MCAZ Medicines Control Authority of Zimbabwe

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REF: B/279/28/29/2023

1st March, 2023

Pharmaceutical & Chemical Distributors
33 Watts Rd New Ardbennie,
Harare,
Zimbabwe

Attention: Ms. T. Simoyi

Dear Madam

RE: CLASS III RECALL INSTRUCTION FOR ROXITHROMYCIN 150MG TABLETS, BATCH NUMBER ABZ021001 FROM IPCA LABORATORIES LIMITED, P.O SEJAVTA DIST. RATLAM-457 001, MADHAYA PRADESH, INDIA

Reference is made to the inspection for IPCA Laboratories Limited on the 1st – 2nd of December 2022, the inspection report, the letter to quarantine the offending batch and the correspondences that followed thereafter. The correspondence from the manufacturer of the product showed that the observed out-of-specification (OOS) result at the 18-month time-point in on-going stability studies under Zone IV b conditions(30°C/75%) on the water content test was valid.

The product is registered in Zimbabwe with Registration number **2001/7.2.5/3922** and has a three-year shelf life. There is possibility that the non-conforming batch is still available on the market. High water content in tablets could result in degradation of the active ingredient and in this case reduced efficacy of the anti-microbial properties of Roxithromycin, amongst other potential risks.

Based on the risk assessment conducted by the Authority, you are required to conduct a **Class III** Recall up to the Retail Pharmacy Level, for all units of batch **ABZ021001** of Roxithromycin 150mg (Curox) tablets, as guided by the MCAZ Guidelines for Notification of a Medicinal Product Problem/Defect and Recall Procedure. A detailed recall report and failure investigation 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 batch 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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C. Samatanga (Mrs.)
for: **DIRECTOR-GENERAL**