Securing Quality Drugs for Mission Trips

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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.

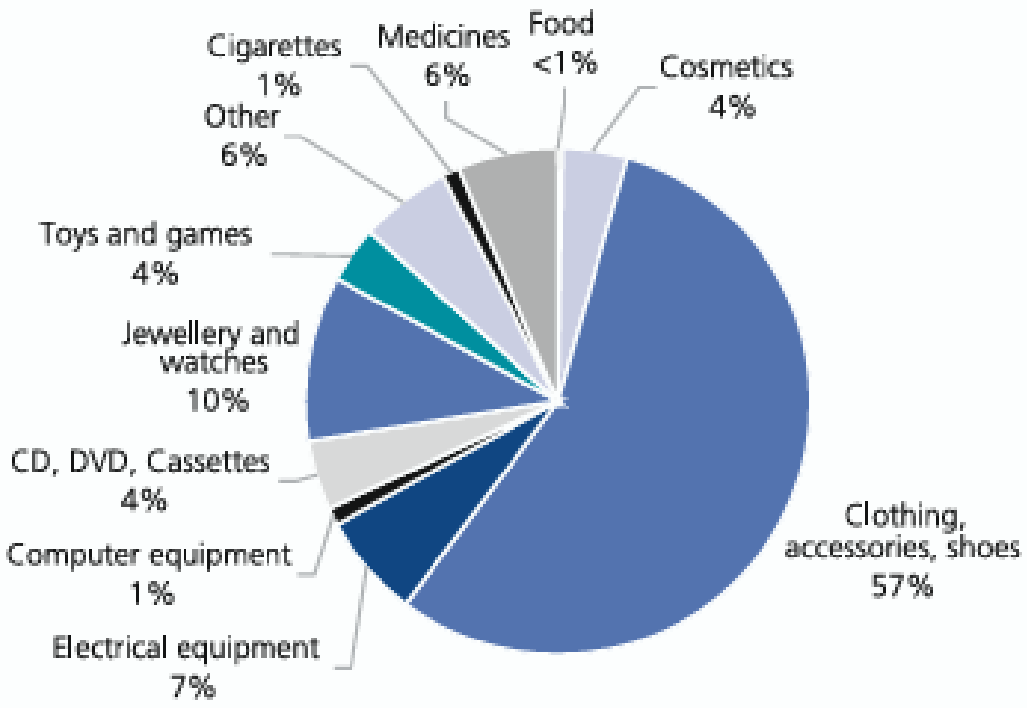
Counterfeit Drug - WHO

- 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

Counterfeit seizures made at the European borders by product type (number of incidents), 2008

UNODC: The Globalization of Crime: A Transnational Organized Crime Threat Assessment (2010), p. 178

