MCAZ Medicines Control Authority of Zimbabwe

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Date: 14th April 2023

To: ALL LICENSED PHARMACEUTICAL WHOLESALERS, PHARMACIES, PUBLIC AND PRIVATE CLINICS AND HOSPITALS, HEALTHCARE PRACTITIONERS, AND CONSUMERS

RE: INSTRUCTION TO QUARANTINE ALL PHOLCODINE-CONTAINING PRODUCTS

The Medicines Control Authority of Zimbabwe (MCAZ) would like to advise all stakeholders of a significant safety issue with pholcodine-containing medicines.

Pholcodine is an opioid medicine that is used for the treatment of non-productive (dry) cough in children and adults. It works directly in the brain, depressing the cough reflex by reducing the nerve signals that are sent to the muscles involved in coughing. Pholcodine-containing products are marketed in Zimbabwe under the brand names **Pholtex Plus** and **Pholtex Forte** with the registration numbers 2018/22.2.5/5734 and 99/22.2.1/3624 respectively.

Available data indicated that the use of pholcodine in the twelve (12) months before general anesthesia with neuromuscular blocking agents (NMBA) such as suxamethonium, and atracurium is a risk factor for developing an anaphylactic reaction upon administration of the NMBA. The hypothesis that pholcodine use could trigger anaphylactic reactions to NMBAs is based on the body producing antibodies against pholcodine, which eventually trigger reactions to NMBAs (cross-sensitization). The Authority noted that there are no effective measures to minimize this risk, nor is there an identified patient population for whom the benefits of pholcodine outweigh its risks. As such, due to the seriousness of the safety risk, all pholcodine-containing products are being withdrawn from the Zimbabwean market.

For health care professionals:

- Advise patients to stop taking pholcodine-containing medicines and consider appropriate alternatives to treat their symptoms.
- Check whether patients scheduled to undergo general anesthesia with NMBAs have used pholcodine in the previous 12 months and remain aware of the risk of anaphylactic reactions in those patients.

For consumers:

- If you need general anesthesia and have taken a pholcodine-containing medicine in the past 12 months, advise your healthcare professional prior to undergoing the procedure.

The Authority would like to draw the attention of all licensed pharmaceutical wholesalers, pharmacies, public and private clinics, and hospitals that they must **quarantine** the stated products.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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R. T. Rukwata (Mr)
DIRECTOR-GENERAL

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