MCAZ Medicines Control Authority of Zimbabwe

106 Baines Avenue
Tel: +263 242 736 981-7
708 255 / 792 165 / 0772 145 191/2/3
Email: mcaz@mcaz.co.zw
Website: www.mcaz.co.zw

P.O. Box 10559
Harare
Zimbabwe

REF: B/279/57/02/2023

19th January, 2023

New Business Development and Regulatory Affairs Manager
Datlabs (Pvt) Ltd,
45 Falcon Street,
Belmont,
BULAWAYO

Attention: Ms. Vimbai Mukakati

Dear Madam

RE: CLASS II RECALL INSTRUCTION FOR METRONIDAZOLE 200MG TABLETS, BATCH 220185 MANUFACTURED BY DATLABS (PVT) LTD, 45 FALCON STREET, BELMONT, BULAWAYO

Reference is made to the product defect, received at the Authority, the quarantine letter sent to you on the 6th of January 2023, and your interim investigation report received on the 16th of January 2023, where you identified that the discoloured tablets were found to have yeast and mould contamination. The product defect indicated that the product in question was showing signs of discolouration.

The product is registered in Zimbabwe with Registration number 2017/7.6/5455. 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 batch, **220185** of Metronidazole 200mg Tablets and suspend manufacturing of the same product awaiting comprehensive determination of the possible root cause. Furthermore, you are requested 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 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 product was distributed to, the quantities used, and the quantities recalled.

Please be advised that the Authority intends to carry out laboratory analysis of the specified batch of the mentioned product at the distributors cost. You will therefore be issued with a proforma invoice once the costs have been calculated.

Please submit a detailed root cause identification and furnish the findings and CAPA to the Authority within fourteen (14) days of receipt of this letter.

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

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

.....

Richard Rukwata (Mr.)
ACTING-DIRECTOR-GENERAL