Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

23 NOV 2018

FDA ADVISORY
No. 2018-320

TO: **ALL HEALTHCARE PROFESSIONALS, RETAIL DRUG OUTLETS AND THE GENERAL PUBLIC**

SUBJECT: **Public warning on the sale/administration/consumption of a particular batch of Losartan Potassium + Hydrochlorothiazide 100 mg/25 mg Tablet manufactured by Lek Pharmaceuticals dd, Ljubljana in Slovenia**

Healthcare professionals, retail drug outlets and other dealers of pharmaceutical products, and the general public, are hereby warned by the Food and Drug Administration (FDA) against the administration, sale, and consumption of the drug product, **Losartan Potassium + Hydrochlorothiazide 100mg/25mg Tablet,** manufactured by Lek Pharmaceuticals dd, Ljubljana in Slovenia, a particular batch/lot of which is being voluntary recalled by Sandoz Inc., per the recent public advisory released by the United States (US) FDA.

The Active Pharmaceutical Ingredient (API), Losartan, manufactured by Zhejiang Huahai Pharmaceuticals Co. Ltd. in Linhai, China, was reported to contain trace amount of the impurity, N-nitrosodiethylamine (NDEA). The said impurity was classified as a probable human carcinogen as per the World Health Organization (WHO) International Agency for Research on Cancer (IARC) wherein such is the categorization due to limited evidence of carcinogenicity in humans.

Losartan Potassium + Hydrochlorothiazide is indicated for the treatment of essential hypertension in patients whose blood pressure is not adequately controlled on losartan or hydrochlorothiazide alone.

Although limited to a certain batch/lot (Lot No. JB8912), the FDA is currently monitoring the subject drug product through heightened Post Marketing Surveillance (PMS) operations, and is coordinating with its Market Authorization Holder or MAH for its immediate recall in the Philippines, pending confirmation of their safety for public consumption.

Retail drug outlets, and other dealers of pharmaceutical products, are warned against the sale of this affected lot of Losartan + Hydrochlorothiazide 100mg/25mg Tablet.

For more information and inquiries, please e-mail us at info@fda.gov.ph or call us at FDA Action Center hotline (02) 821-1162. To report the sale or distribution of the subject drug product despite the issuance of this Advisory, kindly email us via report@fda.gov.ph.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
Director General

20181115110258
20181115110258