

L.E.A.D.E.R.'s Guide for Pharmacists

The Partnership for Safe Medicines is a coalition of more than 60 patient, physician, pharmacist, university, industry and other professional organizations committed to the safety of prescription drugs and protecting consumers against unapproved, counterfeit, substandard, mishandled or otherwise unsafe medicines.

Learn more about the dangers of contraband and counterfeit drugs at www.safemedicines.org or contact us at info@safemedicines.org.

The World Health Organization estimates that as much as 10 percent of medicines sold worldwide are counterfeit. In today's global environment, we are faced with a dangerous problem when these potentially unsafe products move through the drug supply chain.

As pharmacists, you know counterfeit drugs cheat consumers, deny patients the therapies that can alleviate suffering and save lives, as well as can actively harm patients' health.

It is important for all pharmacists to be aware of the dangers of counterfeit drugs, as well as be able to recognize and help prevent counterfeit drugs from reaching patients.

The Partnership for Safe Medicines encourages pharmacists to take an active role in helping to protect the supply chain and protect their customers from counterfeit drugs. Here are six steps for becoming a L.E.A.D.E.R. in the fight to protect patient safety.

L*earn about contraband and counterfeit drugs.* Discover the extent of counterfeit drugs and why they are an illicit public health threat with information from the SafeMeds Email Alert System, SafeMeds Weekly Update, and SafeMeds News Archive.

E*ducate customers.* Help your customers safeguard their health, avoid counterfeit drugs, save money, and buy drugs safely online with consumer educational materials from the Partnership for Safe Medicines.

A*void unsafe medicines and vendors.* Learn the simple steps of S.A.F.E. Sourcing to get authentic drugs from legitimate sources with professional educational materials from the Partnership for Safe Medicines

D*ecline suspicious offers.* Learn how to evaluate unsolicited sales offers and recognize the warning signs of a suspicious offer with professional educational materials from the Partnership for Safe Medicines.

E*valuate your medicines.* Learn how to detect potential counterfeit drugs by evaluating the products, packaging, and labeling of the drug products you stock with professional educational materials from the Partnership for Safe Medicines.

R*eport counterfeit drugs and suspicious vendors.* Help stop counterfeit drugs by reporting suspected counterfeit medicines and suspicious vendors to the proper authorities.

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Learn About Contraband and Counterfeit Drugs

Counterfeit Drugs – The Illicit Public Health Threat

In today's global environment, it doesn't matter if you live in United States, Europe, Asia, or Africa—everyone is at risk from unsafe drugs. All across the world, we are seeing more incidents of counterfeiting involving more types of drugs in more countries. Counterfeit drugs defraud consumers and deny patients therapies that can alleviate suffering and save lives. Unfortunately, in some cases, these fake drugs have caused great harm and fatalities.

According to the U.S. Food and Drug Administration (FDA), the U.S. law defines counterfeit drugs as those sold under a product name without proper authorization. These counterfeit drugs may be:

- Too strong or too weak
- Missing key ingredients
- Made with dangerous ingredients
- Contaminated with foreign, even toxic, materials
- Made in unsanitary or unsterile conditions
- Created using unsafe standards
- Improperly labeled, stored or handled
- Expired (out-of-date)

FACT

Counterfeiting is not limited to brand-name prescription drugs. Counterfeiters also create fake versions of generic and over-the-counter (OTC) drugs, as well as medical products like glucose test strips and pregnancy tests.

A Global Problem

The World Health Organization estimates that as much as 10 percent of medicines sold worldwide are believed to be counterfeit, ranging from around one percent of sales in developed countries to more than 30 percent in developing countries, depending on the geographical area.

According to the Pharmaceutical Security Institute (PSI), counterfeiters sold more than 600 different types of branded, generic and over-the-counter drugs in 2007 (up more than 14 percent from 2006), including expensive lifestyle drugs, inexpensive pain relievers, and essential medicines such as cancer medications, vaccines, antimalarials, cardiovascular drugs, antibiotics, and HIV therapies. Additionally, counterfeiters are using more sophisticated technology and improved packaging to make their fake goods harder to detect.

