

PHARMACY AND POISONS BOARD

PRESS STATEMENT

VOLUNTARY RECALL OF TENOFOVIR/LAMIVUDINE/DOLUTEGRAVIR (300/300/50 MG) MANUFACTURED BY UNIVERSAL CORPORATION LIMITED (UCL)

The Pharmacy and Poisons Board (PPB) and the National HIV and STI control program (NASCOP) is in receipt of several product related market complaints for Tenofovir/Lamivudine/Dolutegravir (300/300/50mg) tablets manufactured by Universal Corporation Limited (UCL).

Following the market complaints related to discoloration of induction seal and discoloration of the tablets the UCL is implementing voluntary recall of all batches of Tenofovir/Lamivudine/Dolutegravir (300/300/50 mg) tablets from the market as a precautionary measure pending the determination of the impact and extent of the quality concern by the Pharmacy and Poisons Board.

The PPB has collected several samples from healthcare facilities and they have been submitted to the Quality Control Laboratory for further analysis.

All healthcare facilities are instructed to quarantine all stocks of the product and accept the products returned by clients.

Currently, the PPB in conjunction with KEMSA and the manufacturer are coordinating the reverse logistics to ensure all quarantined stocks are mopped up and returned to a central place.

Please note that only the Tenofovir/Lamivudine/Dolutegravir (300/300/50mg) manufactured by Universal Corporation Limited is affected by this quarantine and recall.

The PPB would like to assure the public that the Pharmacy and Poisons Board has established mechanisms to ensure that medicines supplied to Kenyan market meet the required quality, safety and efficacy standards. We encourage the public to be vigilant at all times and report any suspected poor-quality medicines or adverse drug reactions to the nearest healthcare facility and the Pharmacy and Poisons Board through https://pv.pharmacyboardkenya.org/padrs/add, mobile application: mPvERS both android & iOS and USSD code at *271# or Email: pv@pharmacyboardkenya.org, Telephone Number: 0795743049.

Dr. F.M. Siyoi CHIEF EXECUTIVE OFFICER

25th November, 2022