How Do I Report Counterfeit Drugs?

Patients: Contact the pharmacy where you got the medication from. If you received drugs from a site you believe is selling counterfeit drugs and your case involves:

- A life threatening situation from taking an FDA approved drug that you purchased online, call 1-866-300-4374 immediately (also contact your health care provider)
- A serious reaction or problem with an FDA-regulated product, fill out the MEDWATCH reporting form at www.fda.gov/medwatch or call 1-800-332-1088 or fill out and mail the FDA form 3000
- A report of a website that you think is involved with illegal drug activity (Counterfeiting), fill out an online form at: http://www.accessdata.fda.gov/scripts/email/oc/buyonline/buyonlineform.cfm
- Receiving emails from websites that you believe are involved with counterfeit drugs, follow the procedure from step (c) and forward the emails to: webcomplaints@ora.fda.gov

Pharmacists: Depending of the circumstances, follow procedures (a) or (b) as listed above. If the case does not pertain to either of the procedures, fill out the form at http://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm. Follow your company’s policy on the appropriate procedures to conduct. Also, contact the manufacturer of the product in question. Finally, notify your state regulator of wholesale distributors at: http://www.nabp.net/programs/assets/ContactVerification.pdf

Who: Organized crime, corrupt government officials, wholesalers, pharmacies

What: Drugs that have a high market value, but for which cheap alternative ingredients are readily available. The cheap ingredients sometimes behave similar to the real drug in tests. This helps disguise the product in quality control tests and/or promotes the reputation of a legitimate manufacturer to a purchaser.

Where: Primarily developing countries or areas where regulatory/policing systems are weak. Countless websites on the internet are involved as well.

Why: The profit margins are incredible for high cost counterfeit drugs made from cheap raw materials. The market size is immense for people who do not have access to legitimate pharmacies and for those seeking more affordable medicine. Many countries have inadequate legislation, regulations, and enforcement which result in minimal punitive consequences for those found guilty of counterfeiting.

Remember, counterfeit drugs are often manufactured under conditions that are not in compliance with the FDA’s Good Manufacturing Practices. They are dangerous and always illegal, help spread awareness of counterfeit drugs.

References:
2. IMPACT: http://www.impactsnet.org/
5. The Partnership for Safe Medicines: http://www.safemedicines.org/
6. The American Council on Science and Health: http://www.theacs.org/

Can You Tell The Difference?

Real

Fake

What Are Counterfeit Drugs?

Counterfeit drugs are deliberately and fraudulently mislabeled with respect to identity and/or source. They may be contaminated or contain the wrong active ingredient, if any at all. They could have the right active ingredient but at the wrong dose.

How Do They End Up In Your Hands?

Infiltration of U.S. Drug Supply

Counterfeit drugs are typically imported from developing countries. These countries do not typically have robust regulatory systems. In addition, the manufacturing processes used to produce counterfeit drugs are often far from compliant with Good Manufacturing Practices enforced by the FDA. Infiltration of U.S. Drug Supply

What Is Being Done?

INTERPOL: The world's largest international police organization which includes 190 countries. It currently has four “operations” which have effectively shut down over 13,000 websites and has seized over 40 million pills (mostly counterfeit) since 2009.

IMPACT: World Health Organization: Created the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). This division has formed a partnership with most of the major anti-counterfeiting organizations. IMPACT works to create coordinated networks between countries to disrupt the production, trading, and selling of counterfeit drugs. It contains 5 “working groups” which address and advise IMPACT participants on specific issues relating to counterfeit drugs.

National Association of Boards of Pharmacy: Created Verified Internet Pharmacy Practice Sites (VIPPS). This voluntary accreditation program confirms with online customers that the site is regulated by a state pharmacy board. The VIPPS seal is included on all accredited sites and serves as a link to the VIPPS website which lists all accredited pharmacies.

Food and Drug Administration: A counterfeit drug task force was created in 2003, but has not published a report since 2008. Nevertheless, the FDA has developed a guidance for industry on anti-counterfeiting as well as standards regarding supply chain security.

The Partnership for Safe Medicines: an active group of not-for-profit organizations and individuals that develop informational material and programs for consumers and healthcare professionals to protect patients against counterfeit drugs. They also create policies and procedures that work as a guide for ensuring safe medicine.

How Do I Report Counterfeit Drugs?

