

Sourcing Medicine for Missions

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Disclosure Information

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I have the following financial relationships to disclose:
I am an Employee of Blessings International.

I will not discuss off label use and/or investigational use
in my presentation.

Learning Objectives

- At the conclusion of this activity, pharmacists should be able to:
 - Define counterfeit medication and identify the financial and human costs thereof;
 - Define substandard medication and identify the financial and human costs thereof;
 - Describe the risks and benefits of obtaining medications in the United States and transporting into developing nations;
 - Describe the risks and benefits of obtaining medications in developing nations;
 - Identify sources of safe medicine for missions;
 - Describe how to apply strategies for sourcing safe medicine for missions.

Quotes from Yogi Bera

- Baseball is 90 percent mental. The other half is physical.
- I always thought that record would stand until it was broken.
- If you come to a fork in the road, take it.
- It ain't the heat, it's the humility.
- If you don't know where you're going, you might wind up some place else.

Donald Rumsfeld

There are known knowns. These are things we know that we know. There are known unknowns. That is to say, there are things that we know we don't know. But there are also unknown unknowns. There are things we don't know we don't know.

Case Study

- September 2006, Panamanian physician reported unusual number of patients with unexplained acute renal failure.
- Patients frequently also presented with severe neurological dysfunction.
- Other symptoms included: nausea, vomiting epigastric discomfort, followed by oliguria or anuria, anorexia and fatigue
- 12 out of 21 patients died, despite dialysis

Counterfeit

- Black's Law Dictionary
 - To forge; to copy or imitate, without authority or right, and with a view to deceive or defraud, by passing the copy or thing forged for that which is original or genuine.

Counterfeit Drug - FDA

- A drug which, or the containers or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

Counterfeit Drug - 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.

Prevalence of Counterfeiting

- 1% of medicines in developed nations are likely to be counterfeit
- 10% of medicines globally are likely to be counterfeit
- 53% of medicines in developing nations are likely to be counterfeit

Financial Cost of Counterfeiting

- Approximately \$40 Billion in 2005¹
- Estimated at \$75 Billion in 2010¹
 - 15% of the legal pharmaceutical market
- For every \$1,000 invested, the return is²:
 - \$20,000 profit from Heroin
 - \$400,000 profit from counterfeit medicine

¹Cheng. Is the drugstore safe? Counterfeit diabetes products on the shelves. J Diabetes Sci Technol 2009.

²Sanofi. The fight against counterfeit medicines: five years on the front lines. 2013.



Human Cost of Counterfeiting

- 20% of Annual Deaths from Malaria Worldwide¹
- 40% of Artesunate contained no active ingredient¹
- Niger Meningitis Epidemic 1995²

¹ Cockburn. Leading world organizations to seek solutions. (2002).

² WHO. Counterfeit Medicines Fact Sheet. (2006).

³Newton, et al. Impact of poor-quality medicines in the 'developing' world. Trends Pharmacol Sci (2010).

Case Study

- 12 out of 21 patients died, despite dialysis and supportive treatment
- 42 case patients / 140 control patients
- Median age 68 years (range: 25 to 91)
- 64% male
- Serum Creatinine $\geq 2\text{mg/dl}$ or acute worsening of pre-existing chronic renal failure

Case Study

- Investigators recognized potential correlation with lisinopril
- Investigators also recognized potential correlation with cough syrup for coughs resulting from the ACE inhibitor
- Cough syrup formulated by local hospital was shown when analyzed to have diethylene glycol

Reasons for Counterfeiting

- Lack of appropriate medicine legislation
- Absence of, or weak national medicines regulatory agency
- Shortage or erratic supply of medicines
- Price differentials
- Trade through several intermediaries
- Inappropriate use of medicines

