MCAZ Medicines Control Authority of Zimbabwe

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REF: B/279/57/2/2022

30th November, 2022

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

Attention: Ms. T. Simoyi

Dear Madam

RE: CLASS III RECALL INSTRUCTION FOR LOSARTAN POTASSIUM AND HYDROCHOROTHIAZIDE TABLETS 50 + 12.5MG (PRESARTAN H 50), BATCH HLK011001 MANUFACTURED BY IPCA LABORATORIES, 125 KANDIVLI INDUSTRIAL ESTATE, CTS NO. 328, KANDIVLI (WEST), MUMBAI 400 067, INDIA.

Reference is made to an e-mail dated 28th of November, 2022 and the correspondence you submitted from the manufacturer in which you requested guidance on the course of action for Losartan Potassium and Hydrochlorothiazide tablets 50+12.5mg (Presartan H 50) tablets, batch number **HLK011001** manufactured by IPCA Laboratories, 125 Kandivli Industrial Estate, CTS No. 328, Kandivli (West), Mumbai 400 067, India. The correspondence from the manufacturer of the product showed that an out of specification (OOS) was reported in related substances at 12-month time point for long term storage condition (30°C/70%RH).

The product is registered in Zimbabwe with Registration number 2015/12.3.5/4980. Non-Compliance with specifications such as related substances tests of the product may result in low therapeutic effects in patients. Since the type of impurity and effects in human beings have not yet been identified, you are instructed to institute a Class III recall.

Please be advised that, the Authority instructs you to recall all units of the batch, **HLK011001** of Losartan Potassium and Hydrochlorothiazide 50+12.5mg tablets. Based on the risk assessment conducted by the Authority, you are required to conduct a Class III 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. .

As part of CAPA, further importation of the product will be suspended pending root cause identification and impact assessment on other batches of the product on the market. The root cause should be submitted within 30 days of initiation of investigations.

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