Patients: Contact the pharmacy where you got the medication from. If you received drugs from a site you believe is selling counterfeit drugs and your case involves:

- A life threatening situation from taking an FDA approved drug that you purchased online, call 1-866-300-4374 immediately (also contact your health care provider)
- A serious reaction or problem with an FDA-regulated product, fill out the MEDWATCH reporting form at www.fda.gov/medwatch or call 1-800-332-1088 or fill out and mail the FDA form 3000
- A report of a website that you think is involved with illegal drug activity (Counterfeiting), fill out an online form at: http://www.accessdata.fda.gov/scripts/email/oc/buyonline/buyonlineform.cfm
- Receiving emails from websites that you believe are involved with counterfeit drugs, follow the procedure from step (c) and forward the emails to: webcomplaints@ora.fda.gov

Pharmacists: Depending of the circumstances, follow procedures (a) or (b) as listed above. If the case does not pertain to either of the procedures, fill out the form at http://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm. Follow your company’s policy on the appropriate procedures to conduct. Also, contact the manufacturer of the product in question. Finally, notify your state regulator of wholesale distributors at: http://www.nabp.net/programs/assets/ContactVerification.pdf

What Is Being Done?

INTERPOL: The world’s largest international police organization which includes 190 countries. It currently has four “operations” which have effectively shut down over 13,000 websites and has seized over 40 million pills (mostly counterfeit) since 2009.

IMPACT: World Health Organization: Created the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). This division has formed a partnership with most of the major anti-counterfeiting organizations. IMPACT works to create coordinated networks between countries to disrupt the production, trading, and selling of counterfeit drugs. It contains 5 “working groups” which address and advise IMPACT participants on specific issues relating to counterfeit drugs.

National Association of Boards of Pharmacy: Created Verified Internet Pharmacy Practice Sites (VIPPS). This voluntary accreditation program confirms with online customers that the site is regulated by a state pharmacy board. The VIPPS seal is included on all accredited sites and serves as a link to the VIPPS website which lists all accredited pharmacies.

Food and Drug Administration: A counterfeit drug task force was created in 2003, but has not published a report since 2008. Nevertheless, the FDA has developed a guidance for industry on anti-counterfeiting as well as standards regarding supply chain security.

The Partnership for Safe Medicines: an active group of not-for-profit organizations and individuals that develop informational material and programs for consumers and healthcare professionals to protect patients against counterfeit drugs. They also create policies and procedures that work as a guide for ensuring safe medicine.

How Safe Are Internet Pharmacies?

The National Association of Boards of Pharmacy recently conducted a study and found that 96% of the 8,000 sites surveyed did not operate in accordance with U.S. pharmacy laws. Furthermore, the World Health Organization estimates that over 50% of internet pharmacies that conceal their physical address, provide counterfeit drugs. 36 million Americans are believed to have purchased drugs from “rogue” internet sites according to CBS. Despite the rampant illegal activity with online pharmacies, some are actually safe to use. Any online pharmacy that is VIPPS accredited is a legitimate practice that provides safe medication.


Who: Organized crime, corrupt government officials, wholesalers, pharmacies

What: Drugs that have a high market value, but for which cheap alternative ingredients are readily available.

Where: Primarily developing countries or areas where regulatory/policing systems are weak. Countless websites on the internet are involved as well.

Why: The profit margins are incredible for high cost counterfeit drugs made from cheap raw materials. The market size is immense for people who do not have access to legitimate pharmacies and for those seeking more affordable medicine. Many countries have inadequate legislation, regulations, and enforcement which result in minimal punitive consequences for those found guilty of counterfeiting.

Remember, counterfeit drugs are often manufactured under conditions that are not in compliance with the FDA’s Good Manufacturing Practices. They are dangerous and always illegal, help spread awareness of counterfeit drugs.

References:
2. Food and Drug Administration: http://www.fda.gov/NewsEvents/PublicHealthAdvisories/ucm165102.htm
4. The American Council on Science and Health: http://www.theacs.org/
5. Pfizer: http://www.pfizer.com/home/

What Should I Look Out For?

Reports of Counterfeit Medicines by Therapeutic Category

- Cardiovascular
- Gastro-intestinal
- Central Nervous System
- Anti-Infectives

One case reflects at least one production lot, e.g. thousands of tablets, capsules, or other forms. Several cases included multiple therapeutic categories (only the most frequent category is included in the chart).


Remember, counterfeit drugs are often manufactured under conditions that are not in compliance with the FDA’s Good Manufacturing Practices. They are dangerous and always illegal, help spread awareness of counterfeit drugs.