In 2007, PSI recorded total of 1759 incidents of counterfeit, stolen or illegally diverted drugs (24 percent more than 2006) in 112 countries.

TOP INTERNET RESOURCES

Partnership for Safe Medicines: www.safemedicines.org

FDA Counterfeit Homepage: www.fda.gov/counterfeit

FDA Q&A on Prescription Drug Marketing Act: www.fda.gov/cder/regulatory/PDMA/PDMA_qa.pdf

FDA Medwatch Program: www.fda.gov/medwatch

FDA-OCI Email Contact: www.fda.gov/oci/

NABP Verified-Accredited Wholesale Distributors: www.nabp.net

NABP Wholesaler-Distributor Regulators: www.nabp.net/vawd/ATLWDs.pdf

ASHP List of Drug Shortages: www.ashp.org/shortage

Learn About Contraband and Counterfeit Drugs (Cont.)

Pharmacists – On the Front Lines

By being aware of where counterfeits come from and how they enter the supply chain, pharmacists can play a major role in detecting unsafe products and stopping them before they reach patients.

The Supply Chain

Counterfeiting Activities

Suppliers are responsible for providing raw materials, excipients (the inert substances found in a drug), active pharmaceutical ingredients and other components manufacturers use to create medical products.

It is during this step that counterfeit ingredients can infiltrate a legitimate manufacturing facility.

Manufacturers oversee drug formation and production and responsible for quality assurance and proper dosage and formulations.

It is during this step that counterfeit ingredients can infiltrate a legitimate manufacturing facility.

Warehousing & Distribution Vendors act as the intermediaries between the manufacturers and the drug acquisition sites.

It is during this step that counterfeiting process takes place in one or more of the below forms:

- Product diversion
- Theft/diversion
- Fraudulent labeling
- Label switching
- Illegal repackaging
- Cutting legitimate products with counterfeit products

Drug Acquisition Sites are the businesses and places where customers and patients can obtain the medications, such as traditional, mail order and online pharmacy stores, hospitals, physicians' offices, hospice sites, retail outlets and long-term care providers.

If the product provided by the vendor is counterfeit, then the pharmacist becomes one part of the chain in this harmful distribution. Healthcare practitioners, including pharmacists and physicians have been involved in drug diversion schemes and counterfeiting.

Patients & Consumers

Counterfeit drugs often find their way into U.S. homes via foreign online drug sellers, most of which are rogue. Consumers may purchase the counterfeit drugs directly from these overseas "online pharmacies" or from an affiliate operating domestically.

Pharmacists can also help by spotting consumers who are using substandard medications by noticing if the patient's health has been deteriorating or has not improved when it should have. They can ask patients what medications they are taking and where they purchase their drugs in order to determine the source for all their medications or if there may be any drug interactions. Many time patients use multiple sources—including online pharmacies—for any drugs not covered by their insurance or that have a high co-payment.

Learn About Contraband and Counterfeit Drugs (Cont.)

SafeMeds Tools

The Partnership for Safe Medicines (www.safemedicines.org) has several free resources to help you stay up-to-date on what's happening here in the U.S. and other parts of the world regarding drug safety, including:

- **SafeMeds News Archive:** The Partnership's Web site maintains a comprehensive list of all relevant news stories from around the globe and is a great way to see the global dimensions of this problem.
- **SafeMeds Weekly Update:** Our free weekly email provides readers with a weekly roundup of what's happening around the world regarding counterfeit drugs, as well as the latest blog entry from the Partnership's experts. Check out past issues of the update in our email archive.
- **SafeMeds Email Alert System:** As part of the FDA's Alert Network, we offer this free email service that sends official alerts from the FDA and other government agencies around the world to anyone—private citizens, public groups, corporations, healthcare practitioners, associations—when specific counterfeit drug incidents are detected.
- **Safe Medicines Blog:** Our weekly blog provides regular, expert commentary from Partnership for Safe Medicines' board members Dr. Bryan Liang, Thomas Kubic, Dr. James Class and Dr. Marv Shepherd.

Spot the Fake

Chalk, powered concrete, boric acid and highway paint have all been used by counterfeiters to make fake drugs. Sometimes these imitations are so good the experts can't always tell the genuine drugs from the fake ones without analyzing its chemical composition.

