

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.

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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.

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Famous People Quotes

- I never really wanted to go to Japan. Simply because I don't like eating fish. And I know that's very popular out there in Africa.
-Britney Spears
- Chemistry is a class you take in high school or college where you figure out 2 plus 2 is 10 or something.
-Dennis Rodman
- I get to go to lots of overseas places, like Canada.
-Britney Spears

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Famous People Quotes

- Being a Scientologist, when you drive past an accident...you know you have to do something about it because you know you're the only one that can really help.
-Tom Cruise
- Is this chicken that I have or is this fish? I know it's tuna but it says "Chicken...By the Sea."
-Jessica Simpson
- I definitely want Brooklyn to be christened, but I don't know into what religion yet.
-David Beckham

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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.

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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

WHO (2006b). Counterfeit medicines: an update on estimates. IMPACT. 33

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.
²Sandif. The fight against counterfeit medicines: five years on the front lines. 2013. 12



Human Cost of Counterfeiting

- 20% of Annual Deaths from Malaria Worldwide¹
- 40% of Artesunate contained no active ingredient¹
- Niger Meningitis Epidemic 1995²
- Unknown Adverse Drug Events³

¹ Cockburn. Leading world organizations to seek solutions. (2002).
² WHO. Counterfeit Medicines Fact Sheet. (2006).
³ Boroni, et al. Serious Adverse Reactions Caused by Counterfeit Drugs. Journal Pharmacovigilance (2006).

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 ≥ 2 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

Rentz, et al. Outbreak of acute renal failure in Panama in 2006: a case-control study. Bull World Health Organ. 2008 Oct; 86 (10): 749-756.

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

World Health Organization. Counterfeit Medicines, 2010. 37

Malaria medicine distributed at a clinic in Switte, Burma

A photograph showing a wooden tray with several small white containers of medicine. A person's hand is visible in the foreground, holding one of the containers. The background shows a person's face, possibly a child, looking towards the camera.

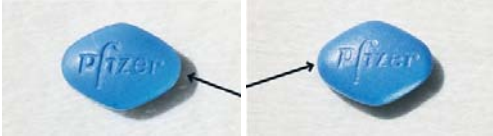
Source: Paula Bronstein/Getty Images 18

Guess the Fake



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Guess the Fake



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Guess the Fake



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Guess the Fake



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Follow-Up

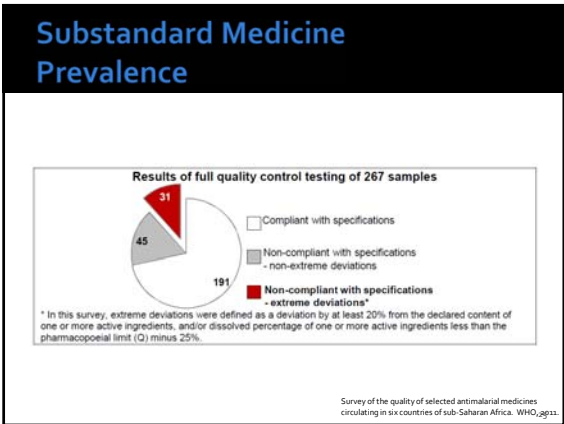


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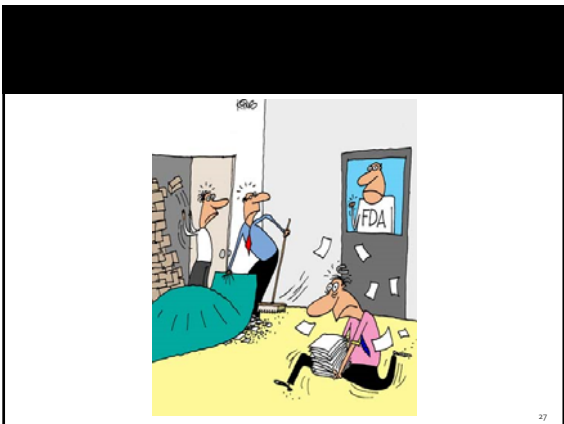
Substandard Medicine Definition

- 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.

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- ### Substandard Medicines Prevalence
- 8.5% of Thailand Market¹
 - 16% of Myanmar Medicines Failed Quality Tests¹
 - 26% of Rifampicin
 - 24% of Cotrimoxazole
 - 69% Artemisinin-containing anti-malarial medicines substandard in Democratic Republic of Congo²
- ¹WHO. World health organization steps up action against substandard and counterfeit medicines. 2009.
²Basit, et al. Combating poor-quality anti-malarial medicines: a call to action. (2016) Malaria Journal 16



- ### Types of Failures
- Lower content of API and higher content of related substances
 - Failure to meet dissolution rates
 - Failures in mass uniformity tests
- Survey of the quality of selected antimalarial medicines circulating in six countries of sub-Saharan Africa. WHO, 2011

- ### Examples of Failures
- Primaquine tablets contained 19-168% active ingredient
 - Gentamicin-resistant *Pseudomonas aeruginosa* in gentamicin eye-drops
 - Methylprednisolone injection lead to fungal meningitis
- Survey of the quality of selected antimalarial medicines circulating in six countries of sub-Saharan Africa. WHO, 2011

- ### 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
- Newton, et al., Trends Pharmacol Sci. 2010 Mar; 31(3): 99-101. 30

Pros of Obtaining Medicine In-Country

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

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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

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Street Vendor in Haiti



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Medicine for sale in a Côte d'Ivoire street market



SOURCE: Issouf Sanogo/Getty Images 34

Mission Pharmacy



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Pharmacy in Ghana



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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

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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

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Sourcing Medicine for Missions

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

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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

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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

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Sourcing Medicine for Missions

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

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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

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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

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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/>

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