MCAZ Medicines Control Authority of Zimbabwe

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REF: B/279/57/05/2023

5th September 2023

The Supervisor
Pharmaceutical and Chemical Distributors (Pvt.) Ltd
t/a Pharmaceutical and Chemical Distributors,
33 Watts Road,
Harare

Attention: Ms. Tendayi Simoyi

Dear Madam

RE: CLASS II RECALL INSTRUCTION FOR APO-ACYCLOVIR 200MG TABLETS FROM APOTEX, CANADA

Reference is made to the product alert and recall issued by Health Canada through World Health Organisation. The affected lots of the product exceeded acceptable intake limit of 0.024 ppm for nitrosamine impurity N-nitrosodimethylamine (NDMA).

The product is registered in Zimbabwe with Registration number 05/18/1999. Non- compliance with specifications of product quality may result in loss of function and harm to the patient.

Please be advised that, the Authority instructs you to recall all units of the batches, **TE5048 & TK5832** of Apo-acyclovir 200mg Tablets. Furthermore, the manufacturer is required to initiate impact assessment on all the other batches that were being manufactured on the same equipment trail. Based on the risk assessment conducted by the Authority, you are required to conduct a Class II recall up to retail level as guided by the MCAZ Guidelines for the Notification of a Medicinal Product Problem/Defect and Recall Procedure. A detailed recall report should be submitted within thirty (30) days of receipt of this letter. The recall report should indicate the quantities of the product supplied on the market, the list of institutions the product was distributed to, the quantities used, and the quantities recalled.

Please acknowledge receipt of this letter within 48 hours of receipt.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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pp Richard T. Rukwata (Mr.)
DIRECTOR-GENERAL
/lfm

25 1997-2022 YEARS
OF PROTECTING PUBLIC AND ANIMAL HEALTH