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REF: B/279/35/05/2023

CIRCULAR 5 of 2023

Date: 23rd of February, 2023

To: ALL LICENSED PHARMACEUTICAL WHOLESALERS, PHARMACIES, PUBLIC AND PRIVATE CLINICS AND HOSPITALS

RE: **INSTRUCTION TO QUARANTINE TETRACYCLINE HYDROCHLORIDE OPHTHALMIC OINTMENT USP 1% MANUFACTURED BY GALENTIC PHARMA (INDIA) PVT. LTD, R-673, T.T.C. MIDC RABALE, THANE-BELAPUR ROAD, NAVI MUMBAI-400701, MAHARASHTRA, INDIA**

Reference is made to WHO product alert No. 2/2023 for Tetracycline Hydrochloride Ophthalmic Ointment USP 1%, which was received on the 22nd of February 2023. The product alert report indicated that a range of quality issues were detected upon physical examination of random samples of the following product batches: **AF20011, AF21160, AF21161, AF22031, AF22032, AF22093, AF22100, AF22101, AF22107, AF20097, AF22021, AF22105, AF20060A, AF22025, AF22026 & AF22061**. Quality issues detected included particles ranging in colour, size, and shape on the nozzle, in the cap and in the ointment inside each tube, black spots and brown splotches on the inner foil layer of the tube, and phase separation.

The Authority would like to draw the attention of all licensed pharmaceutical wholesalers, pharmacies, public and private clinics, and hospitals that they must quarantine any of the affected batches of the reported product. The above are further instructed to advise the Authority of their stock status if they have any of the affected batches.

The Authority shall communicate a plan of action once investigations are complete.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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C. Samatanga (Mrs.)

for: **DIRECTOR-GENERAL**

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