

**Fifth Global Forum on Pharmaceutical Anticounterfeiting
Fort Lauderdale, FL**

February 24-16, 2010

Conference Report

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Implemented by U.S. Pharmacopeia

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About PQM

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID's response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical leadership to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States Government. It may be reproduced if credit is given to PQM and USP.

Abstract

Dr. Patrick Lukulay and Ms. Veerle Coignez, Pharmaceutical Management Advisor at USAID, attended and gave presentations at the Fifth Global Forum on Pharmaceutical Anticounterfeiting in Fort Lauderdale, FL February 24-26, 2010.

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Key Words

Reconnaissance International, counterfeit, substandard

Background

The first Global Forum (GF) on Pharmaceutical Anticounterfeiting, held in Geneva in 2002, was a major new initiative in the fight against substandard/counterfeit drugs. It marked the first time that representatives from various factions (government agencies, NGOs, law enforcement, public health experts, regulatory bodies, pharmaceutical manufacturers, distributors, and authentication suppliers) had come together to discuss measures to tackle this problem. In 2005, the second GF in Paris focused on communication, education, detection, and deterrence in the fight against counterfeit and substandard drugs, and the third GF in Prague concentrated on ways to make anticounterfeiting policies effective. Focusing on systems for safety in the global arena, the fourth GF was the first to be held in the United States. All GFs are organized by Reconnaissance International, based in the United Kingdom. More information regarding any of the GFs can be found at:

<http://www.reconnaissance-intl.com/pharmaceutical/pharma-news-home-page>

Overview

The theme for this fifth GF was “End-to-End Protection: from Active Pharmaceutical Ingredient to Patient,” reflecting current pharmaceutical concerns and the Forum’s wide range of stakeholders. This GF was held in Fort Lauderdale, Florida, February 24-16, 2010, and was attended by 180 representatives from national drug regulators, pharmaceutical companies, patients’ and safe medicines advocates, and anti-counterfeiting product and service providers from 20 countries in the developed and developing world. Forum attendees discussed the urgent action that is necessary in the face of the threats to patient health.

The agenda of the GF is available in *Annex 1*.

On the first day of the GF, Ms. Veerle Coignez, Pharmaceutical Management Advisor at USAID, gave a presentation on “USAID and the Threat of Substandard and Counterfeit Medicines to Global Health,” and Dr. Patrick Lukulay discussed “The Hunt for Counterfeit/Substandard Medicines in Developing Countries.” Ms. Coignez’s presentation can be found in *Annex 2*, while Dr. Lukulay’s presentation can be found in *Annex 3*.

The Sixth Global Forum on Pharmaceutical Anticounterfeiting is scheduled for May 2011 in London, England.

Agenda: Fifth Global Forum on Pharmaceutical Anticounterfeiting

Thursday February 25

8.30 **Forum Welcome and Introduction**
am *Ian M Lancaster, Randall Burgess, Reconnaissance International*

SESSION 1: END-TO-END PROTECTION - WHY IT'S NEEDED

8.45 **Counterfeit Medicines - the Cost to Healthcare Budgets**
am *Jim Thomson, European Alliance for Access to Safe Medicines*
Ian Banks, European Men's Health Forum

9.10 am **The Impact of Counterfeits on Parallel Trade & Pharmaceutical Distribution**
Karen Mostert, Business Insights

9.35 am **Global Policy Developments and Political Challenges**
Laurie Self & Lisa Peets, Covington & Burling

10.00
am Refreshment Break and Exhibition Viewing

10.30 **National Requirements for the Authentication of Pharmaceutical Products**
am *Andres Diaz Cote, Figurazione (tbc)*

10:55 **Generic Medicines: Friend or Foe?**
D.G. Shah, Indian Pharmaceutical Alliance

11:20 **The Role of Donor Organizations in Building Anti-Counterfeiting Capacity**
Thomas Woods, Woods International

11:45 **USAID's "Promoting the Quality of Medicines" Program**
US Agency for International Development; US Pharmacopeia

12:15
pm **Q&A & Panel Discussion**

12:30
pm **Lunch & Exhibition Viewing**

SESSION 2: KEEPING THE SUPPLY AND DISTRIBUTION CHAINS CLEAN

1.45 pm **Details to follow**

2.10 pm **Progress Report on EFPIA's Data Matrix Pilot Project**
Anthony Barron, EFPIA

2:35 pm **Is that genuine: GSI's Web Authentication and Pharmaceutical Tracking Project**
Laurent Vieille, GSI France

3:00 pm **Break & Exhibition Viewing**

3.30 pm **Progress and Policy at NAFDAC**
Paul Orhii, NAFDAC

4.15 pm **Deployment of fully portable Raman devices for product authentication**
Mike Claybourn, AstraZeneca

4.45 pm **Training to Ensure Meditag is Effective**
Ismail Mazlan, Ministry of Health, Malaysia

5:10 pm Question & Answer Panel Discussion

5.25 pm Networking Cocktails to relax and chat with the day's speakers, to view the exhibition of anti-counterfeiting providers and to catch up with all participants.

Friday February 26

SESSION 3: PROTECTION FROM PHARMACY TO PATIENT

8.30 pm **Internet Buying: Is it so Dangerous**
Roger Bate, American Enterprise Institute

8.55 pm **Protecting and Risk Management for Pharmaceutical Companies**
Vaughn Volpi, Pica Corporation

9.20 am **Forensic Analysis in Support of Counterfeit Investigation**
Anthony L Zook, Merck

9.45 am **The Role of On-Dose Technologies**
Dean Hart, NanoGuardian

10.10
am **Break & Exhibition Viewing**

10.40
am **Unit Level Serialization and Cell Phone Authentication**
Stephen Wood, Covectra

11.05
am **Will Serialization Make Authentication Obsolete**
Jim Rittenburg, Authentix

11.30
am **Engaging the Consumer**
Huda Midani, Schreiner ProSecure

11.55
am **Authentication in the Hands of the Patient**
Alex Dodoo, Pharmaceutical Society of Ghana; Ashifi Gogo, Sproxil

