The Partnership for **SAFE MEDICINES** *i* **SAFEMEDICINES**. *org*

Frequent Asked Questions

Q: What are counterfeit drugs?

A: Counterfeit drugs include any fake or substandard medicine that is below the FDA's established standards of quality but hide this fact. Counterfeit drugs can be any, or all, of the following things:

- 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- Expired (out-of-date)

Q: Why are counterfeit drugs dangerous?

Fact: Counterfeit drugs are not limited to brand-name prescription drugs. Counterfeiters also create fake versions of generic and over-the-counter (OTC) drugs.

A: Not only do counterfeit drugs defraud consumers, they deny patients the therapies that can alleviate suffering and save lives—and in too many cases, counterfeit drugs cause great harm and fatalities. They can cause allergic reactions, heavy metal poisoning, as well as promote drug resistance strains of diseases. These fake drugs may consist of anything from chalk, powdered concrete, and boric acid (or worse) and are sold as if they were real drugs. Because counterfeiters are very good at making their product look like the real thing, it is easy to confuse these harmful products with the real thing.

Q: What types of drugs are counterfeited?

A: Any drug, from an antibiotic to a pain medication, can be counterfeited. In 2007, counterfeiters sold more than 600 different types of branded, generic and over-the-counter drugs and used improved packaging to make their counterfeit goods harder to detect.

Q: Aren't counterfeit drugs only a threat in developing countries?

No. In fact, counterfeit drugs can, and have shown up in both online and traditional pharmacies based in the United States. In August 2007, the FDA warned consumers who recently filled prescriptions at two Medicine Shoppes in Baltimore they may have received expired or counterfeit drugs.

If the online pharmacy you are purchasing from is a state-licensed pharmacy located within the U.S., then the likelihood of receiving a counterfeit drug is lower. However, when you look to purchase drugs through online pharmacies located outside of the U.S., you should proceed with caution. These pharmacies are not regulated by the same strict guidelines that the U.S. places on pharmacies located domestically, increasing your chance of purchasing a counterfeit drug.

Q: Are counterfeit drugs commonly found in the United States?

A: The World Health Organization estimates that counterfeit drugs range from less than 1 percent in developed countries to more than 30 percent in some developing countries. Currently, the United States has one of the safest drug supplies in the world because our pharmaceutical supply system is "closed" to importation. Although most of the counterfeit drugs in the United States are not in our normal supply chain, adulterated, fraudulently-obtained, expired or counterfeit drugs remain an issue in the United States. Especially anytime consumers venture outside of the U.S.'s currently closed system, there is a very real risk to their health and welfare.

Q: If I purchase or obtain medications over the Internet, should I be concerned about counterfeit drugs?

A: Yes. While the Internet has made it possible to compare prices and buy products without ever leaving home, it has also made it easy for unscrupulous people to sell unapproved and counterfeit drugs to unsuspecting customers. In some countries, this is a rare occurrence; in others, it is an everyday reality. Based on its assessment of more than 1,000 Internet drug

Fact: Counterfeit drugs often funorganized crime and other crimin activities such as terrorism, child and slave labor, human trafficking By buying counterfeit drugs you a unwittingly supporting this. outlets selling medicine online, the National Association of Boards of Pharmacy (NABP) found that 97 percent of these sites appear to be operating out of compliance with state and federal laws or established patient safety and pharmacy practice standards.

The Partnership for Safe Medicines offers several tools, including "Tips for Safe Online Buying" and "Warning Signs," to teach consumers how to safely order prescription drugs over the Internet.

Q: The Web site says the drugs are from Canada, doesn't that mean that they are safe?

A: No. Just because a Web site looks good and says its drugs come from Canada, it doesn't mean it's legitimate online pharmacy. In fact, by marking the drugs "for export only," drug exporters can make Canada a post office box for fake or low-quality drugs from China, India, and other countries notorious for ineffective and sometimes lethal products.

Importing drugs from European countries such as Great Britain are not any safer. European Union parallel importation and trade laws provide an opportunity for the inadvertent entry of counterfeit drugs into legitimate supply chains and markets.

Q: Are there ways I can tell if a drug is counterfeit?

