



**American Enterprise Institute**

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# **The Global Impact of Fake Medicine**

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# Outline

USP Drug Quality and Information Program

- ◆ Definition of counterfeit and substandard medicines
- ◆ Why it is a problem and why the business thrives
- ◆ Current situation: Extent of the problem
- ◆ What can be done about the problem



# Definitions

- ◆ **Fake/counterfeit** – Deliberately mislabeled for identity and/or source. Can be branded or generic. May include products with correct API, wrong API(s), without API or with sub-dosed API or with fake packaging.
- ◆ **Substandard** – Legally branded or generic product that does not meet official standards for identity, quality, purity, strength, packaging, and labeling.

Should the definition of counterfeit include patent infringement? Is this a quality assurance issue?

Should customs agents act as patent police?





# Causes of Proliferation of Counterfeit and Substandard Medicines

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- ◆ Lucrative business
- ◆ Demand is high for cheap medicines
- ◆ Weak or absent drug regulatory control (1/3 of African countries)
- ◆ Weak law enforcement and penal sanctions
- ◆ Imports via Free Trade Zones (e.g., Dubai, UAE)
- ◆ Corruption and conflict of interest
- ◆ Poor quality API used
- ◆ High taxes and import duties make legitimate trade prohibitive



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# Consequences of Using Fake and Substandard Medicines

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- ◆ Diminished trust in health care systems
- ◆ Waste of financial resources
- ◆ People go untreated—leads to prolonged illness or, possibly, death
- ◆ Wrong chemical—could lead to death
- ◆ Subpotent treatment can lead to resistance and treatment failure



# World Health Organization Study Africa – 2000

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## **Chloroquine**

- ◆ 20–67% failed content specification
- ◆ 5–33% failed dissolution specification

## **Sulfadoxine-Pyrimethamine**

- ◆ 5-28% failed content specification
- ◆ 75–100% failed dissolution specification

**Africa – 2008**

**QAMSA Study underway in 10 African countries**



# Medicine Quality Data: Cambodia 2003

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- ◆ 451 samples collected, 7 different antimalarials
- ◆ 122 (27%) samples were counterfeit
- ◆ Fake drugs available
  - ▶ ~22% fake in registered shops
  - ▶ ~28% fake in unregistered shops

Quinine	Artesunate	Mefloquine	Chloroquine	Tetracycline
Fake / Samples (%)	Fake / Samples (%)	Fake / Samples (%)	Fake / Samples (%)	Fake / Samples (%)
30 / 39 (76.9)	7 / 41 (17.1)	2 / 25 (8.0)	4 / 31 (12.9)	8 / 39 (20.5)



# What Can Be Done About the Problem

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- ◆ Proper and timely detection
- ◆ Robust legislation and regulation
- ◆ Education
- ◆ Raising awareness and sensitization



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# Counterfeit Detection

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## Detecting Counterfeits



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# The Art of Counterfeiting

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Hong Kong, 2000



Counterfeit

Genuine

“Perfect”  
Fake Lamivudine



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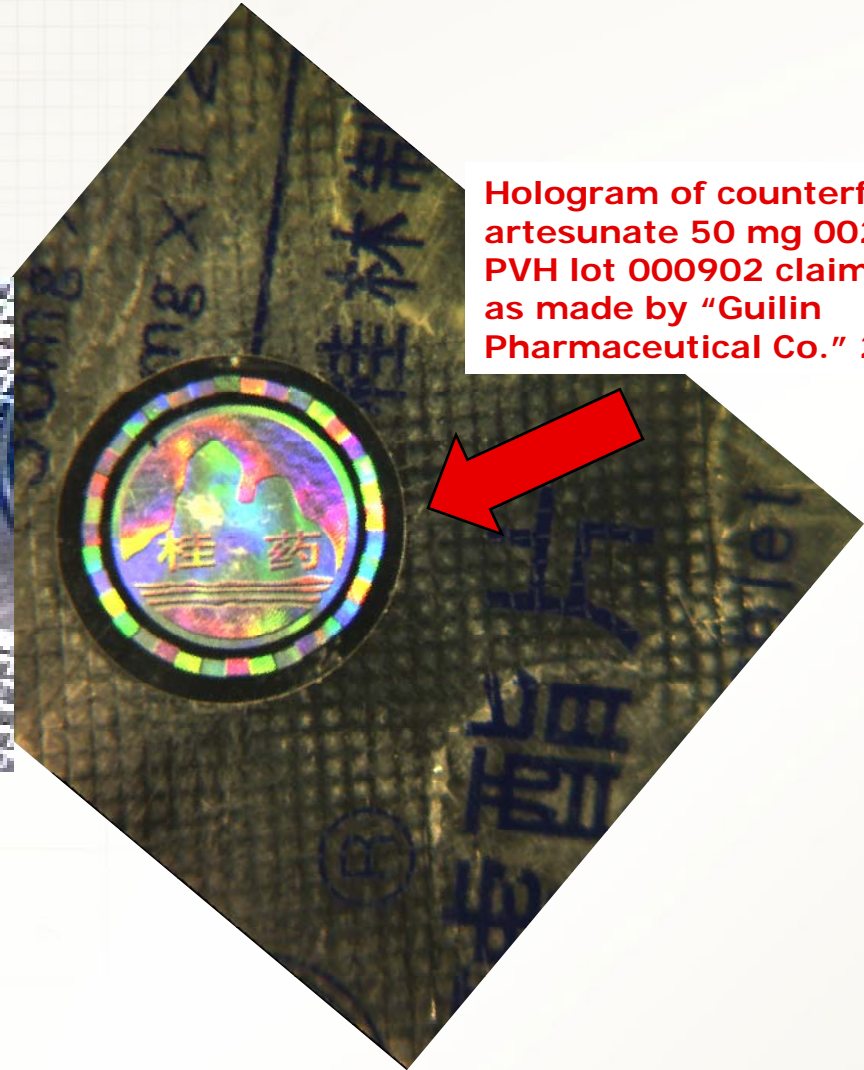
# The Art of Counterfeiting