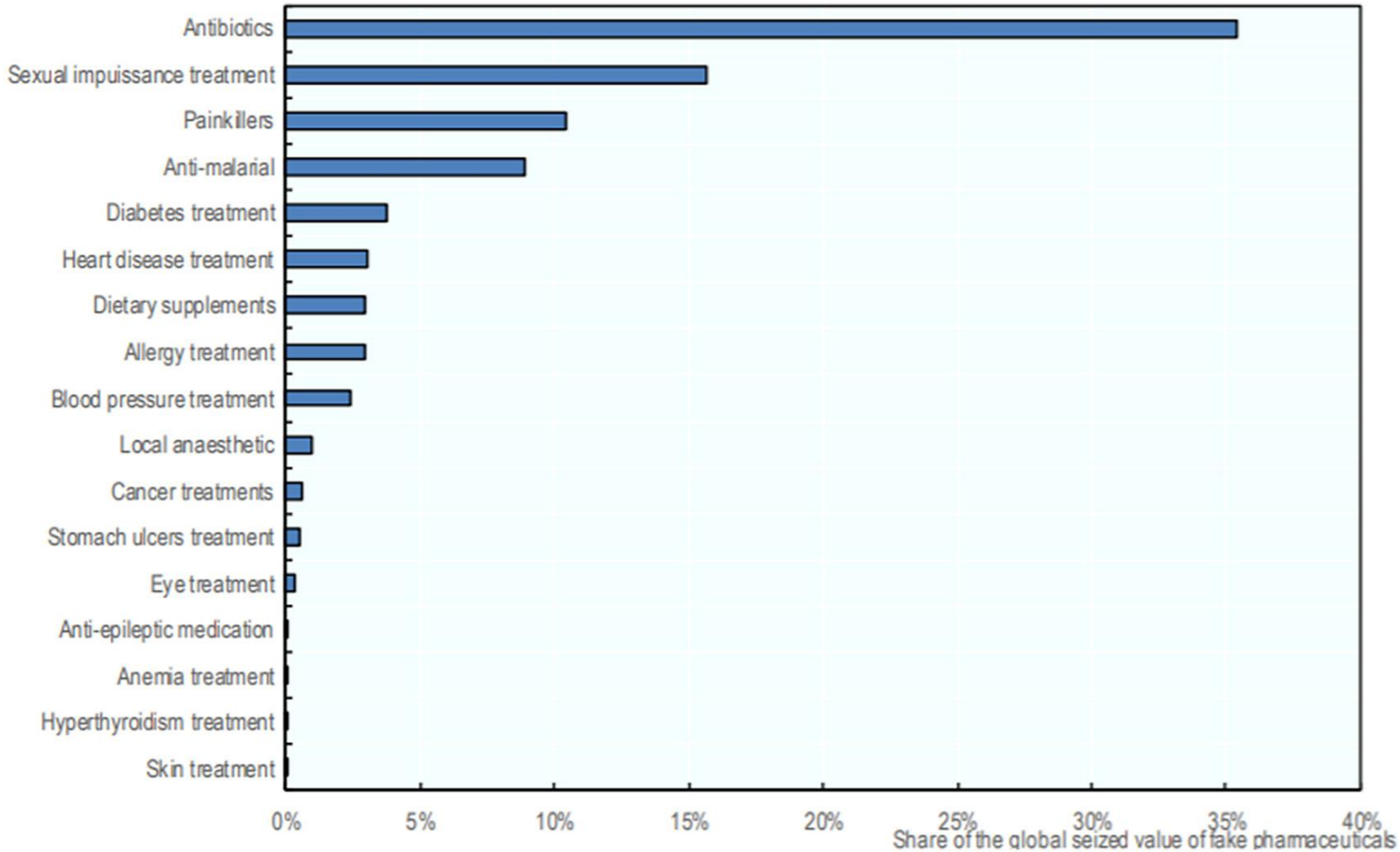


Prevalence of Counterfeiting

- 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.

Prevalence of Counterfeiting



Feeney A, Goad J, Flaherty G (2024) Global perspective of the risks of falsified and counterfeit medicines: A critical review of the literature. Travel Medicine and Infectious Disease. Vol. 61, September-October 2024, 102758.

Financial Cost of Counterfeiting

- Approximately $40 Billion in 2005[1]
- Approximately $200 Billion annually in 2020[2]
- For every $1,000 invested, the return is[3]:
  - $20,000 profit from Heroin
  - $400,000 profit from counterfeit medicine

[1]Cheng. Is the drugstore safe? Counterfeit diabetes products on the shelves. J Diabetes Sci Technol 2009.
[2]Mwai. Fake drugs: how bad is Africa's counterfeit medicine problem? BBC Reality Check 2020.
[3]Sanofi. The fight against counterfeit medicines: five years on the front lines. 2013.

Human Cost of Counterfeiting

- 20% of Annual Deaths from Malaria Worldwide[1]
- 40% of Artusenate contained no active ingredient[1]
- Niger: Meningitis Epidemic 1995[2]
- Cameroon: Counterfeit Chloroquine seized in 300 pharmacies and hospitals[3]

[1] Cockburn. Leading world organizations to seek solutions. (2002).
[2] WHO. Counterfeit Medicines Fact Sheet. (2006).
[3] Kindzeka. Cameroon seizes fake Coronavirus drugs sold by scammers. (2020).

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 $\geq$ 2mg/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.

