The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Macleods Pharmaceuticals Limited is initiating a Retail level Recall of Losartan Potassium and Hydrochlorothiazide Tablets, USP 50mg /12.5 mg. This recall is being conducted with the knowledge of the United States Food and Drug Administration.

This recall is based upon a complaint received for the product Losartan Potassium and Hydrochlorothiazide Tablets, USP 50mg /12.5 mg. The complaint received was regarding the discovery of a glass piece found in a bottle of Losartan Potassium & HCTZ 50/12.5 mg, batch number BLK2304A tablets from a pharmacy in the USA market.

Upon initial visual inspection, it has been determined that the foreign material received from the complainant is not glass, but rather a plastic-like substance. The foreign material is distinct from the product and is not embedded in the tablet, ensuring easy visibility to the naked eye. Based on the health hazard evaluation, the foreign material is deemed non-toxic to humans. Therefore, it is unlikely to impact the therapeutic effectiveness and systemic availability of the Losartan Potassium and Hydrochlorothiazide Tablets.

Given the foreign material's high detectability and non-toxic properties, along with its minimal anticipated effect on therapeutic efficacy and systemic availability, it is proposed that the subject batch be voluntarily recalled from the market at a class II (Retail level)

The batch was distributed during the period of 13th December 2023 & 29th December 2023.

PRODUCT: Losartan Potassium and Hydrochlorothiazide Tablets, USP 50mg /12.5 mg

NDC NUMBER: 33342-050-44

LOT/BATCH NUMBER: BLK2304A

EXPIRATION DATE: 07/2025