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## Counterfeiting has become increasingly sophisticated



Hologram on a genuine artesunate blister pack produced by Guilin Pharmaceutical Co.



Hologram of counterfeit artesunate 50 mg 002-03 PVH lot 000902 claimed as made by "Guilin Pharmaceutical Co." 2006



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# Authentication Techniques

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- ◆ Radio-frequency Identification (RFID)
- ◆ Electromagnetic ID Tagging (EMID)
- ◆ Scratch Panel
- ◆ DNA-Coding
- ◆ Short Message Service (SMS) text—  
Ghana, USA and India



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# Chemical Testing Methods Used in Field

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## GPHF Minilab<sup>®</sup>

Everything needed for drug testing fits into two transportable units, each about the size of a suitcase and weighing about 40 kg



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# Spectroscopic Methods of Counterfeit Detection

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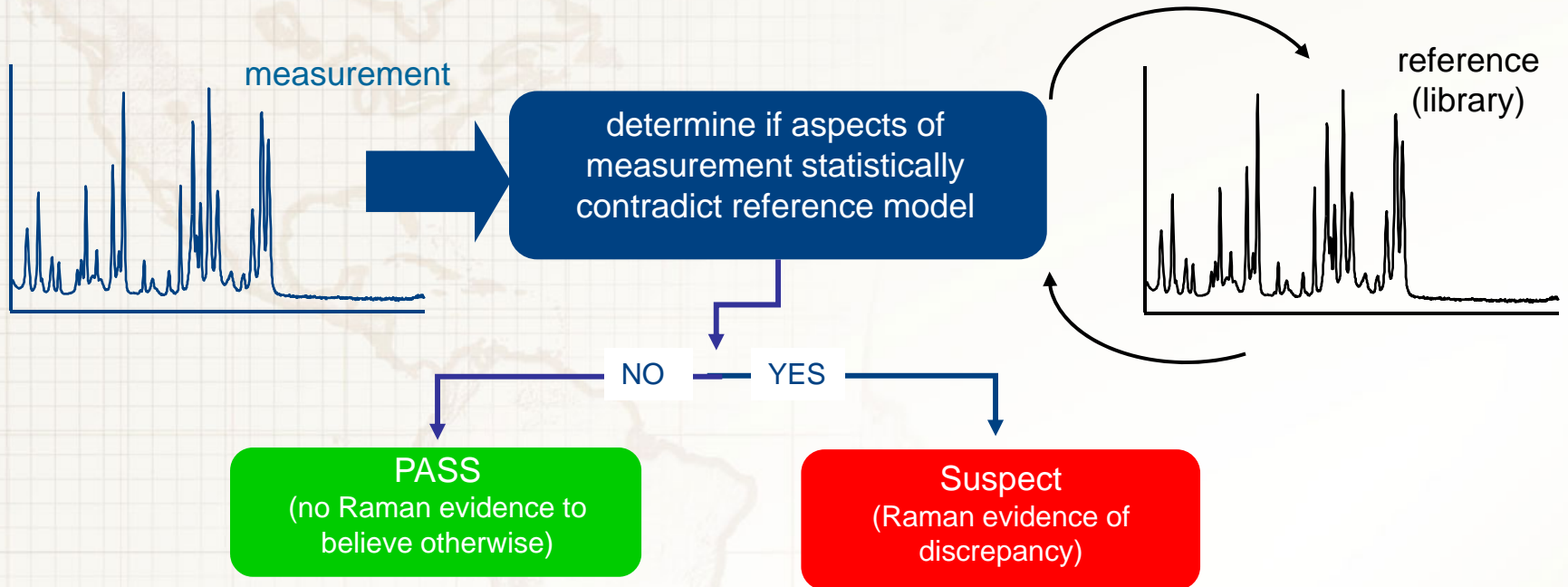


