



PROMOTING THE QUALITY OF MEDICINES



A faint, grayscale world map serves as the background for the slide, centered behind the title text.

Initiatives to Promote Drug Quality in Developing Countries

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Current Reality

There is no shortage of medicines ... BUT, *there is a shortage of quality-assured medicines*



Quality Standards

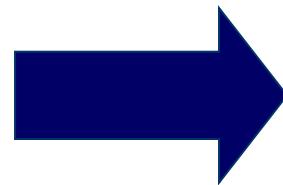
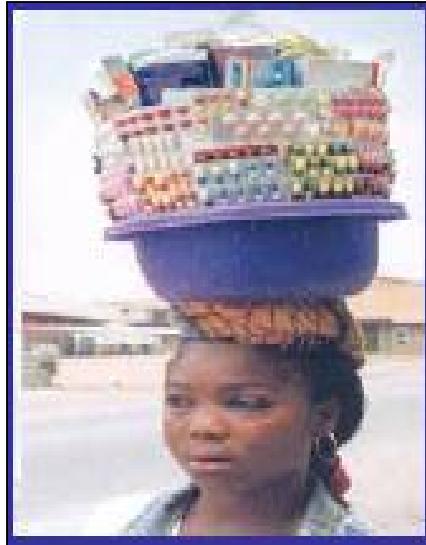
- Cannot talk about quality without concept of standards
- Cannot talk about standards without the authority to enforce the standards



The End Game

Unregulated —

Business owner
diagnoses, prescribes,
and dispenses



Regulated —

Doctor or health care worker
diagnoses and prescribes,
pharmacist dispenses



Poor Regulation

- Capacity to regulate
 - Legal basis to regulate (Law)
 - Human Resource Capacity (People)
 - Financial resources (Money)
- Freedom and independence to regulate
 - From political interference or political will

Regulation- What is lacking

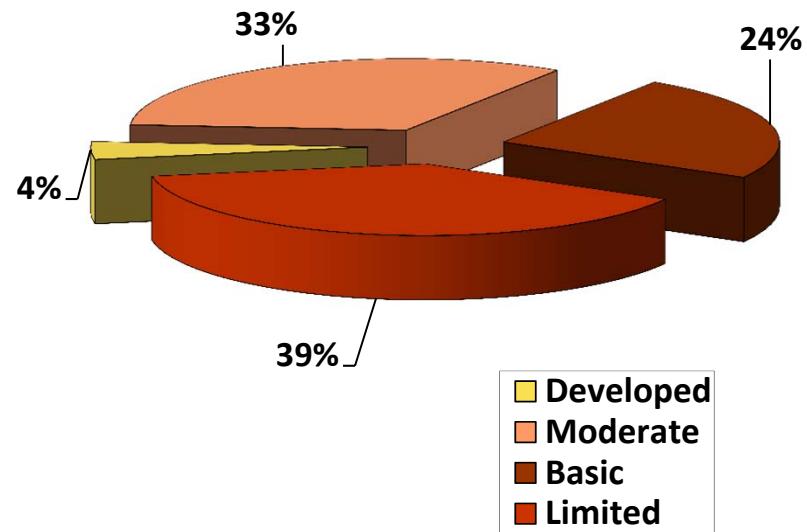
- In adequate product registration
- Poor market surveillance
- Poor facility inspection capacity
- Poor quality control testing capacity

Poor Regulation

- Capacity to regulate: human resource capacity
- Freedom to regulate: free from political interference
- Means to regulate: financial resources

Due to chronic shortages of human, technical, financial and other resources many National Medicines Regulatory Authorities (NMRAs) in Africa don't have the full capacity to perform **most core regulatory functions**