Here are some examples of what actual counterfeit drugs look like. Notice how well counterfeiters package their products to look authentic.

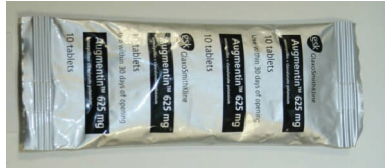
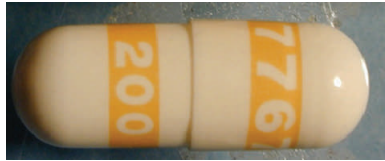
Can you tell which one is the fake drug in each of these pairs?



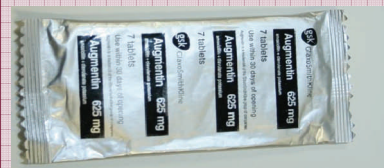
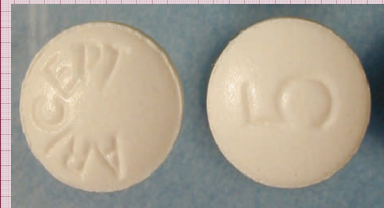
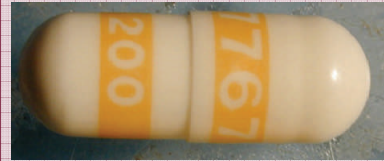
Learn About Contraband and Counterfeit Drugs (Cont.)

Can you tell which one is the fake drug in each of these pairs?

Approved



Counterfeit



Educate Customers

The Partnership for Safe Medicines

The Partnership for Safe Medicines' Web site features a comprehensive consumer resources center that helps individuals learn about the threats endangering the safety of our prescription drugs and how to minimize their risk of getting a counterfeit drug. These free resources include:

- **Safe Savings:** This informative brochure arms consumers with the right information to purchase their medications at a more affordable price AND avoid the serious safety risks that accompany purchasing imported medicine.
- **S.A.F.E. D.R.U.G.:** This "how-to" guide helps consumers identify and protect against counterfeit medicines by showing patients how to judge whether their medications are safe and provides tips on what to do if a drug has been compromised.
- **Partnership for Prescription Assistance:** The Partnership for Prescription Assistance (PPA) helps uninsured and financially struggling patients get access to nearly 500 healthcare and prescription assistance programs that offer medicines for free or nearly free.

Visit www.safemedicines.org for more consumer and professional resources and to learn how you and your organization can help support quality assurance programs that establish a drug distribution system that is without compromise.

Avoid Unsafe Medicines and Vendors

Sourcing is an important first step. Begin by establishing a list of trusted alternative sources.

Acquire a copy of the source's license from your state wholesale distributor regulatory board. A list of these is available online from the National Association of Boards of Pharmacy (www.nabp.net/vawd/ATLWDs.pdf).

Form 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 (www.fda.gov/cder/regulatory/PDMA/PDMA_CPG.pdf).
- To see a list of current drug shortages, consult the online Drug Shortage Resource Center of the American Society of Health-System Pharmacists (www.ashp.org/shortage).

Ensure 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.

Decline Suspicious Offers

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.

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 or phone number
- Promises the availability of a drug during a shortage
- Contains misspellings of ingredient and/or brand names
- Offers generic forms of drugs when none have been approved by the FDA
- Does not possess a dedicated hard/land telephone line and relies solely on a mobile phone

Suspicious Vendors

- Does not have a wholesale license from the state licensing authority
- Wants payments in cash only
- Refuses to pass on required 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 an inventory or product list that is in constant turnover

Evaluate Your Medicines

While some counterfeit drugs are nearly indistinguishable to the legitimate product, many counterfeit drugs leave visual clues or have physical traits that can help you judge whether or not the medicines are real.

When you start carrying a medicine, create a “baseline” of the drug’s characteristics, including its appearance, taste, smell, texture, reactions and packaging. Compare the medicine you vendors provide with what it is supposed to this baseline. When comparing packaging, look for differences in paper, printing, color, and fonts (i.e., is it the same size, raised print, embossed, etc.).

