MCAZ Medicines Control Authority of Zimbabwe

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REF: B/279/28/111/2022

9th June, 2022

The Compliance and Regulatory Pharmacist
Pharmaceutical and Chemical Distributors (PCD)
33 Watts Street
HARARE

Attention: Ms. T. Simoyi

Dear Madam

RE: CLASS II RECALL INSTRUCTION FOR LEFLUNOMIDE 20MG TABLETS, BATCH NUMBER B326H001 FROM TORRENT PHARMACEUTICALS LIMITED, INDRAD-382 721, DIST, MEHSANA, INDIA

Reference is made to an e-mail dated 8th of June, 2022 and the correspondence you submitted from the manufacturer in which you requested guidance on the course of action for Leflunomide 20mg tablets, batch number **B326H001** manufactured by Torrent Pharmaceuticals Limited, Indrad-382 721. Dist. Mehsana, India. The correspondence from the manufacturer of the product showed that an out of specification (OOS) was reported in dissolution tests at 12-month time point for long term storage condition (30°C/70%RH).

The product is registered in Zimbabwe with Registration number 2007/3.3/4477. Non-Compliance with specifications such as dissolution data of the product may result in low therapeutic effects in patients hence this requires a Class 2 recall.

Please be advised that, the Authority instructs you to recall all units of the batch, **B326H001** of Leflunomide 20mg tablets. 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 acknowledge receipt of this letter within 48 hours of receipt.

Yours faithfully
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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Richard Rukwata (Mr.)
ACTING-DIRECTOR-GENERAL