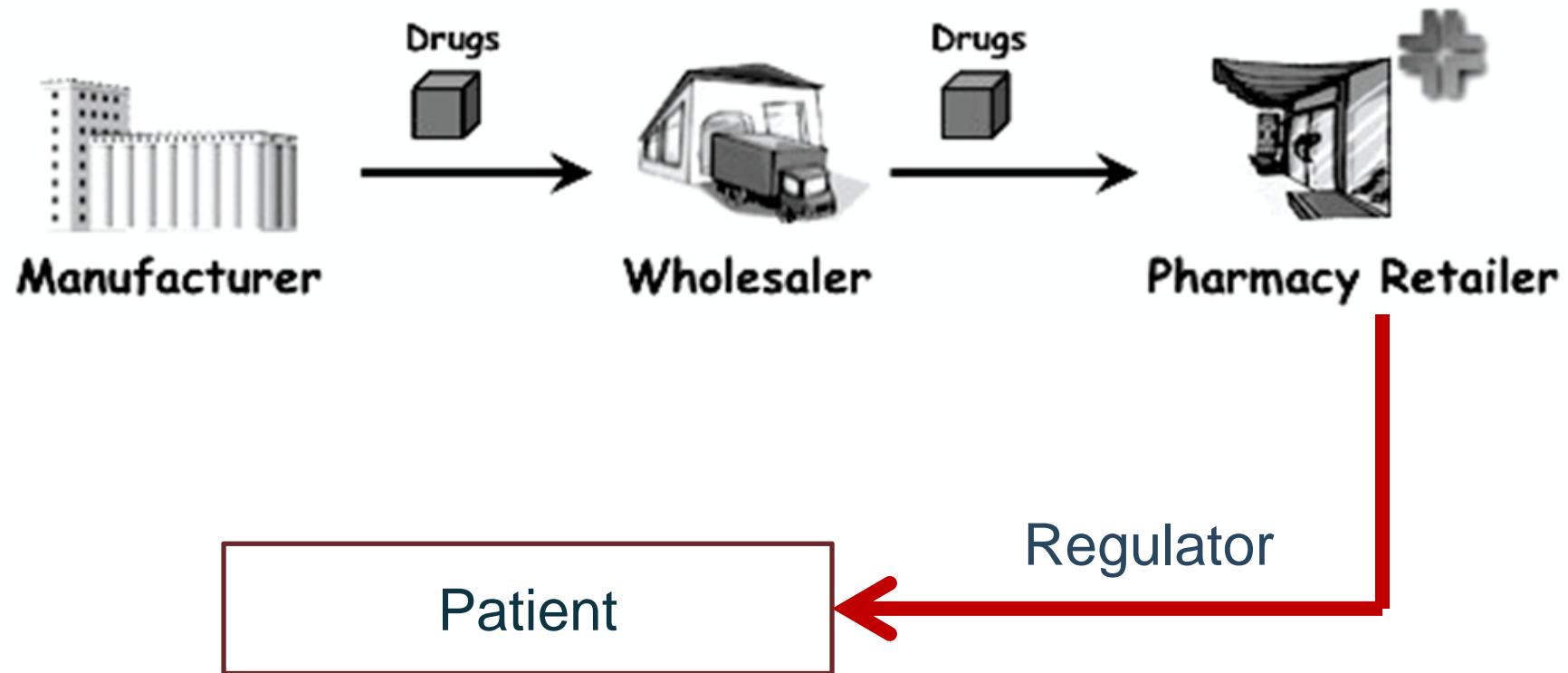
Medicines Regulatory capacity in 46 WHO AFRO Member States:



Source: WHO/AFRO/EDP/04.5: Availability of Drug Regulatory and Quality Assurance Elements in Member States of the WHO African Region, 2004, Brazzaville.

- Constrained by lack of good infrastructure in country
- Lack of access to capital
- Lack of human resource capacity
- Poor access to raw materials and supporting industries to support local manufacturing
- Lack of economy of scale

Supply Chain



Quality Assurance of Medicines: Program Objectives

Build capacity and strengthen QA systems

- Strengthen medicines quality control labs
- Establish Medicines Quality Monitoring programs

Help increase supply of QA medicines

- Improve manufacturers' GMP compliance
- Support WHO Prequalification Programme

Promoting the Quality of Medicines

(PQM Program, 2009-2019)

Combat counterfeit and substandard medicines

- Collaborate with IMPACT, INTERPOL & other initiatives
- Raise awareness w/PSAs, communication campaigns

Provide technical leadership

- Advocate globally about importance of medicines quality
- Promote new counterfeit/sub-standard detection technologies



Africa

- ▶ Angola, Burundi, Ethiopia, Ghana, Guinea, Kenya, Liberia, Mozambique, Nigeria, Senegal, Tanzania

Asia

- ▶ Burma, Cambodia, China, India, Indonesia, Laos, Nepal, Philippines, South Korea, Thailand, Vietnam

Latin America and Caribbean

- ▶ Brazil, Colombia, Ecuador, Guatemala, Guyana, Peru, Suriname

Europe/Eurasia

- ▶ Kazakhstan, Ukraine, Uzbekistan

*as of October 1, 2013

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- Medicines Quality Monitoring
- Heartbeat of drug regulation in developing countries
- Detects failures in registration systems
- Detects deficiencies in procurement practices
- Detects supply chain deficiencies



