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

IMPORTANT NOTICE:

FDA Withdrawal of UKONIQ® (umbralisib) 200 mg Tablets Effective May 31, 2022

Dear Partner,

Please be advised that on May 27, 2022, FDA issued a notice in the Federal Register officially withdrawing approval of New Drug Application for UKONIQ, effective May 31, 2022 ("FDA Withdrawal Notice"). The notice states: "Distribution of UKONIQ (umbralisib tosylate) tablets, EQ 200 mg base, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d))." The FDA Withdrawal Notice is available at https://www.federalregister.gov/documents/2022/05/31/2022-11631/tg-therapeutics-inc-withdrawal-of-approval-of-new-drug-application-for-ukoniq-umbralisib-tosylate. This action follows the voluntary withdrawal of sale of UKONIQ that TG Therapeutics announced on April 15, 2022.

TG Therapeutics and its distribution partners are required to **stop distributing UKONIQ as of May 31, 2022**. More specifically, we request that your organization take the following actions immediately:

- **Stop all distribution of UKONIQ (umbralisib) 200 mg tablets effective May 31, 2022**
- **Return all remaining inventory of UKONIQ (umbralisib) 200 mg tablets via the TG Returns Policy as soon as possible.**

Please acknowledge receipt of this letter by replying to your TG Therapeutics point of contact by the end of the day on May 31, 2022, and feel free to contact us if you have any questions about the information contained in this letter. We are grateful to our distribution partners who helped to make UKONIQ available to patients since its launch in February 2021.