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# TruScan™ System Logic

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Method Result

 **Pass** [Add Note](#)

SampleID: opp6533264  
Method: manganese sulfate

 12/8/2006 9:45 AM

Method Result

 **Fail** [Add Note](#)  
[Discover](#)

SampleID: 885444  
Method: Polystyrene  
Note:

 12/8/2006 9:48 AM



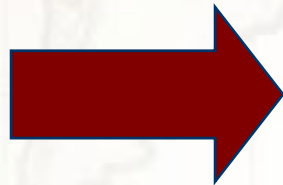
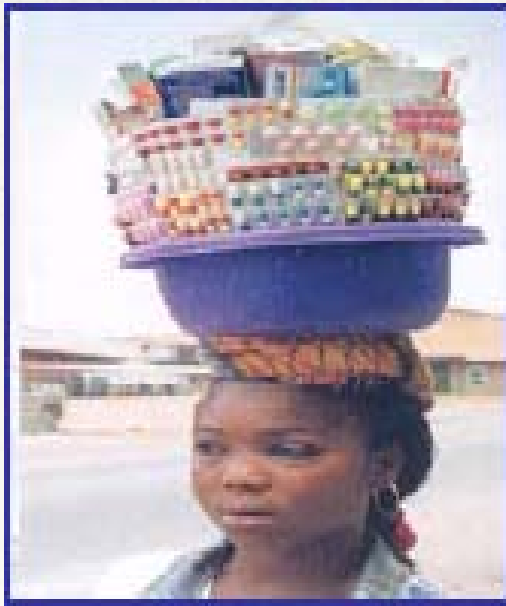