Southeast Asia Sentinel Sites

Increased # of sites:

2003: 17

2006: 28

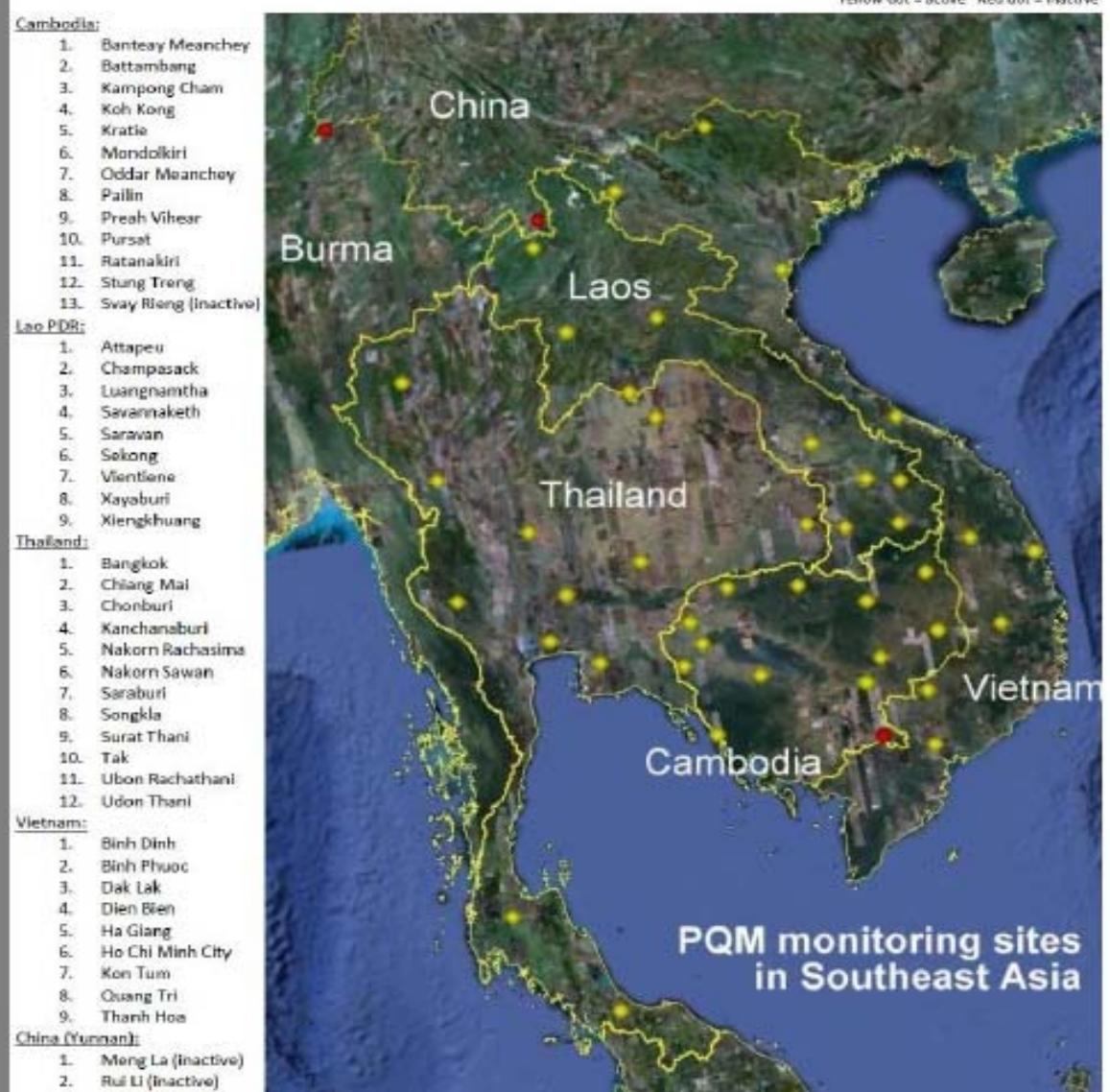
2012: 53

(3 inactive: 2 in Yunnan China and 1 in Cambodia)



