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/Pharmacy level Withdrawal of Candesartan Cilexetil Tablets USP 4 mg. This drug product withdrawal is being conducted with the knowledge of the Food and Drug Administration.

This Withdrawal has been initiated due to an Out-of-Trend (OOT) result reported in the Organic Impurities test (via HPLC) during the 12-month stability study of Candesartan Cilexetil Tablets USP 4 mg (Batch #12250325B) under long-term storage conditions (25°C/60% RH). The observed result for Impurity E was reported at 0.50% (Specification Limit: Not More Than 0.5%).

As part of the Health Hazard Assessment (HHA), a comprehensive review of available scientific and medical literature was conducted. The review revealed no reports associated with Out of Trend results for Impurity E in Candesartan Cilexetil Tablets USP 4 mg. Additionally, no similar product quality complaints related to this issue have been reported to date. Furthermore, an evaluation of medical literature and spontaneous safety reports confirmed that no adverse events have been associated with the affected batch (12250325B). The observed OOT result is not expected to impact patient safety, as the observed result remains within the approved predefined specification limits.

Hence, as a precautionary measure, the subject batches are proposed to a Withdrawal from the market as a Retail level.

The batches were distributed during the period of 04th March 2025 to 19th February 2026.

Product Name	NDCs	Lots/Batches	Exp. Date
Candesartan Cilexetil Tablets USP 4 mg	33342-114-10	12250325B	01/2027
	33342-114-07	12250325C	01/2027
	33342-114-07	12241681A	11/2026
	33342-114-10	12241681B	11/2026
	33342-114-07	12251342A	06/2027
	33342-114-10	12251342B	06/2027