

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

Comprised of more than 65 non-profit organizations, the **Partnership for Safe Medicines** is a public health group committed to the safety of prescription drugs and protecting consumers against counterfeit, substandard 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.

Prescription and over-the-counter medicines are an integral part of modern healthcare. As a physician, you know patients rely on these products to treat everything from minor conditions to life-threatening diseases. But there is a silent, often unrecognized, danger that is undermining patient safety—counterfeit drugs in the medicine supply.

Not only do counterfeit drugs defraud consumers, they deny patients therapies that can alleviate suffering and save lives. In too many cases, counterfeit drugs cause harm, including allergic reactions, heavy metal poisoning, drug resistance and death. These fakes are sold as if they are legitimate products but may consist of anything from chalk and powdered concrete to antifreeze and boric acid.

The Partnership for Safe Medicines encourages physicians to take an active role in promoting patient safety and protecting patients from counterfeit drugs. Here are six steps for becoming a L.E.A.D.E.R. in the fight to protect patient safety:

Look into counterfeit medicines as an etiology for therapeutic failure.

When a patient is not clinically responding as expected to a medicine, the differential diagnosis should include a potential counterfeit drug.

Educate patients. Empower patients to safeguard their health and avoid counterfeit drugs with free resources that explain how to use the S.A.F.E. D.R.U.G. checklist to maintain patient safety, save money while ensuring the safety of their medicines, find legitimate online pharmacies and access established programs if they need help paying for medicines.

Acknowledge why patients turn to online drug sellers. Recognize at-risk patients by understanding why a patient may purchase medicines online and discuss the risks and challenges of buying medications over the Internet.

Dispense free samples. If using brand name drugs, sample packs can help patients establish a “baseline” of a medicine’s characteristics, including its appearance, taste, texture, reactions and packaging.

Evaluate suspect medicines. Learn how to detect potential counterfeit drugs by evaluating products, packaging and labeling of the drug products you prescribe for any suspicious nature.

Report counterfeit medicines. Help shut down these criminal operations by reporting suspected counterfeit medicines and suspicious vendors to the proper authorities, including the FDA, law enforcement and state regulators.

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Look into Counterfeit Medicines as an Etiology for Therapeutic Failure

Any drug, from an antibiotic to a pain medicine, can be counterfeited. In fact, counterfeit drugs are not limited to brand-name prescription drugs. Counterfeiters also create fake versions of generic and over-the-counter (OTC) drugs. And because these criminals are very good at making their products look legitimate, it is easy to confuse these dangerous fakes with the real thing.

When a patient is not responding to, or has an unusual reaction to a medicine, there could be a number of reasons why, including the potential for fake drugs. Counterfeit drugs can have any, or all, of the following characteristics:

- Missing key ingredients
- Too strong or too weak
- Use the wrong active ingredient
- Contain dangerous contaminants
- Made in unsanitary or unsterile conditions
- Use unsafe manufacturing methods
- Use improper labels

To assess these concerns, it is important for a physician to ask the patient questions regarding medications in a safe, non-judgmental manner. The World Health Professionals Alliance recommends gently asking the following questions to help determine the legitimacy of a patient's medical product:

- *Where did you purchase your medicine?*
- *Was the packaging of your medicine new and clearly labeled?*
- *If you have taken the drug before, did your medicine have any unexpected taste, behavior or side effects?*
- *Does the medicine take longer than usual to have an effect?*

Educate Patients

The Partnership for Safe Medicines' website – www.safemedicines.org – features a comprehensive consumer resource center that helps physicians provide patients with information on drug supply safety. Here, materials are available about the threats endangering the safety of the prescription drug supply and how to minimize their risk of getting a counterfeit drug. These free, downloadable resources include:

