

ICHP Position Statement - Pharmaceutical Gray Market

ICHP discourages the use of the gray market to purchase medications. In addition, ICHP fully supports the Drug Supply Chain Security Act¹ (DSCSA), which requires that pharmacies follow certain requirements to protect patients from receiving harmful medications, such as counterfeit or other illegitimate drugs. DSCA creates a tighter, closed prescription drug distribution system to prevent harmful drugs from entering the supply chain, detect harmful drugs if they do enter the supply chain, and enable a rapid response when such drugs are found.

Key principles of the DSCSA require that a pharmacy:

- Confirm that the entities with which a pharmacy does business, including manufacturing, repackagers, wholesale distributors, third-party logistics providers, and pharmacies, are licensed or registered.
- Receive, store, and provide product tracing documentation that allows product tracking, i.e., transaction information, transaction history, and transaction statement.
- Investigate and quarantine suspect and illegitimate medications; ensure that patients do not receive such medications; and report such cases to the Food and Drug Administration.
- Following these requirements will help prevent potential patient exposure to unsafe medications that are purchased through unknown distributors often used on the gray market.

Background

1. Healthcare organization accreditation standards require that the healthcare system establish procedures to manage drug shortages. If an organization's process includes obtaining medications from secondary wholesalers, specific criteria must be established on when such sources will be used.
2. "The American Society of Health System Pharmacists recommends that health systems verify that a wholesaler is registered to distribute products in their state prior to purchasing drug products from non-contracted wholesalers."² Registration is also required by Illinois law. Prescription drugs should preferentially be purchased from a registered prescription drug wholesaler.

3. Many secondary wholesalers are registered and regulated under state law even though they purchase medications from sources other than the manufacturer. The concern is that some of these medications may be stolen, adulterated, counterfeited, or damaged during inappropriate storage and handling. Diligence beyond verifying registration is required whenever the wholesaler is unknown to the purchasing pharmacy.³
4. ASHP states that "healthcare organizations must establish clear guidelines for dealing with situations in which a product is available only from a compounding source or non-traditional source or when a critical drug is not available at all. Each healthcare organization must determine its philosophies on purchasing drugs from the gray market or compounding pharmacies and on inhouse compounding."⁴
5. Illinois law permits pharmacies to engage in limited sales of prescription drugs to practitioners for office use or to other pharmacies. Purchases from licensed pharmacies should be subjected to the same diligence that is undertaken when a drug is purchased from a secondary wholesaler.

References

1. Drug Supply Chain Security Act-Overview of Product Tracing Requirements-September 2015. <https://www.fda.gov/media/93779/download> (accessed 11/30/2020)
2. ASHP guidance for purchasing drug products in short supply (revised 7/2012). <http://ashp.org>, last accessed 12/28/2012.
3. American Society of Health-System Pharmacists. ASHP Guidelines for Selecting Pharmaceutical Manufacturers and Suppliers. Am J Hosp Pharm 1991; 48:523-4.
4. American Society of Health-System Pharmacists. ASHP Guidelines on Managing Drug Product Shortages. Am J Health-Syst Pharm 2018; 75:1742-50.

Approved 09/2013

Revised 01/2018, 2/2021

Reviewed 3/2023