MCAZ Medicines Control Authority of Zimbabwe

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Press Statement

21 July 2023

RE: Substandard (contaminated) syrup 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 syrup medicines identified in WHO Region of Africa. Like other regulators globally, MCAZ has been notified by the World Health Organization (WHO) through Medical Product Alert Number 5/2023 of the circulation of substandard products identified in Cameroon and reported to WHO on 13 March 2023.

The product known as NATURCOLD Syrup whose stated manufacturer is listed on the product packaging as FRAKEN INTERNATIONAL (England). The United Kingdom national regulatory authority, the MHRA, has confirmed to the WHO that no such manufacturer exists in the UK. Therefore, the stated manufacturer has not provided guarantees to WHO on the safety and quality of these products.

The stated active ingredients of NATURCOLD syrup are listed as paracetamol, phenylephrine hydrochloride & chlorpheniramine maleate. The combination of these three ingredients is used to relieve symptoms associated with the common cold, flu, and allergic rhinitis.

This product is reported to contain unacceptable amounts of diethylene glycol as contaminants. To date, this product has been identified in Cameroon, 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

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DIRECTOR-GENERAL