Malaria medicine distributed at a clinic in Switte, Burma



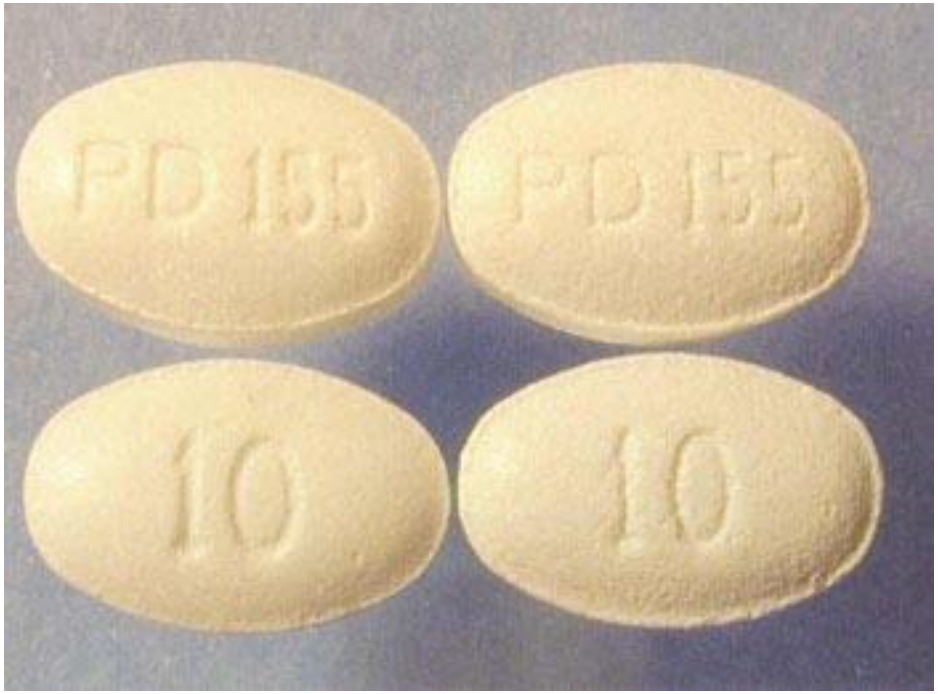
Source: Paula Bronstein/Getty Images

Guess the Fake





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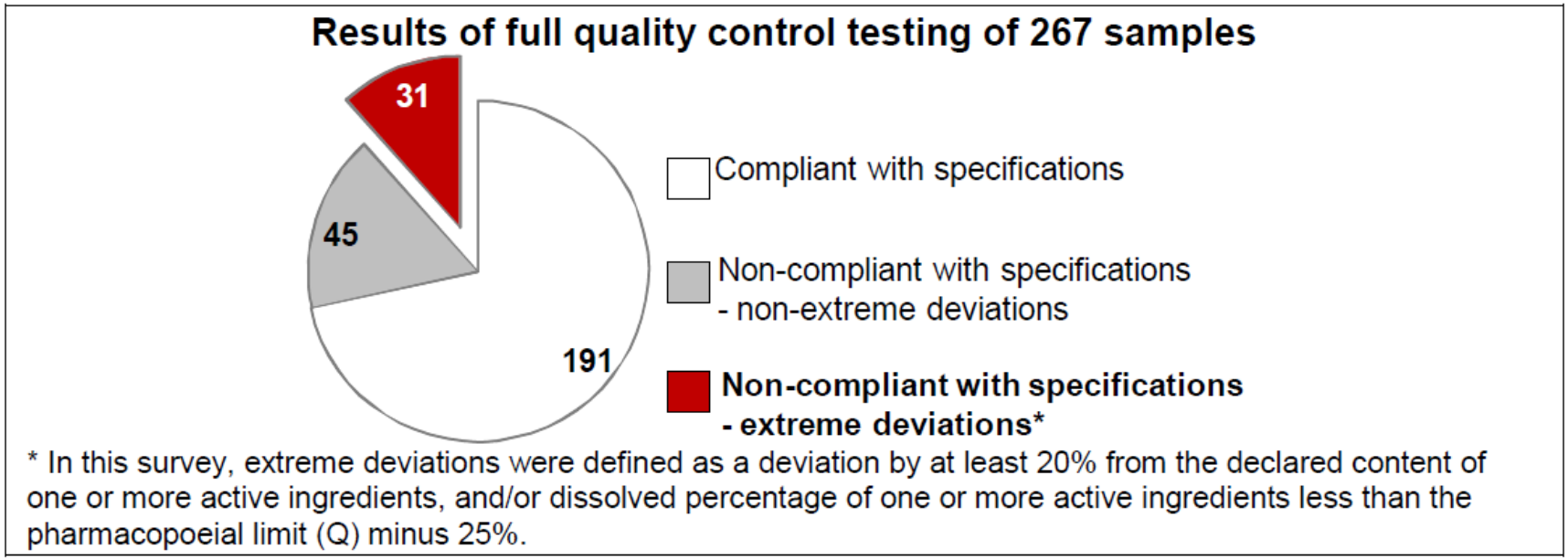
Follow-Up



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



Survey of the quality of selected antimalarial medicines circulating in six countries of sub-Saharan Africa. WHO, 2011.

Substandard Medicines Prevalence

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

WHO. World health organization steps up action against substandard and counterfeit medicines. 2003.

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-resistent *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 resistence 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 (3-3); 99-101.

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/

Evaluation

