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.

Eugia US LLC (f/k/a AuroMedics Pharma LLC) has initiated a recall to the Retailer level for the product Tirofiban Hydrochloride Injection 5 mg/100 mL (50 µg/mL) bag- from the US market due to OOS (Out of specification results) in the commercial stability, at long term condition (25°C ±2°C /40%RH ± 5% Horizontal), during 3 Month(s) sample analysis in the batch no: 3TF24002A in the test related substance (By UPLC), for Any unspecified degradation product is not complying with specification (NMT 0.2%) (Reference OOS: E3OOS250027).

As an impact assessment, Tirofiban Hydrochloride injection 12.5 mg/250 mL (50µg/mL), B. No 3TF24001 is observed with OOT (out of trend) result for similar impurity. Hence as an abundant caution, batch number 3TF24001 is also subjected for recall.
Tirofiban hydrochloride injection premixed is supplied as a sterile solution in water for injection, for intravenous use. The pH of the solution ranges from 5.5 to 6.5 adjusted with hydrochloric acid and/or sodium hydroxide.

Injecting Tirofiban Hydrochloride injection with out of specification level for unspecified degradation product may reduce the drug's efficacy and pose potential health risks.

Tirofiban hydrochloride monohydrate is an off-white, non-hygroscopic, free-flowing powder, with a molecular weight of 495.07. It is very slightly soluble in water.

Eugia US LLC began shipping this batch to customers nationwide on July 3, 2024.

PRODUCT	NDC NUMBER	LOT NUMBER	EXPIRATION DATE
Tirofiban Hydrochloride Injection 5 mg/100mL (50 µg/mL) bag	55150-429-01	3TF24002A	November 2026
Tirofiban Hydrochloride Injection 12.5 mg/250mL (50 µg/mL) bag	55150-430-01	3TF24001	March 2026