12.20 pm **Question & Answer Panel Discussion**

12.30 pm **Lunch**

SESSION 4: TECHNOLOGIES FOR PREVENTING AND DETECTING COUNTERFEITS

1.45 pm **Industry Co-operation to Combat Fakes in Brazil**
Jose Werner, Dannemann Siemsen

2.10 pm **PCIDs and Other Dosage Based Authenticators**
David Schoneker, Colocon

2.35 pm **Product Brand Integrity in Latin America**
Stephanie Brecht, Baxter Healthcare

New and Emerging Technologies

3.00 pm **Photonic Crystals for Pharmaceutical Anti-Counterfeiting**
Andre Arsenault, Opalux

3.15 pm **Laser Surface Authentication**
Mark McGlade, Ingenia Technology (tbc)

3.30 pm **Integral Lens Arrays and Edible Security**
Daniel L Lau, University of Kentucky

3.45 pm **Internet Governance to Stop Counterfeit Medicines**
John Horton, LegitScript

4:00 pm **Question & Answer Panel Discussion**

4:15 pm **Summary and Close of Fifth Global Forum**



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Annex 2

USAID and the Threat of Substandard and Counterfeit Medicines to Global Health

Veerle Coignez, MA, MPH, CPH

5th Global Forum on Pharmaceutical Anti-Counterfeiting

Miami, February 24-26, 2010



- I. USAID Medicines Quality Assurance (MQA) Programming
- II. USAID Combating Substandard and Counterfeit Medicines (SCM)
- III. A Closer Look at Anti-Counterfeiting Technologies and their Relevance for USAID MQA Programming (by Patrick Lukulay, PhD)



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PART I

Promoting the Quality of Medicines





1. USAID and Medicines Quality Assurance (MQA): An Overview

- USAID has always been focused on quality assurance of USAID-procured medicines
- In 1990s: influx of donors and medicines, growing concerns re substandard/counterfeit medicines, anti-microbial resistance
- In 2000: U.S. Pharmacopeia Drug Quality and Information (USP DQI) Program – evolves into a 10-year, \$25 million program

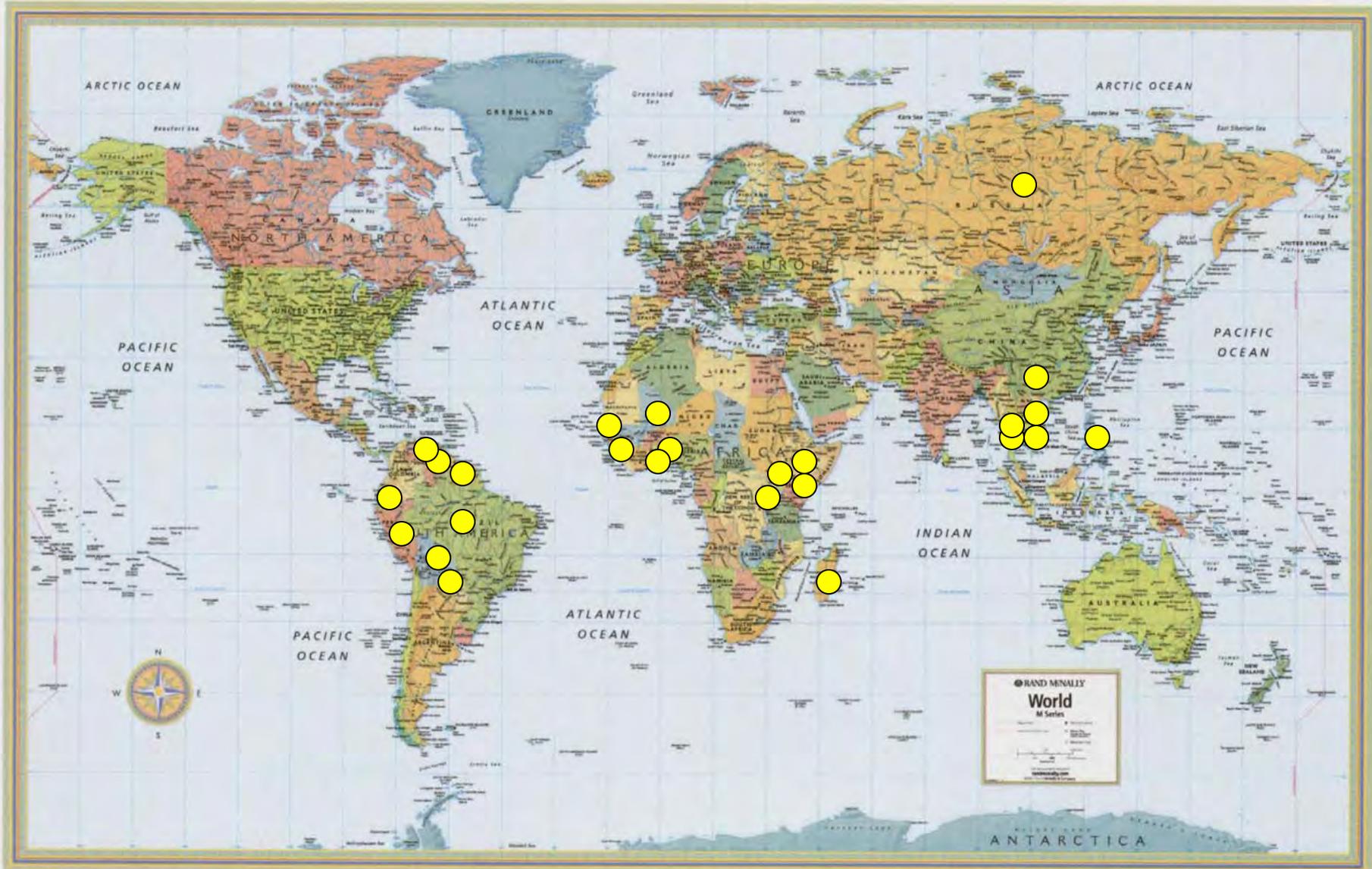
Promoting the Quality of Medicines (PQM) Program

- A 5-year program (until 2014); \$35 million ceiling
- Focus on quality of (essential) medicines in the public and private sectors in low-resource countries
- Implementing partner: **U.S. Pharmacopeia**
- Active in 20+ countries in Latin America, South East Asia, Africa, and Eurasia