A: 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 taking a medicine, create a "baseline" of the drug's characteristics, including its appearance, taste, texture, reactions and packaging. Compare the medicine you receive with what it is supposed to look, taste and feel like. When comparing packaging, look for differences in paper, printing, color, and fonts (i.e., is it the same size, raised print, embossed, etc.).

Q: I think I purchased a counterfeit drug, now what should I do?

A: If you have any concerns about the quality of your drugs, or have confirmed there is a difference in packaging, labeling, or pills, immediately contact the pharmacy where you purchased them. If you purchase a generic version of a prescription drug, be aware that color and packaging may change if a pharmacy receives the generic version from a new distributor. You may also want to contact the FDA, your State Board of Pharmacy and the manufacturer of the medication to report your concerns. The Pharmaceutical Security Institute can assist you in contacting the manufacturers and has additional information concerning counterfeit medicines on their Web site, www.psi-inc.org. The FDA can be contacted by calling toll-free 1-800-FDA-1088 (1-800-332-1088) or online at www.fda.gov/medwatch.

Do not throw the suspect product away; the appropriate authorities may want to have it for analysis. However, it is important that you and any family members do not confuse this medication with any legitimate prescription drugs you may be taking. Clearly mark the medicine as suspect and make sure it is unavailable to you or others in your family until you can send the suspect medication to the appropriate local law enforcement officials or dispose of it safely.

Q: Where can I purchase medicines online safely?

A: The safest online pharmacies are accredited by the Verified Internet Pharmacy Practice Sites (VIPPS). Created by the National Association of Boards of Pharmacy (NABP), VIPPS is the most trusted and respected means for the public to distinguish between legitimate and illegitimate online drug sellers. Visit **www.vipps.info** for a complete listing of VIPPS pharmacies.

Q: How can I save money without compromising drug safety?

Many consumers are not aware that the prices for medications can differ from pharmacy to pharmacy, city to city, state to state. Take your entire list of medications to local pharmacies to find the best total price at *one* pharmacy. Using one pharmacy, and developing a relationship with your pharmacist, is the safest way to check for drug interactions, duplications and possible side effects—and get the best value for your money. If you're 65 years or older, many pharmacies offer a 10 percent senior discount. Be sure to ask about it.

In addition to comparing prices at safe, fully-licensed pharmacies, ask your healthcare provider and pharmacist about generic alternatives or purchasing a 90-day supply of your medicine instead of a 30-day supply. Generic drugs offer savings of 25-50 percent over brand name drugs and doctor and pharmacist might be able to prescribe higher-dosage pills that can be split. *NOTE: Never split pills without talking to your pharmacist!*

Q: Where can I get help paying for my medications?

A: Rather than turning to questionable online pharmacies, the Partnership for Safe Medicines recommends turning to the Partnership for Prescription Assistance (PPA). The 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. Patients can call toll-free, **1-888-4PPA-NOW (1-888-477-2669)**, to talk with a trained specialist who will guide them through the application process or visit **www.pparx.org**.

NeedyMeds is a 501(3)(c) non-profit with the mission of helping people who cannot afford medicine or healthcare costs. The information at NeedyMeds is available anonymously and free of charge. Visit **www.needymeds.org**.

Q: I know what medicine my healthcare provider will prescribe, why do I still need a prescription to order it online?

A. Our laws require that certain drugs can only be dispensed with a valid prescription because they are not safe for use without the supervision of a licensed healthcare provider. Before a healthcare provider issues a prescription for a drug the patient has never taken before, he or she must first examine the patient to determine the appropriate treatment. Web sites that don't require a prescription, or only ask customers to fill out a questionnaire before getting a prescription drug, bypass this critical in-person evaluation and deny consumers the protection provided by a licensed healthcare provider.

Fact: It is illegal to sell a prescription medication in the U.S. without a prescription. If an online pharmacy allows you to do this, then it is not an accredited pharmacy, and your chances of receiving a counterfeit drug are much higher.

Unfortunately, patients have died from drugs they purchased from online sellers without a valid prescription. These deaths may have been avoided if these patients had gone to their doctor to get a prescription.