

# Simple Steps for S.A.F.E. Sourcing:

## Step 1: Avoid Unsafe Medicines & Vendors

### WHAT'S THE ISSUE?

*In today's global environment, health care professionals should be aware of where their pharmaceutical products are coming from. Counterfeit, adulterated, or fraudulently-obtained products remain an issue in the United States.*

*We are faced with a dangerous problem when these potentially unsafe products move through the drug supply chain undetected and without regard to storage and handling requirements.*

*Drug counterfeiters defraud consumers, deny ill patients the therapies that can alleviate suffering and save lives, and in some cases, can cause great harm.*

*Although most of today's counterfeited products are not introduced into the "normal supply chain" which delivers medication to community and hospital pharmacies nationwide, it is important for all pharmacies to be aware of the dangers of counterfeit products as well as be able to recognize and help prevent them from reaching patients.*

*Pharmacists are encouraged to consider the steps in this guide for safe sourcing.*

**SOURCING:** Establish a list of trusted alternative sources ahead of time. You can do this by:

**ACQUIRING** a copy of the source's license from your state wholesale distributor regulatory board. A list of these is available at: <http://www.nabp.net/vawd/ATLWDs.pdf>.

**FORMING** a list of key drug products which are at risk of shortages, diversion or counterfeiting. You can use this list to help determine which alternative vendors will best suit your needs.

- To determine factors based on the likelihood of tampering or counterfeiting, consult the Food and Drug Administration's 2006 PDMA Policy Compliance Guide at: [http://www.fda.gov/cder/regulatory/PDMA/PDMA\\_CPG.pdf](http://www.fda.gov/cder/regulatory/PDMA/PDMA_CPG.pdf).
- To see a list of current drug shortages, consult the home page of the American Society of Health-System Pharmacists at: <http://www.ashp.org/shortage/>.

**ENSURING** that your sources will verify that:

- The drug's **pedigree** meets state and federal standards.
- The product is **not diverted**.
- There have been no changes that would alter the **original manufacturer's warranties or guarantees**.
- The product has been **stored and handled properly**.

# Simple Steps for S.A.F.E. Sourcing:

## Step 2: Detect Unsafe Medicines and Vendors

### WHAT'S THE ISSUE?

Pharmacists can also play a major role in detecting unsafe products and stopping them before they reach patients. You can use this list of risk factors to acquaint yourself with issues that might cause concern. See Step 3 for instructions on how to report suspicious activity.

#### UNSOLICITED SALES OFFERS

- Advertises itself as located outside of the U.S or lists a foreign telephone number
- Does not provide a listed physical address
- Promises availability in a time of shortage
- Contains misspellings of ingredient and/or brand names
- Offers generic forms of drugs when none are approved in U.S.
- Does not possess a dedicated hard telephone line or list a phone number

#### SUSPICIOUS VENDORS

- Does not have a wholesale license from the state licensing authority
- Wants payment in cash only
- Refuses to pass on pedigree documentation
- Refuses to certify that product is not diverted, not stolen, or not counterfeit
- Refuses to divulge source of the product
- Refuses to disclose expiration date or lot number of the product
- Offers a price that is too good to be true
- Has inventory product list in constant turnover

#### PRODUCT

- Tablets are the wrong color
- Product comes in a different dosage form than the FDA approved product
- Tablet markings are not correct
- Wrong product or wrong dosage level
- Package insert or components are missing

#### PACKAGING

- Packages of single product come from multiple lot #s
- Boxes look worn, tattered, not up to quality of established reliable sources
- Package labels or label colors near the expiration date are faded
- Product packaging is missing overt markings such as color shifting ink, raised printing, holograms
- Seals or sealing taps over the product openings are missing
- Seals or sealing taps appear to be broken or tampered or appear abnormal
- Product comes in different quantities than normally or usually distributed
- Printed text is different in size or design than normal

#### LABELS

- Labeling or packaging contains misspellings
- Labeling looks dirty and scuffed or at odd angle
- Labeling written in foreign language or for foreign market
- Extra glue or tacky residue remains on the outside edge of label
- Labels indicating "not for resale" or physician use only

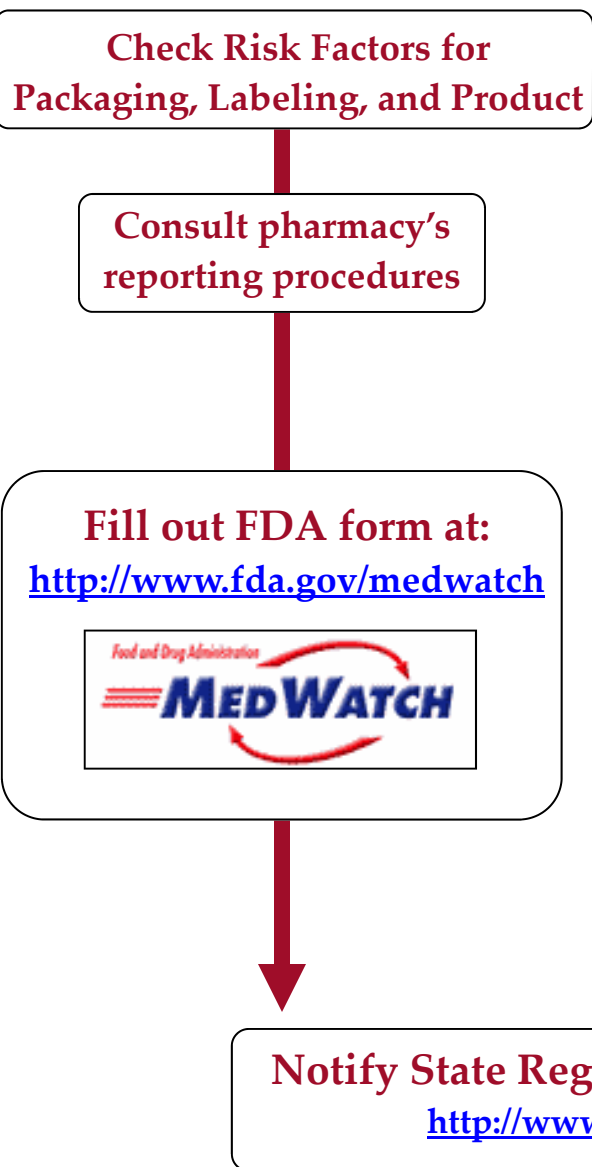
# Simple Steps for S.A.F.E. Sourcing:

## Step 3: Report Unsafe Medicines and Vendors

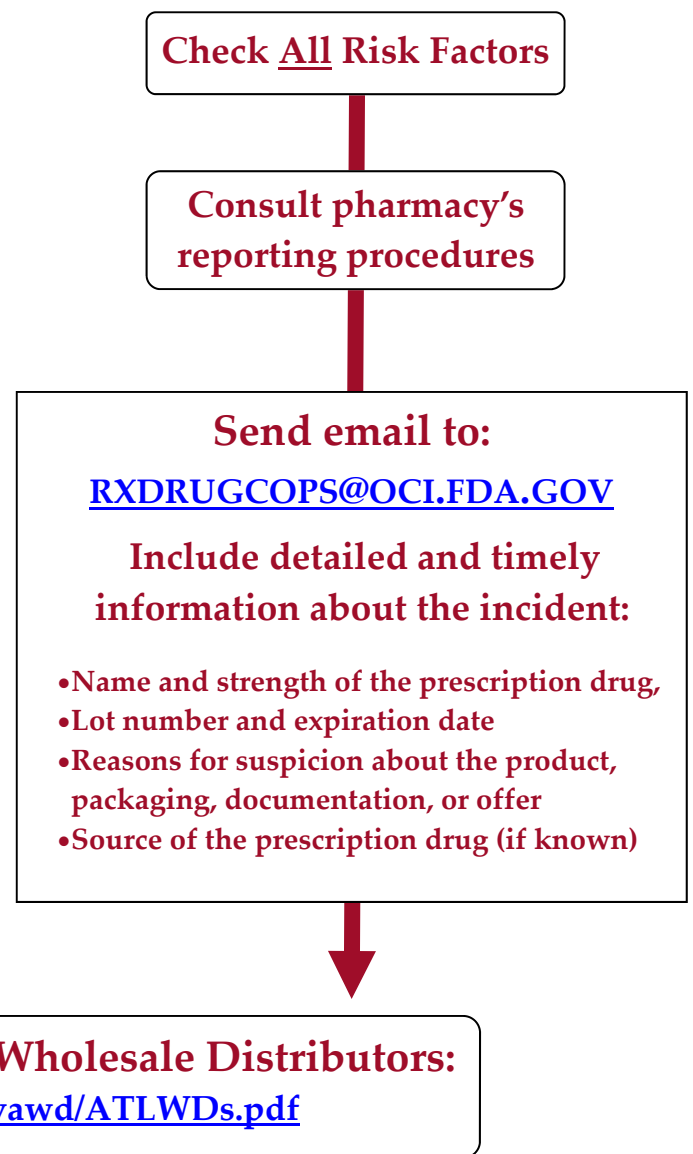
### WHAT'S THE ISSUE?

Your cooperation is an essential part of FDA's and state regulators' efforts to protect the public from diverted, counterfeit, and otherwise unsafe prescription drugs. You can use this guide to help health and law enforcement officials. You can also assist by maintaining copies of unsolicited offers, pedigrees, or other pertinent documents, as well as any suspicious products.

### For Suspicious Products



### For Suspicious Vendors



# Simple Steps for S.A.F.E. Sourcing:

## Step 4: Learn More About Resources

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### TOP INTERNET RESOURCES

- Safe Sourcing Homepage: <http://www.safemedicines.org/sourcing.php>
- FDA Counterfeit Homepage: <http://www.fda.gov/counterfeit>
- FDA Q&A on Prescription Drug Marketing Act: [http://www.fda.gov/cder/regulatory/PDMA/PDMA\\_qa.pdf](http://www.fda.gov/cder/regulatory/PDMA/PDMA_qa.pdf)
- FDA Medwatch Program: <http://www.fda.gov/medwatch>
- FDA-OCI Email Contact: [rxdrugcops@oci.fda.gov](mailto:rxdrugcops@oci.fda.gov)
- NABP Verified-Accredited Wholesale Distributors: <http://www.nabp.net/index.html?target=/vawd/intro.asp&>
- NABP Wholesaler-Distributor Regulators: <http://www.nabp.net/vawd/ATLWDs.pdf>
- ASHP List of Drug Shortages: <http://www.ashp.org/shortage/>

### ABOUT THIS DOCUMENT

“Simple Steps for Safe Sourcing” was approved by the Board of the Partnership for Safe Medicines on November 18, 2006. It will be subject to periodic revisions. Comments and suggestions can be submitted to [information@safemedicines.org](mailto:information@safemedicines.org). It was developed in cooperation with the following groups:

- American Pharmacists Association
- American Society of Health-System Pharmacists
- College of Pharmacy, University of Texas-Austin
- Health Industry Group Purchasing Association
- Institute for Health Law Studies, California Western School of Law
- National Association of Chain Drug Stores
- National Alliance of State Pharmacy Associations
- National Community Pharmacists Association
- Pharmaceutical Security Institute
- Pharmaceutical Research and Manufacturer of America

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- National Association of Drug Diversion Investigators
- Nevada Board of Pharmacy
- Texas Pharmacists Association