you are in possession of the above-mentioned product, please return it to your healthcare provider or supplier who should in turn notify ZAMRA.

If you suffer any adverse drug reaction/event having used this product, you are advised to seek immediate medical advice and report the incident to the National Pharmacovigilance Unit at Zambia Medicines Regulatory Authority by phone: +260 211 432 356/+260 //956 521 094 or email address at: npvu@zamra.co.zm or pharmacy@zamra.co.zm.

Should the public need further clarification, please do not hesitate to contact the Secretariat.

Makomani Siyanga (Mr.)
DIRECTOR-GENERAL