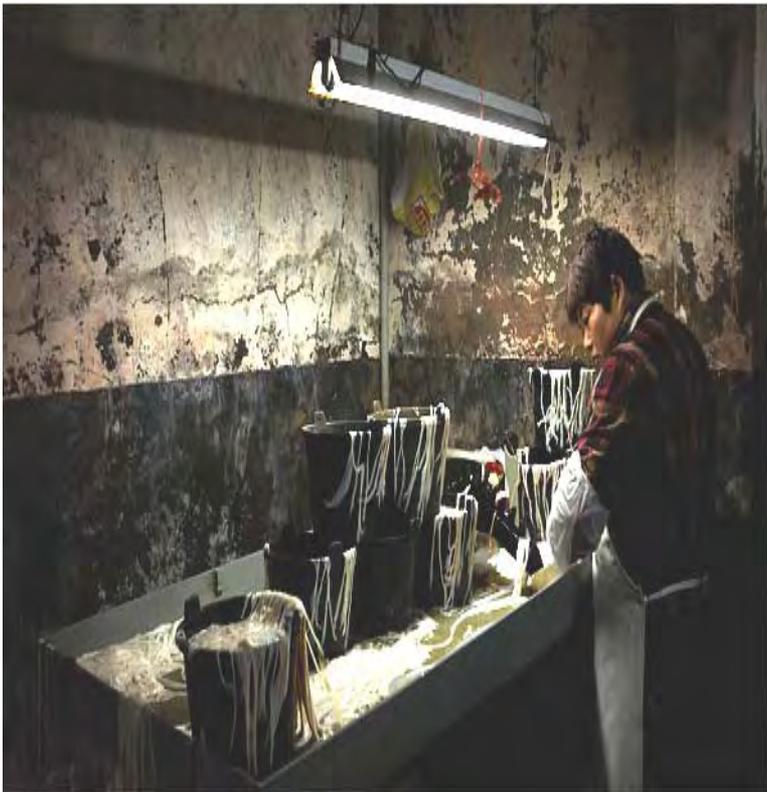
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PQM in the World in 2010



3. USAID/GH Perspective: SCM – A Health Threat First and Foremost

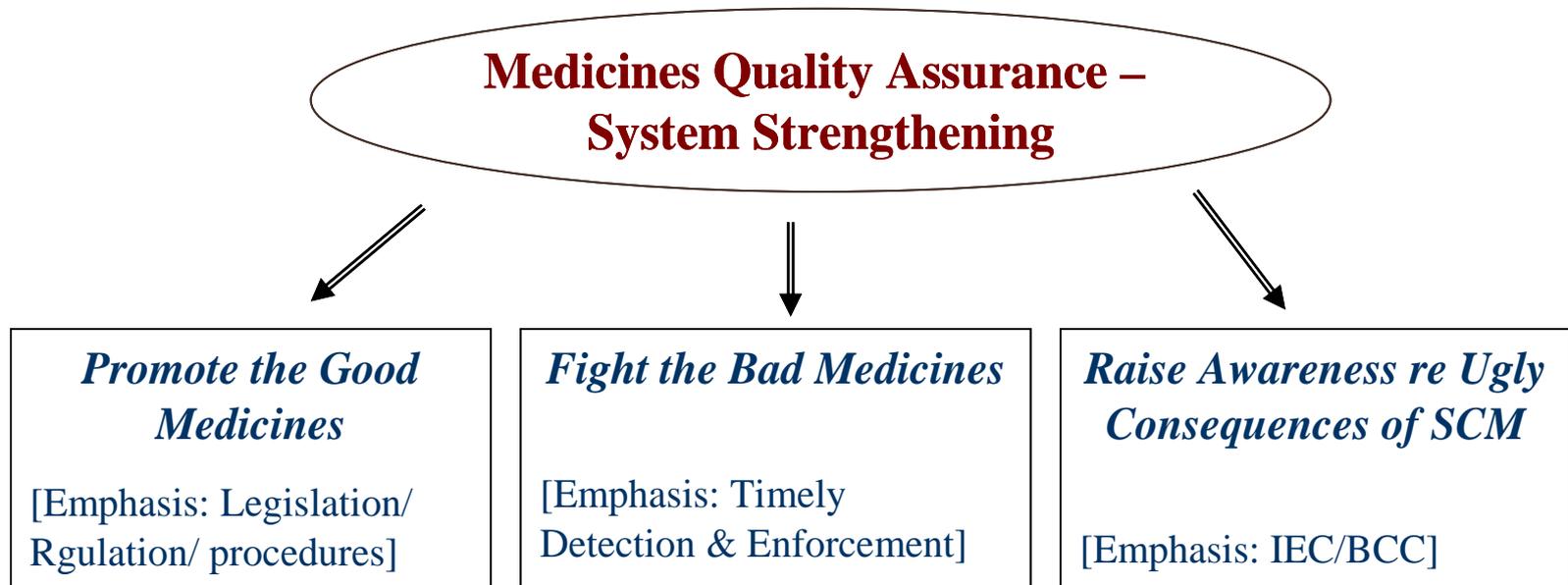
USAID/Global Health Bureau seeks to combat *substandard medicines*, incl. *counterfeits*, for their health, financial, and system impact



SPOT THE DIFFERENCE...