Syrups and Liquid Medicines

SHOULD

- Have the same characteristics as known authentic sample of the medication, including its viscosity, coloring and smell

SHOULD NOT

- Have particulate matter or floating objects in the liquid/syrup unless it is a suspension
- Have patients complain or mention the syrup has a different taste or flavoring than before

Injectable Medicines

SHOULD

- Be in ampoules with uniform shapes and that open or break in the same way
- Be in vials with the same colors, labels, bottle size and shape as a known authentic sample of the medication
- Have intact seals and metal coverings
- Have a uniform characteristics as previously used vials, including the softness of tops (seal, gourmets, rubber seals or metal tops)

SHOULD NOT

- Have any particulate matter or floating objects in the solution
- Have patients complain or report pain or redness at the injection site
- Generate different readings from a handheld spectrophotometer than the real medicines

Tablets, Capsules, Pills & Lozenges

SHOULD

- Appear uniform in its shape and color
- Have a uniform texture, including its
 - Coating, such as a film-coating, sugar-coating or enteric-coating
 - A base that is fully covered
 - Uniformly polished, free of powder, and non-sticking
- Be free of embedded surface spots and foreign particle contamination
- Have uniform and identical markings (scoring, lettering, etc.)
- Be free of breaks, cracks, splits or pinholes
- Smell the same as the original

SHOULD NOT

- Be the wrong color
- Be a different strengths dosage than the FDA approved products
- Have incorrect markings
- Be the wrong product or wrong dosage level

Evaluate Your Medicines (Cont.)

Packaging

SHOULD

- Have its strength—the amount of active ingredient per unit—clearly stated on the packaging
- Be properly sealed
- Contain a package insert
- Have a container and closure that protects the drug from the outside environment for the duration of its shelf life
- Have the appropriate container and closure for the drug inside
- Have smudge-proof ink on the package insert or packaging

SHOULD NOT

- Come from multiple lot numbers
- Look worn, tattered, or not up to quality of established reliable sources
- Have packaging labels or label colors near the expiration date that are faded
- Be missing overt markings such as color shifting ink, raised printing, holograms
- Have seals or sealing tabs over the product openings that are missing or appear to be abnormal or tampered
- Have printed text different in size or design than normal

Manufacturing Information

SHOULD

- Display a legible and correct manufacturer name and logo
- Display an authentic logo or hologram (if applicable) that changes color when viewed from different angles
- Have registered the drug in the country

SHOULD NOT

- Be missing the manufacturer's full address or logo
- Have faded, illegible or expired manufacture and expiration dates

Labels

SHOULD

- Have its strength—the amount of active ingredient per unit—clearly stated on the label
- Indicate the drug under this dosage form is registered and authorized for sale in the country
- Match the information and design of its packaging
- Contain legible, permanent information on the label
- Be a drug sold legally in the country
- Contain the registered symbol ® following the trade name
- Have a trade name and the active ingredient name that correspond to the registered drug
- List the same number of tablets label and the container
- Have a package insert that is printed on the same colored or same quality paper as the original

SHOULD NOT

- Contains misspellings
- Looks dirty and scuffed or placed at an odd angle
- Have labeling written in foreign language or for foreign market
- Indicate "not for resale" or physician use only
- Contain extra glue or tacky residue remains on the outside edge of label

Report Counterfeit Drugs and Suspicious Vendors

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

Check risk factors for packaging, labeling and product



Consult pharmacy's reporting procedures



Fill out FDA's Form 3500 to report the product at www.fda.gov/medwatch



For Suspicious Vendors

Check **all** risk factors



Consult pharmacy's reporting procedures



To report the vendor to the FDA visit the website www.fda.gov/oci/
Include detailed and timely information about the incident, such as:

- Name and strength of the drug
- Lot number and expiration date
- Reasons for suspicion about the product, packaging, documentation, or offer
- Source of the prescription drug (if known)



Notify state regulator of wholesale distributors
www.nabp.net/vawd/ATLWDs.pdf

About the Partnership for Safe Medicines

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Board of Directors

The Partnership for Safe Medicines' Board of Directors authorizes official Partnership publications and directs all activity. Board members are not compensated for their work with the Partnership. Day-to-day operations are conducted by the Partnership's Executive Director in the Washington, D.C. area.

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