# Good Legislation and Good Regulation

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## Unregulated

Business owner  
Diagnoses,  
Prescribes,  
Dispenses



## Regulated



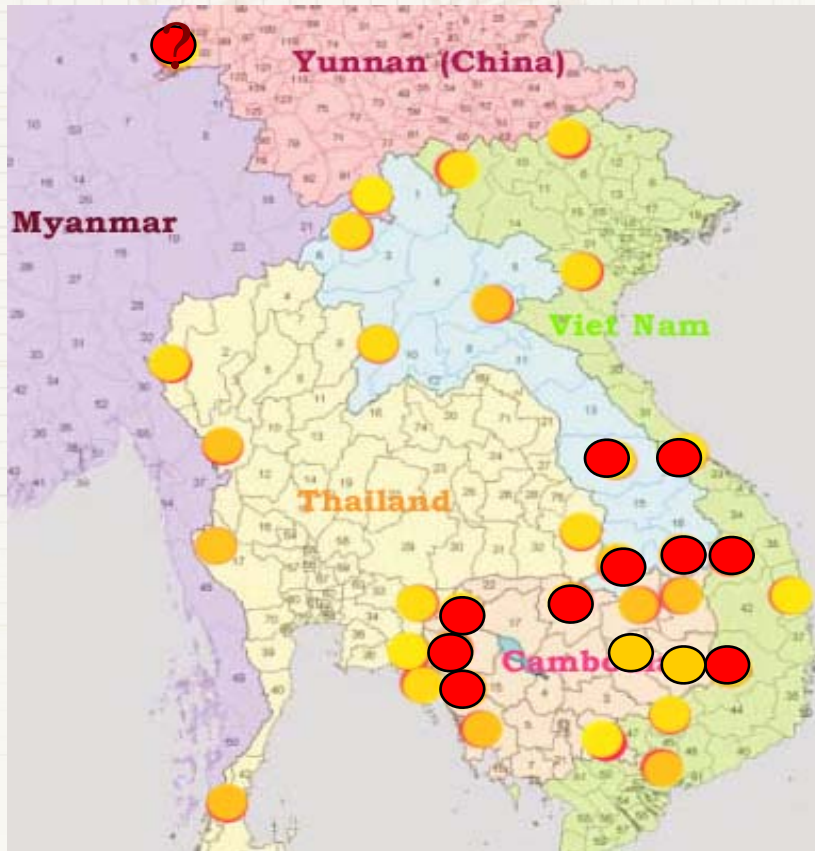


# Routine Drug Quality Monitoring Example Mekong

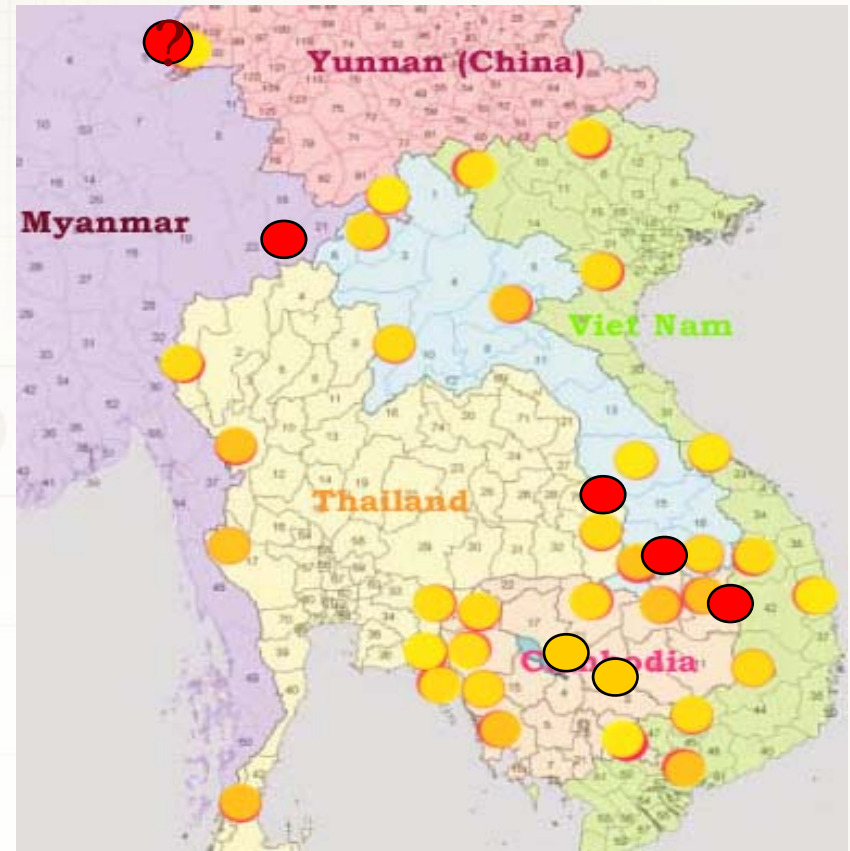


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2005—mid-2006



mid-2006—2007



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# Drug Quality Monitoring in Ghana

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## Sentinel Sites

- ▶ Bolgatanga
- ▶ Kumasi
- ▶ Ho
- ▶ Accra
- ▶ Tarkwa

Sites were selected by stakeholders based on the following criteria:

- ▶ Epidemiological
- ▶ Geographical
- ▶ Administrative
- ▶ Areas known for traffic in fake drugs
- ▶ Border provinces



# Information

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## Raising Awareness about Medicine Quality

- ◆ Public Service Announcements
- ◆ Documentary—Counterfeits in SE Asia
- ◆ Publications—news, articles, journals
- ◆ Drug Quality Matrix

**Antimalarial Drug Quality**  
A. Smine,\* S. Phanouvong,\* L. Chanthap,\* R. Tsuyuka,† N. ...  
\*United States Pharmacopeia Drug Quality and Information Program (USP DQI) 12601 Twinbrook Park and †National Laboratory for Drug Quality Control, Phnom Penh Cambodia

**Pharmacie PSA**  
Director: Mark Hammond  
S.E. Asian & Vietnamese Versions

**Matrix of Drug Quality Reports Affecting USAID-assisted Countries by U.S. Pharmacopeia Drug Quality and Information Program**  
October 1, 2008  
USP DQI 12601 Twinbrook Park, Rockville, MD 20852  
Created by Joyce Fimo-Dagones, M.D., Ph.D., and J.P. Anderson, D.Phil.

**Ensuring the Quality of Medicines in Resource-Limited Countries**  
AN OPERATIONAL GUIDE

IN COLLABORATION WITH  
World Health Organization  
National Drug Authority of Uganda - Program for Appropriate Technology to Health  
National Pharmaceutical Control Bureau of Palau - National Institute for Drug Quality Control of Vietnam  
Pharmaceutical Control Authority of Zimbabwe - Cosmos International  
Program Science for Health: National Pharmaceutical Management Plan Program



# COUNTERFEIT DRUGS

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## Demand Quality

Manufacture



Wholesale



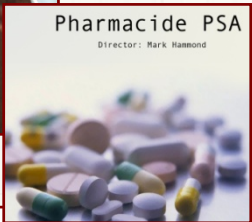
Pharmacy



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# Conclusion



- ◆ Educating and training regulators, QC laboratories, and manufacturers
- ◆ Pursuing new technologies for counterfeit detection
- ◆ Raising awareness of import role drug quality plays in public health
- ◆ Making available proper public standard for testing



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*Questions?*



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# Thank You

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