

FAQs About Counterfeit Pharmaceutical Drugs

What are counterfeit pharmaceutical drugs?

Counterfeit pharmaceutical drugs are broadly defined as medicines that fall into four categories:

- a. Fake medication that contains no active ingredient
- b. A different drug than the one prescribed
- c. A diluted version of the real drug
- d. Unapproved foreign versions of a drug sold in the U.S.

How serious is this problem?

The threat to the safety of the world's prescription drug supply is growing. The Center for Medicines in the Public Interest projects that global revenues lost due to counterfeit drug sales will reach \$75 billion by 2010, nearly double in only five years.

What is being done about this issue?

The FDA formed a Counterfeit Drug Task Force in July 2003. The FDA found that implementing new technologies to track and trace each pharmaceutical drug would help secure the integrity of the drug supply chain.

How can this tracking and tracing, known as "drug pedigree," be done?

Technology now exists to provide an accurate electronic drug pedigree, which is a secure record that documents where the drug was manufactured and distributed under safe and secure conditions. This is using 2D barcodes, RFID (radio frequency identification), and other types of sensors. GSMS, Inc. (Golden State Medical Supply) of Camarillo, California, is one of the first companies in the nation to adopt the technology that will help it and its customers to manage serialized drug pedigree information.

Who will enforce the pharmaceutical drug pedigree system?

State governments will enforce the system because states license and regulate wholesale drug distributors and have an important role in regulating the drug distribution supply chain. The California Board of Pharmacy is the first state agency to require an electronic pedigree system to track and trace the passage of prescription drugs through the entire supply chain. The new law goes into effect on January 1, 2011.

Why is it taking so long to implement this system?

Currently there are voluntary tracking and tracing methods already being used. In addition, the state of California, in partnership with the FDA, is working to develop unique federal identifier standards to ensure that the state and federal standards remain consistent.

Are there currently any particular areas of concern?

The FDA has warned consumers about the dangers associated with buying prescription drugs over the internet. Consumers who buy prescriptions online are urged to review the FDA warning that was issued in May 2007.

Are any particular types of pharmaceutical drugs more prone to be counterfeited?

The National Association of Boards of Pharmacy published a list of 30 medicines especially susceptible to counterfeiting—more than two-thirds treat either cancer or HIV/AIDS. Counterfeiters favor those drugs because they are expensive and thus more lucrative. However, all prescription drugs are susceptible to the insidious world of counterfeiting.

What should consumers know about how and where they purchase their pharmaceutical drugs?

Pharmacies are regulated by state laws. They must be licensed in the states in which they conduct business. In addition, most states also require licenses for out-of-state pharmacies that ship medications. Federal agencies, such as the FDA and the Drug Enforcement Administration (DEA), also regulate the sale of drugs.

How can I report suspected counterfeit drugs?

You should report suspected counterfeit drugs to the pharmacist who sold you the medication and to your doctor if you are experiencing any medical problems. Your pharmacist will know whether there has been a change in the color, shape, taste, or packaging of the medication, and how to report your concern to the FDA. You can also report your suspicions directly to the FDA by calling the MedWatch program at (800) 332-1088.