MCAZ Medicines Control Authority of Zimbabwe

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P.O. Box 10559
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Zimbabwe

REF: B/279/57/04/2023

28th March 2023

Quality Assurance Pharmacist
Cospharm Pharmaceuticals,
12896 Madokero Industrial Area,
HARARE

Attention: Ms. Eugenia Manyonga

Dear Madam

RE: CLASS II RECALL INSTRUCTION FOR POVIDONE IODINE (BETACLEANSE®) 10% SOLUTION FROM COSPHARM PHARMACEUTICALS, 12896 MADOKERO INDUSTRIAL AREA, HARARE

Reference is made to the product defect received at the Authority, the quarantine letter Ref no. B/279/28/41/23, and your investigation report. The product defect indicated that the product in question was showing perceived low effectiveness due to low assay, change in consistency and causing burns to patients.

The product is registered in Zimbabwe with Registration number 2022/14.1.4/6292. 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, **5220031, 5220033 and 5220034** of Povidone Iodine (Betacleanse®) 10% solution and suspend manufacturing of the same product awaiting a holistic corrective and preventive action. 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 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 batches of the mentioned product at the distributors cost. You will therefore be issued with a proforma invoice once the costs have been calculated.

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

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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