4. USAID/GH Strategic Approach: *“The Good, The Bad, The Ugly”*

NEEDED: QUALITY ASSURED MEDICINES

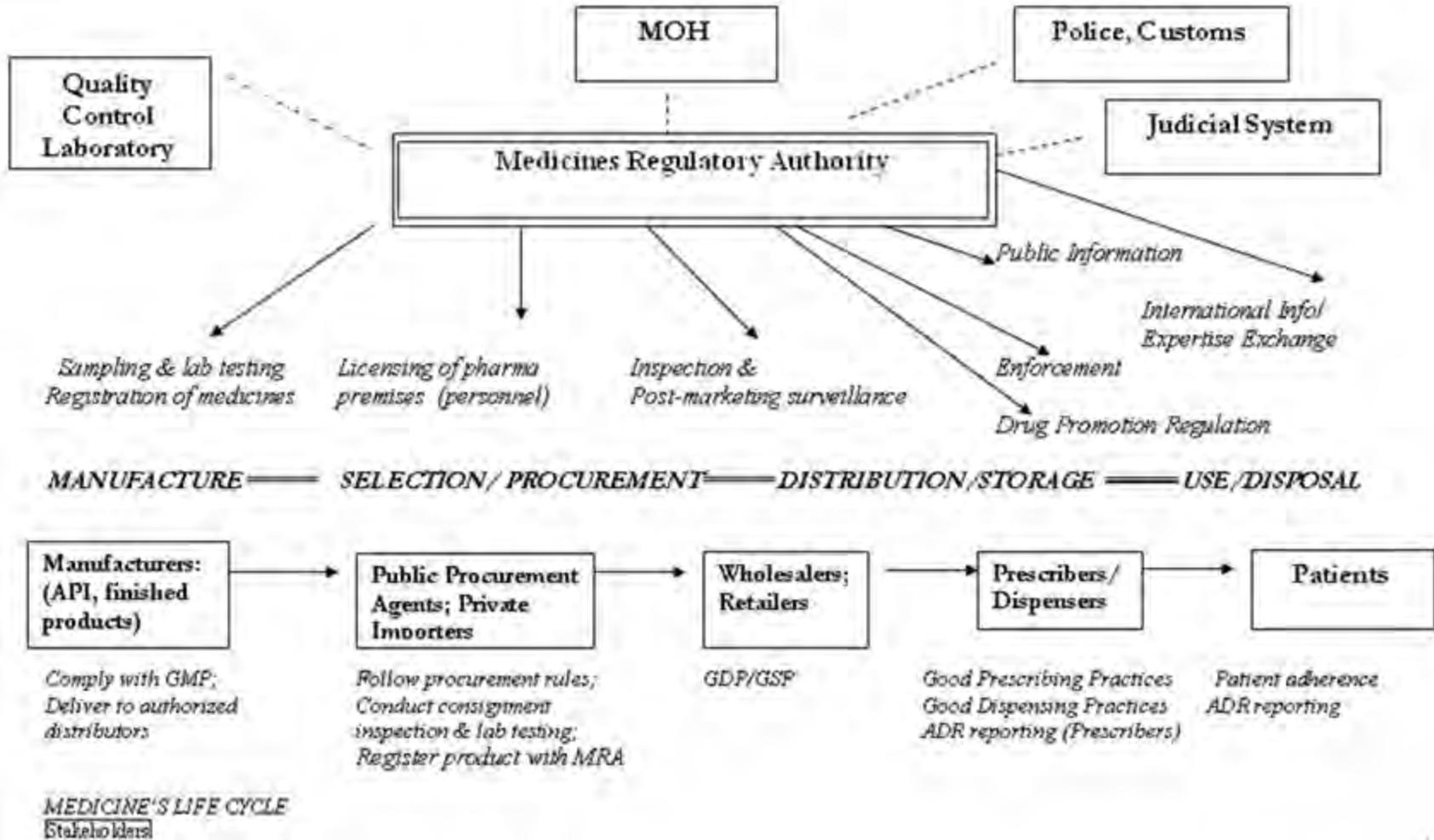


Note: USAID three-pronged strategy is system-based; addresses demand and supply; and operates at national and international levels



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Medicines Quality Assurance System: A Reference Framework





5. Signature PQM Activities (1)

- ◆ Strengthening national MQA systems: *e.g.*
 - *Strengthening medicines regulatory authorities*
 - *Strengthening national quality control labs*
 - *Reinforcing MQA in procurement, registration, and licensing*
 - *Setting up post-marketing surveillance systems*

- ◆ Increasing supply of quality assured medicines: *e.g.*
 - *Supporting WHO pre-qualification program*
 - *Assessing/improving GMP compliance of selected manufacturers*
 - *Developing pharmacopeial monographs for priority medicines where no other public standards exist*

- ◆ Combating substandard and counterfeit medicines (SCM): *e.g.*
 - *Supporting post-marketing surveillance*
 - *Promoting networks for information exchange and enforcement cooperation*
 - *Cooperating with international initiatives such as IMPACT*

- ◆ Providing technical leadership, global advocacy: *e.g.*
 - *Quality of Antimalarials in Sub-Saharan Africa (QAMSA Report)*
 - *Development and evaluation of anti-SCM tools, approaches, methodologies*

1. A Key Role for Post-Marketing Surveillance (PMS)

- ◆ PMS: Sampling, screening, and testing of medicines at strategically chosen sentinel sites – cf. Three-level approach of visual inspection, basic testing, confirmatory testing
- ◆ USAID/USP have pioneered PMS as an effective MQA intervention in low resource countries in Latin America, South East Asia, and Africa – cf. Cambodia and Ghana examples
- ◆ Provides information for targeted corrective actions (e.g. 2 rounds/year); builds pressure for strengthening quality control capacity and for improving MQA system
- ◆ Forms basis for regional/international cooperation; special operations - e.g. INTERPOL Operations Jupiter (2005) and Storm (2008) used USP DQI PMS data

