ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

URGENT PRODUCT RECALL: PHARMA DYNAMICS (PTY) LIMITED and DENK PHARMA GmbH & Co. KG Issue Voluntary Recall of LOSARTAN-CONTAINING PRODUCTS

Date:12th October 2021

To: Distributors, Wholesalers, Retailers, Healthcare Professionals, General Public

Pharma Dynamics (Pty) Limited and Denk Pharma GmbH & Co. KG are voluntarily recalling **ALL** batches of Losartan-containing products to the consumer level. This follows the detection of an azido impurity in Losartan above the acceptable limit.

Pharma Dynamics (Pty) Limited products are Zartan Co 50/12.5 (Losartan 50mg/Hydrochlorothiazide12.5mg) and Zartan Co (Losartan 100mg/Hydrochlorothiazide 25mg) while Denk Pharma GmbH & Co. KG products are all strengths of Losar-Denk (Losartan Potassium) and CoLosar-Denk (Losartan/Hydrochlorothiazide).

The affected products, which are locally distributed by Yash Pharmaceuticals Limited (Zartan Co), Sterelin Medical & Diagnostics Limited and Penguin Pharmaceuticals Limited (Losar-Denk and CoLosar-Denk), contain single Losartan (an angiotensin II receptor type AT_1 antagonist) or a combination of Losartan and Hydrochlorothiazide (a diuretic), indicated for the treatment of hypertension.

The impurity, also known as 4-Chloro-Azidomethyltetrazole (CAS:727718-93-6), was detected during routine assessment and is formed during the manufacture of the active ingredient. The impurity is considered a mutagen, but the specific carcinogenic risk following long term use in humans is unknown. There is no immediate risk to patients taking this medication and not treating the condition may pose a greater health risk to the patient.

The supply of the product will resume after all measures have been put in place to ensure the level of the impurity meets the internationally acceptable standards.

If you are in possession of the above-mentioned products, please return the product to the health facility or pharmaceutical establishment from where it was obtained. If you suffer any adverse drug reaction/ event having used these products, you are advised to seek immediate medical attention and report the incident to the National

Pharmacovigilance Unit at Zambia Medicines Regulatory Authority by phone on; +260 211 432 350/ 260 211 432 356/ +260 956 521 094 or email address using npvu@zamra.co.zm or pharmacy@zamra.co.zm.