- **Safe Savings:** This informative brochure arms patients with information to purchase medicines at more affordable prices AND avoid the serious safety risks accompanying purchasing from suspect sources. Available in English, Spanish, Chinese, Tagalog and Vietnamese.
- **S.A.F.E. D.R.U.G.:** This “how-to” guide provides patients with systemic methods of how to assess their medicines and provides tips on what to do if a drug has been compromised. Available in English, Spanish, Chinese, Tagalog and Vietnamese.
- **Partnership for Prescription Assistance:** The Partnership for Prescription Assistance (PPA) helps uninsured and financially struggling patients obtain access to nearly 500 healthcare and prescription assistance programs, which offer medicines for free or nearly free.
- **Frequently Asked Questions (FAQs):** This collection of questions presents a quick overview of counterfeit drugs and why they are so dangerous. Available in English, Spanish, Chinese, Tagalog and Vietnamese.
- **What You Don't Know About Importing Drugs From Canada:** This fact sheet explains why drug importation programs, including government-sponsored programs, have significant risks. Physicians should particularly be vigilant and inform their most vulnerable patient populations of these risks, including minorities, seniors and fixed income patients, who may attempt to use suspect sources due to price sensitivity and other concerns.
- **Save Money Safely on Prescriptions From Online Pharmacies:** When it comes to medicine, the Internet can be a prescription for disaster since there are thousands of websites that pose as legitimate pharmacies but are unfortunately only criminal enterprises. This fact sheet describes the hidden dangers of buying medicine online and how to find the safest online pharmacies.

Acknowledge Why Patients Turn to Online Drug Sellers

Purchasing drugs from online pharmacies can be convenient and economical. However, the Internet has also made it easy for unscrupulous people to illegally and unsafely sell prescription medicines to anyone with a means of paying. The World Health Professionals Alliance lists several common reasons why a patient may turn to the Internet to buy their medicines.

- **Saving money:** For patients who pay for most of their medication costs themselves or have large co-pays, buying from the Internet could be seen as a way of reducing treatment costs. But most patients do not realize these online “pharmacies” are not accredited by the National Association of Boards of Pharmacies, nor regulated by the U.S. Food and Drug Administration (FDA) or any other government authority. In fact, many of these fake online pharmacies are run by large criminal organizations looking to make millions of dollars by selling fake drugs with little or no active ingredient.
- **Bypassing the need for a prescription:** For some patients, the ability to get a prescription-only medicine without a prescription is the driving force for purchasing medicine online. This could be due to an unwillingness to discuss “embarrassing” lifestyle issues, such as erectile dysfunction and depression. Another reason a patient may seek out illegal online drug sellers is prescription drug abuse.
- **Increasing the range of possible treatments:** Some patients turn to the Internet for medicines because they want access to products or medicines that are not yet authorized in the United States.
- **Increasing access to medicines:** In some rural areas, there may be only a few brick and mortar pharmacies to service hundreds of square miles. For these patients, having a prescription drug delivered to their door by an online seller is especially appealing.

These are significant issues for patients and can be addressed by physicians with the aid of PSM’s tools and materials that provide patients with safe alternatives. Open and transparent discussion between doctor and patient can provide important opportunities to ensure patient safety and promote public health.

Dispense Free Samples

Whenever possible, physicians can promote patient safety by providing patients with a sample of a medicine when it is first prescribed. Samples can help patients establish a “baseline” of a medicine’s characteristics, including its appearance, taste, texture, reactions and packaging.

However, be sure to explain to patients that manufacturer samples are usually only available for brand name medicines and not generic products. Generic versions of medicine may differ in shape or color between manufactures, but they still are safe and effective products.

Evaluate Suspect Medicines

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

Whenever possible, use a known-to-be authentic sample of the medicine to create a “baseline” of the drug’s characteristics (including its appearance, taste, smell, texture, reactions and packaging) and compare suspect medicines against this baseline. Also, examine the medicine’s packaging and look for differences in paper, printing, color and fonts (i.e., is it the same size, raised print, embossed, etc.). Physicians directing patients to keep a “drug diary” with these characteristics can help keep the patient as part of the safety team and the last barrier to harm. In fact, recent cases of counterfeits were detected by patients.

Syrups & 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 ampules 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:
 - 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 or have incorrect markings
- Be a different strengths or dosage than the FDA approved products
- Be the wrong product or wrong dosage level

Evaluate Suspect 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 or 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 on the label and the container
- Have a package insert that is printed on the same colored and quality paper as the original

SHOULD NOT

- Contain misspellings
- Look dirty, scuffed or placed at an odd angle
- Have labeling written in a foreign language or for a 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 Medicine

Your leadership is an essential part of the 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.

For Suspicious Products

Check risk factors for packaging, labeling and product



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



For Suspicious Vendors

Check risk factors listed in the L.E.A.D.E.R.'s Guide for Pharmacists



Visit www.fda.gov/oci to report the vendor to the FDA. Include 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

The Partnership for Safe Medicines is a coalition of more than 65 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.

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