2. PMS in Action

Example 1: Cambodia

MQA Improvement since 2003

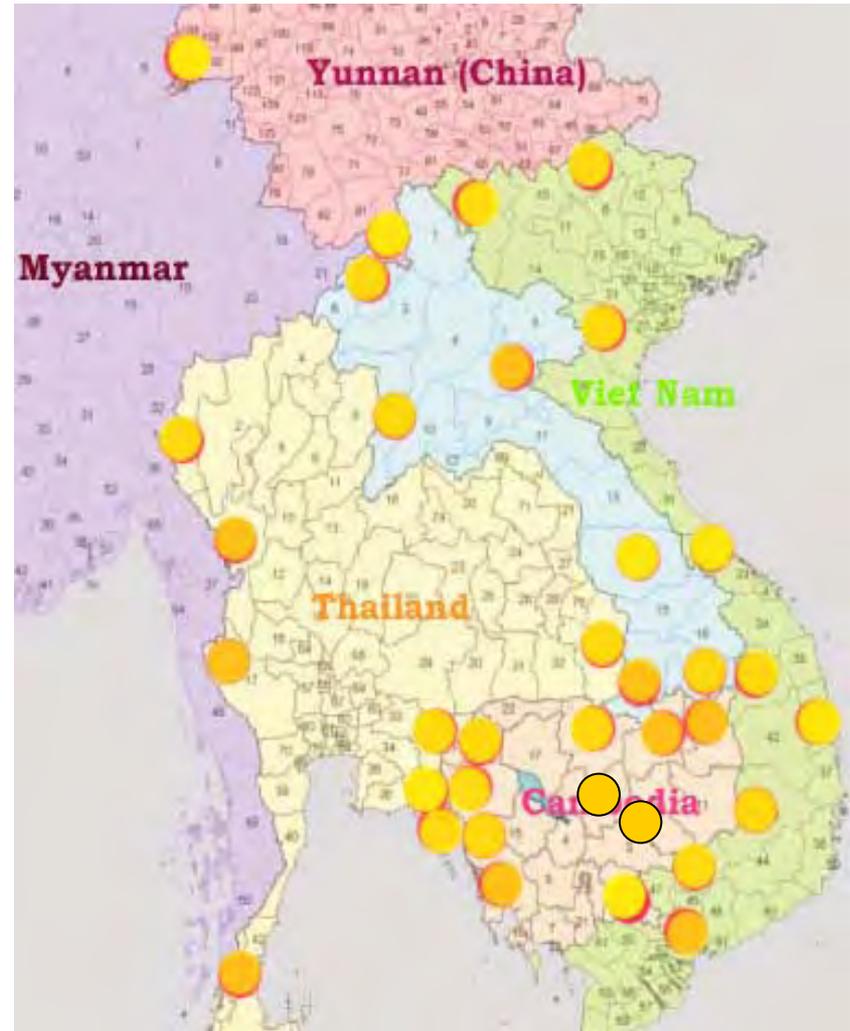
- (i) Lab strengthening
- (ii) Post-marketing surveillance (PMS), with enforcement
- (iii) Active public awareness campaign, e.g. PSA & videos

PMS (932 AML samples, 2003-08)

2003-2004: 23% & 27% failure rate

2006-2007: 11% & 8% failure rate

Source: USP, 2009



Example 2: Ghana

PMS facilitates timely detection of counterfeit Coartem (Summer 2008)



Sentinel site selection criteria include:

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

Source: USP, 2009



3. PMS Challenges

- ◆ Not as easy as it seems: availability of equipment and supplies, human resources, timely/accurate testing and reporting
- ◆ How to best catch SCM?
 - Careful selection of sentinel sites
 - Adjustment of sampling and testing protocol
 - Use of appropriate screening tool in function of USAID/PQM goals
- ◆ The biggest challenge of all: Corrective action/enforcement



- ◆ Comprehensive, system-based approach: best chance for sustainable results in combating SCM
- ◆ Challenges include financial and human resources
- ◆ Technological advances will increasingly facilitate anti-SCM efforts
- ◆ *Conditio sine qua non*: Political Commitment



Annex 3

5th Global Forum on Pharmaceutical Anti-Counterfeiting
Miami, FL ♦ February 24-26, 2010

The Hunt for Counterfeit/Substandard Medicines in Developing Countries

Patrick H. Lukulay, Ph.D.

Director, Promoting the Quality of Medicines Program
Implemented by United States Pharmacopeia



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The Hunt for Counterfeit/Substandard Medicines in Developing Countries





I. What Makes a Product Substandard?

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- ◆ Inferior raw materials – impurities
- ◆ Inferior inactive ingredients – poor bioavailability
- ◆ Unstable formulation – short shelf life
- ◆ Poor GMP – contamination & cross contamination
- ◆ Poor process control – inconsistent product



II. How to Detect Substandard/Counterfeit Medicines

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Two classes of techniques

- ◆ **Authentication** - Product Brand Control
 - ▶ Is the product what it claims to be and made by whom it claims to be made?

- ◆ **Quality Control** - Product Quality Control
 - ▶ Does the product meet quality specifications?



(1) Authentication Techniques

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Questions:

- ◆ Is the product what it purports to be?
 - ▶ Is active ingredient present?
 - ▶ Is it correct active ingredient?
 - ▶ Does it mimic a brand product?

Tools:

- ◆ Visual Inspection
- ◆ Spectroscopic (Raman, NIR fingerprint)
- ◆ Barcodes, holograms, scratch technologies





Spectroscopic Methods of Counterfeit Detection- Truscan

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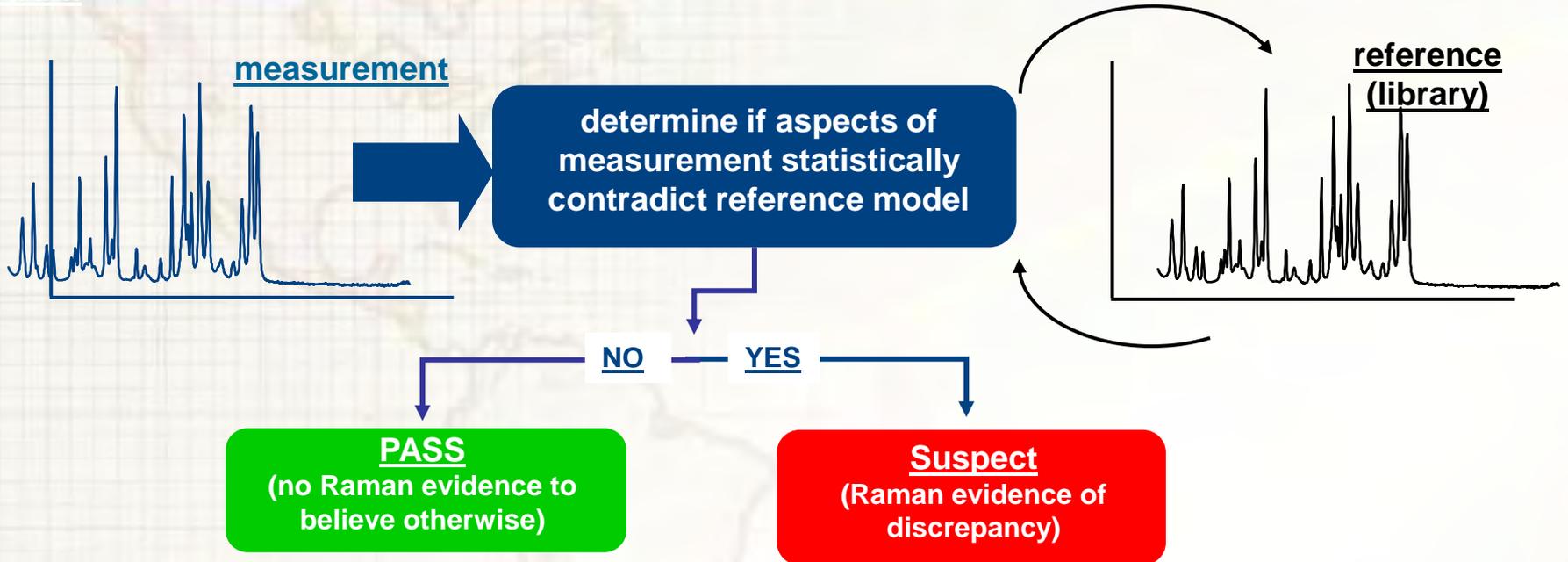




