Counterfeit Medicine & Internet Pharmacies

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What is a Counterfeit Drug?

According to the World Health Organization (WHO):

"A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."
Recombinant Human Growth Hormone misused/abused for “body building”

Indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance.
Example #2: Avastin

Approved for:
- Glioblastoma (GBM) Brain tumor
- Metastatic Colorectal Cancer (mCRC)
- Non–Small Cell Lung Cancer (NSCLC)
- Metastatic Kidney Cancer (mRCC)

Patients with life-threatening conditions purchased counterfeit medicines that did not contain active treatment ingredients.
Examples #3-4: Tamiflu and Lipitor

LEFT: Tamiflu

RIGHT: Lipitor

For more information, read the FDA Consumer Update article titled "The Possible Dangers of Buying Medicines over the Internet" at: www.fda.gov/ForConsumers/ConsumerUpdates/ucm048396.htm
Q: How Big is the Problem? A: Global Concern

- 27.5 million counterfeit medicines retained by European Customs Authorities
- 36% of anti-malaria drugs in Southeast Asia are falsified
- 550 million doses of illicit medicine seized in Africa during the «Biyela» operation
- 9.8 million illegal and counterfeit drugs seized during «Pangea VI» operation
- 10% of the world’s medicines are counterfeit
- Up to 30% of medicines in developing countries are counterfeit
- 50% of cases, medicines purchased over the Internet from illegal sites that conceal their physical address have found to be counterfeit

Infographic prepared by Sanofi, accessed via www.fakemedicinesarearealdanger.com/web/about-counterfeiting on April 9, 2015
Map of a Rogue Internet Pharmacy Operation

1. Customer places order
Customer orders prescription drugs from a rogue Internet pharmacy in Russia. The pharmacy’s website uses servers in Brazil and China.

2. Payments processed
Customer payments for the prescription drugs are processed by a bank in Azerbaijan.

3. Prescription drugs sent
Prescription drugs are shipped from India to the customer.

Source: Christian Kreibich, © 2011 Institute of Electrical and Electronics Engineers (data); Map Resources (map).

Screenshot of a Rogue Internet Pharmacy Website That Sold Counterfeit and Misbranded Drugs, 2006

Rogue Internet Pharmacy Website That Received a Warning Letter from FDA in 2012 as Part of Operation Pangea

Patient Safety is Paramount

• Patient consequences of receiving counterfeit drug can be devastating
• Life saving, not just life style
• Even those drugs with 60-80% of labeled active ingredient can have significant negative clinical impact
Drug manufacturing equipment... or cement mixer
Where would you rather get your medicines?

Source: GSK Counterfeit Medicines, February 21, 2004
Where would you rather get your medicines?

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Is Any Medicine Purchased Online Safe?

Yes, assuming appropriate precautions. Per FDA, a safe website should:

• Be located in the United States and licensed by the state board of pharmacy where the Web site is operating (check www.nabp.net)
• Have a licensed pharmacist to answer your questions
• Require a prescription from your doctor or other health care professional licensed in the United States to write prescriptions for medicine
• Have a mechanism to speak to someone if you have problems

Organizations Fighting for Patients

- CSIP
- Alliance for Safe Online Pharmacies
- VIPPS
- LegitScript
- Pharmaceutical Security Institute
- THE PARTNERSHIP FOR SAFEMEDICINES.org
- PhRMA
What Else Can We Do?

- **Education, Education, Education**
  - Empower consumers to make smart choices when shopping online
- **Recently Enacted Authorities**
  - Increased criminal penalties
  - Destruction authority
  - Increased oversight and licensure of repackers and wholesale distributors
  - Track and trace
- **Develop best practices and encourage compliance**
- **Investigations and enforcement**
- **Continued dialogue and exploration of other partnership opportunities**
- **Maintain integrity of closed U.S. supply chain**