Malaria medicine distributed at a clinic in Switite, Burma



Source: Paula Bronstein/Getty Images

Guess the Fake



Guess the Fake



Guess the Fake



Guess the Fake



Follow-Up



Substandard Medicine

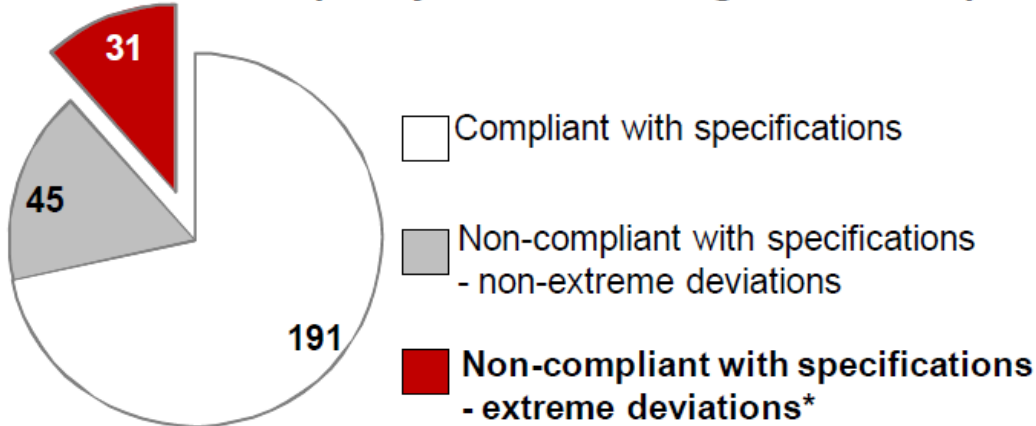
Definition

■ WHO

- Genuine medicines produced by manufacturers which do not meet quality specifications set for them by national standards.
- Substandard medicines are pharmaceutical products that do not meet their quality standards and specifications.

Substandard Medicine Prevalence

Results of full quality control testing of 267 samples



* In this survey, extreme deviations were defined as a deviation by at least 20% from the declared content of one or more active ingredients, and/or dissolved percentage of one or more active ingredients less than the pharmacopoeial limit (Q) minus 25%.

Substandard Medicines Prevalence

- 8.5% of Thailand Market
- 16% of Myanmar Medicines Failed Quality Tests
 - 26% of Rifampicin
 - 24% of Cotrimoxazole



Types of Failures

- Lower content of API and higher content of related substances
- Failure to meet dissolution rates
- Failures in mass uniformity tests

Examples of Failures

- Primaquine tablets contained 19-168% active ingredient
- Gentamicin-resistant *Pseudomonas aeruginosa* in gentamicin eye-drops
- Methylprednisolone injection lead to fungal meningitis

Impact of Poor Quality Medicines

- Increased mortality and morbidity
- Engendering of drug resistance and loss of medicine efficacy
- Loss of confidence in health systems and health workers
- Economic loss
- Adverse effects from incorrect active ingredients
- Increased burden for health workers and regulators

Pros of Obtaining Medicine In-Country

- No customs issues
- No extra baggage
- Help the local economy
- Build relations with local pharmacies and local officials

Cons of Obtaining Medicine In-Country

- Counterfeit and substandard medicines
- Not the right medicines
- Not enough of what is needed
- Time spent sourcing medicines
- Patients prefer medicines from the US

Street Vendor in Haiti



Medicine for sale in a Côte d'Ivoire street market



SOURCE: Issouf Sanogo/Getty Images

Mission Pharmacy



Pharmacy in Ghana



Pros of Transporting Medicine into Country

- Confidence in quality of medicines (trustworthy and accurate)
- Ability to verify appropriate amount
- Ability to “pre-pack” if desired
- Team can prepare formulary / medication list prior to trip
- Nationals prefer US medicines over locally produced or acquired medicines

Cons of Transporting Medicine into Country

- Medicines may be taxed or confiscated
- Medicines may be subject to unknown conditions
- Amount of medicines are limited by team size
- Formulary must be carefully selected

Sourcing Medicine for Missions

- Hospital or local pharmacy
 - Quality Product
 - Known Quantity
 - Cost could be a concern
 - Ability to purchase

Sourcing Medicine for Missions

- Manufacturer or Sales Representative
 - Cost Effective
 - Quality Product
 - Quantity may vary
 - Ability of future teams to duplicate
 - May take a lot of time to contact multiple sources

Sourcing Medicine for Missions

■ Various Donations

- Cost Effective
- Quality may vary depending on source
- Quantity may vary
- May take a lot of time to contact multiple sources

Sourcing Medicine for Missions

■ Missions Wholesalers

- Quality Product
- Known Quantity
- Cost Effective
- Future teams more easily duplicate the generics

Sourcing Medicine for Missions

- Purchase In-Country
 - No Customs issues
 - No extra baggage
 - Quality may be of concern
 - Quantity may vary
 - May take time to source

Other Important Information

- Obtain paperwork to show authorities (medicine names, lot numbers, expiration dates, etc.)
- Keep in original sealed containers
- Obtain paperwork to show the medicine will be a gift to those being treated
- Take “in-date” medicines
- Always refer to the stock as medicines, not drugs
- Leave excess with responsible health care professional – Don't re-import Import for Export medicines

Additional Literature

- Bulletin of the World Health Organization
 - <http://www.who.int/bulletin/en/>
- US Food and Drug Administration – Counterfeit Medicine
 - <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/default.htm>
- Partnership for Safe Medicines
 - <http://www.safemedicines.org/>