TruScan™ System Logic

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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



Spectroscopic Tools - Advantages

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- ❑ Unique Raman signature of compounds makes it a good identification tool
- ❑ Excellent for raw material inspection
- ❑ Non-destructive and fast analysis time
- ❑ Portable and mobile
- ❑ No extensive training required for use



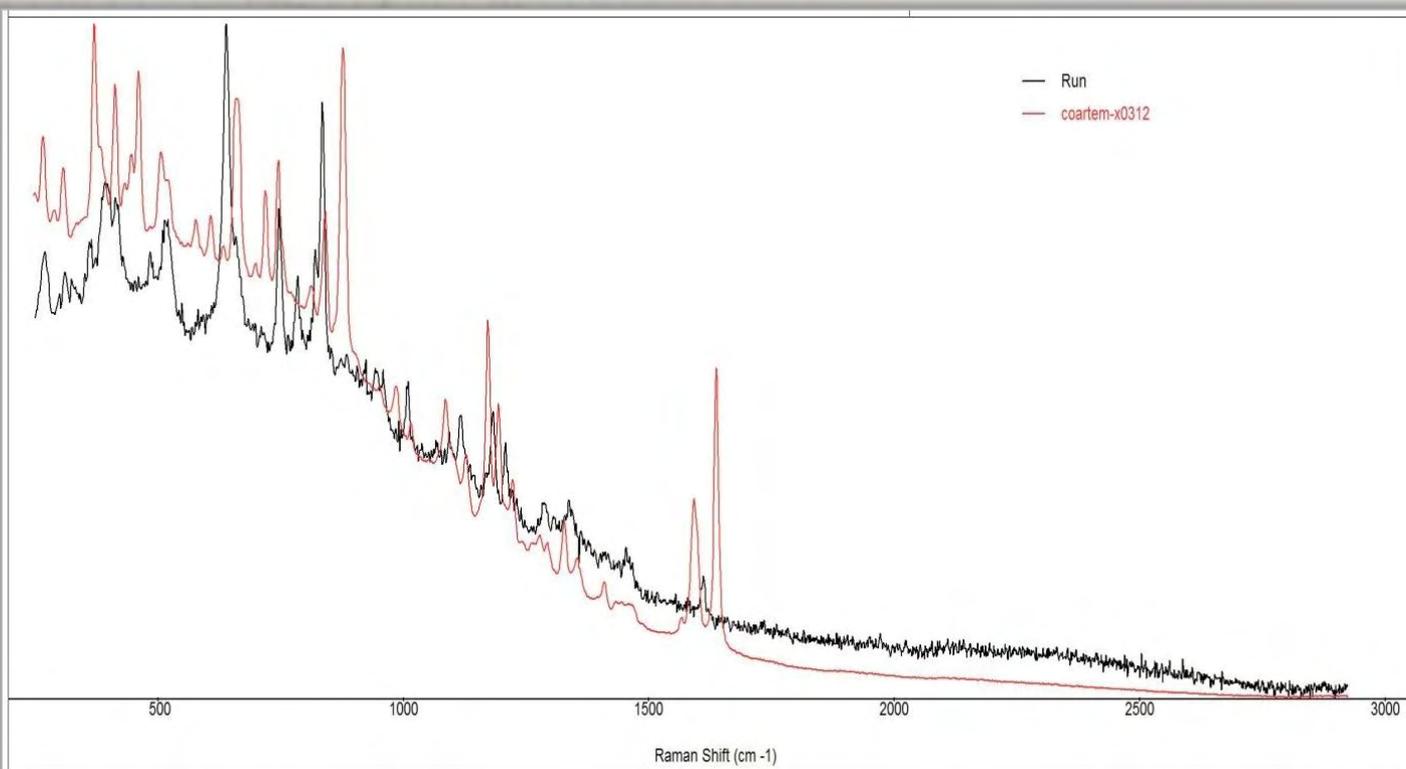
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Spectroscopic Tools - Disadvantages

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- ❑ Not all products have Raman or NIR spectrum, e.g., artesunate—very weak Raman fingerprint
- ❑ Raman signature of some compounds very strong, e.g., SP—problematic discriminating
- ❑ Fluorescence background problematic for Raman—reduces sensitivity
- ❑ Generally non-quantitative, e.g., fixed dose



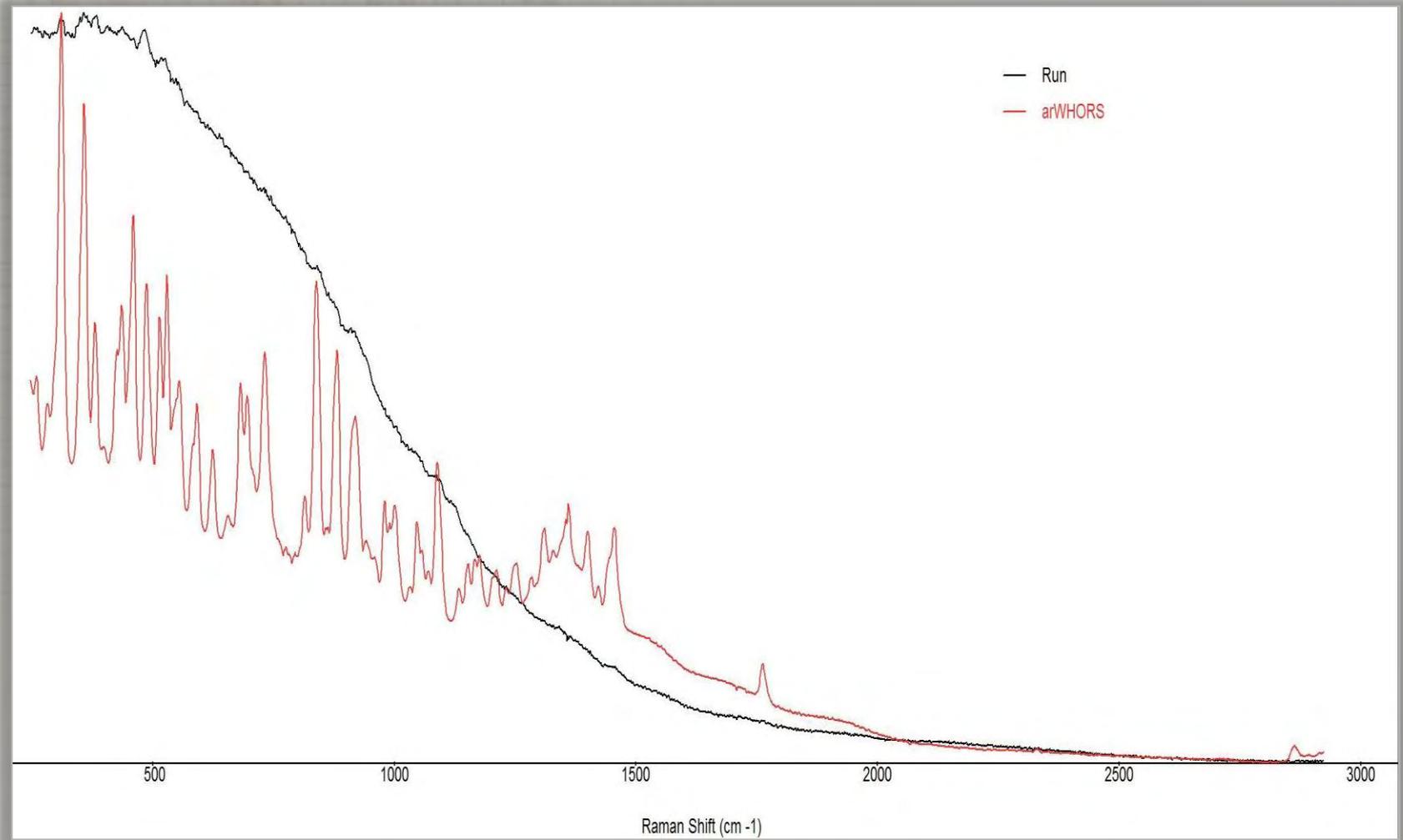
- ▶ Unique Raman fingerprint differentiates Tylenol from Coartem
- ▶ Excellent tool for identification



Weak Artesunate Raman Signature

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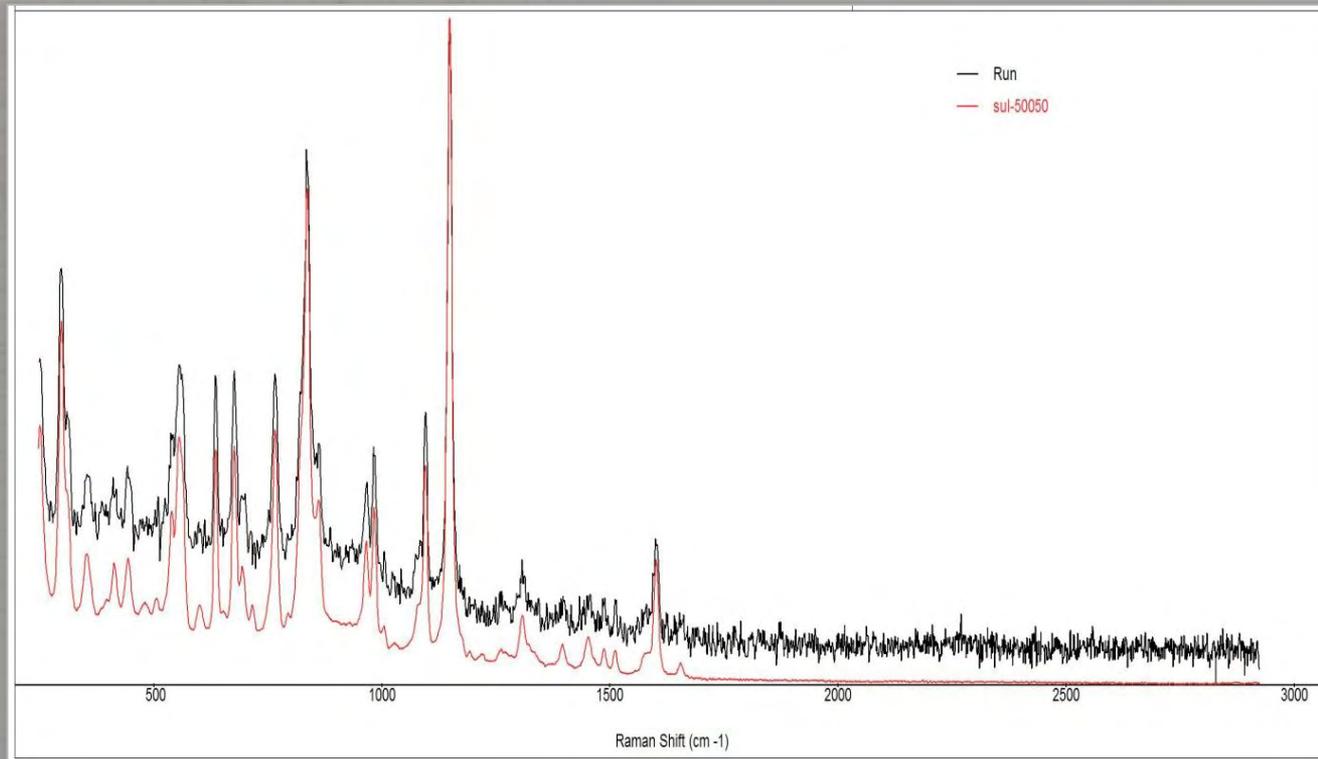




Raman Fingerprint of SP: (degraded vs. undegraded)

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- ▶ Strong Raman signal inhibit detection of poor quality SP
- ▶ Poor quality control tool
- ▶ Poor tool for quantification



(2) Quality Control Techniques Wet Chemistry

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Questions:

- ◆ Are all quality attribute specifications met?
 - ▶ Identification
 - ▶ Assay
 - ▶ Impurities
 - ▶ Dissolution (performance test)
 - ▶ Content Uniformity



(2) Quality Control Techniques Wet Chemistry

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Tools

- ◆ Screening tests
- ◆ Confirmatory test in national laboratories

Note

- ◆ Financial and human resource constraints exist in developing countries



PQM Program Uses GPHF Minilab® as Quality Control Screening Tool

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GPHF Minilab®

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



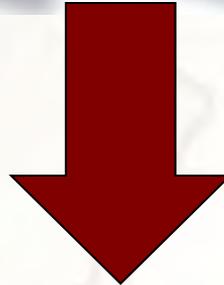


PQM - Two Step Approach

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Screening



Confirmatory Testing





Quality Control Screening Tools

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Advantages

- ❑ Quantitative and comprehensive
- ❑ Conclusive

Disadvantages

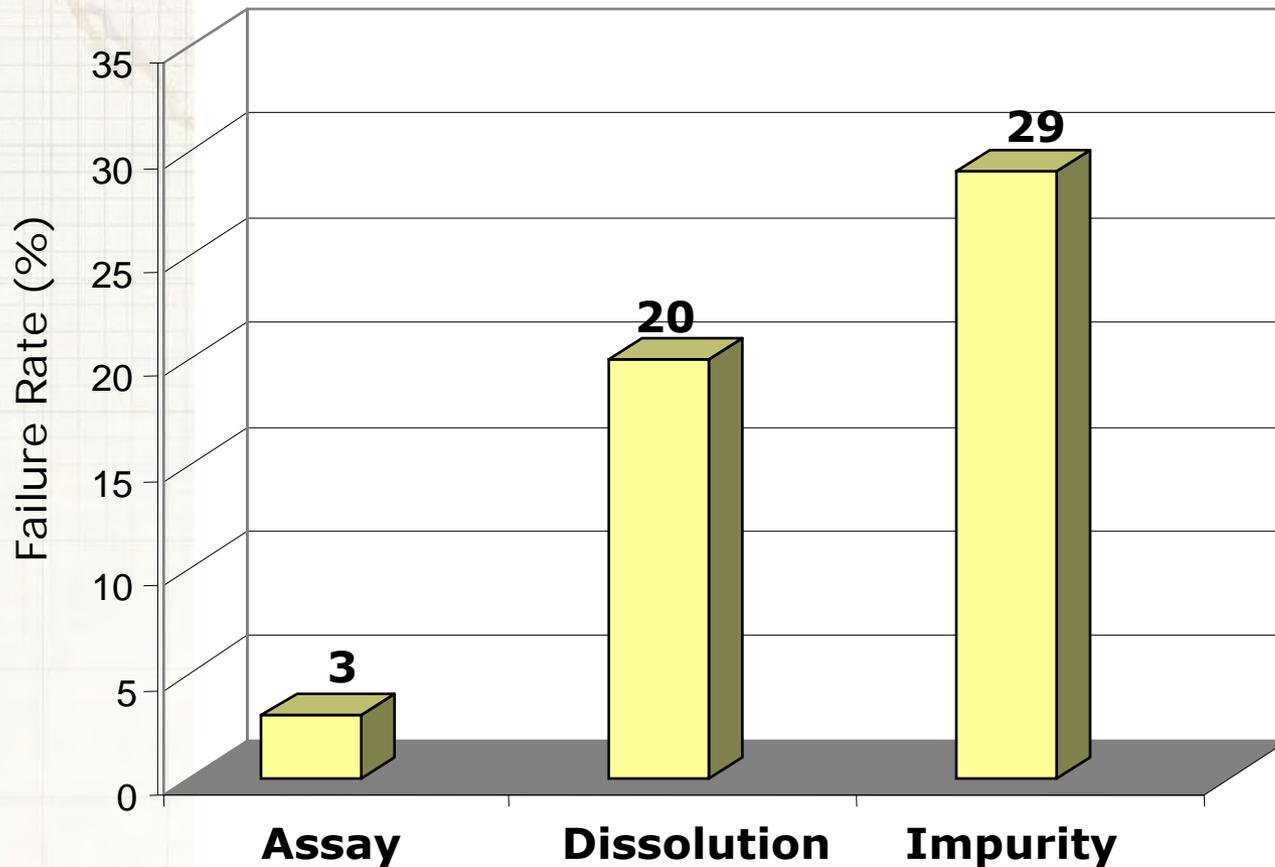
- ❑ More training required and labor intensive
- ❑ Require replenishable goods for continuous operation
- ❑ Bulky and less portable



Quality of Antimalarial Medicines in Africa (QAMSA) Study – 2009

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ACT Failure Rate for Assay, Dissolution, and Impurity Tests



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Spectroscopic vs. Quality Control Tools

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- ◆ Spectroscopic tools are excellent **identification** tools:
 - ▶ Useful for brand control and protection
 - ▶ Useful for customs inspections (unknowns)
- ◆ Spectroscopic tools are primarily good **anti-counterfeiting** tools
- ◆ If the program activity is focused on **substandard medicines**, either genuine or counterfeit, a **quality control screening tool** is most appropriate



Conclusion

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- ◆ PQM seeks to combat counterfeit and substandard medicines in low resource countries, including through postmarketing surveillance
- ◆ Appropriate technologies can be effectively used in developing country settings
- ◆ Capabilities of technologies must be understood for effective implementation
- ◆ Don't use a hammer when a screwdriver is needed



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Questions?



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Thank You

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