Program expanded to include ABT, ATB, ARV, and AI products

Leveraged support from GFATM in Laos, Cambodia, and Vietnam



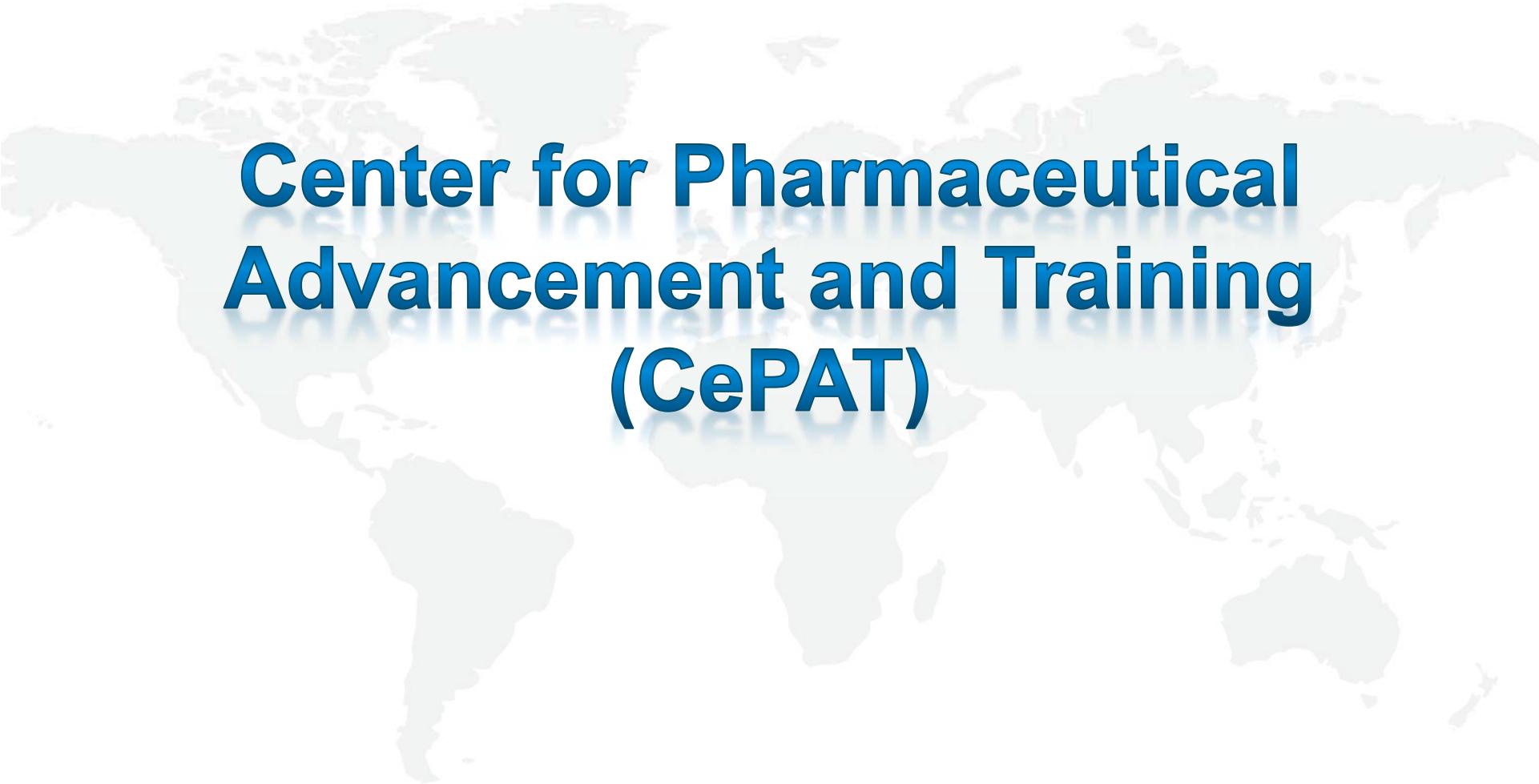
Power of post-market surveillance – Case study Ghana

- Medicines Quality Monitoring
- 90% of oxytocin and ergometrine failed quality specifications
- High failure rate in public sector
- 90% of products not registered
- Over 80% of products not stored properly





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Center for Pharmaceutical Advancement and Training (CePAT)



State of the Art Analytical Laboratory



Poor patient education and awareness

- Focus on price over quality

Fragmented wholesale supply chain

- Numerous wholesalers and informal retail outlets

Impediments to availability of quality medicines

- Heavy dependence on imports
- Local production hindered

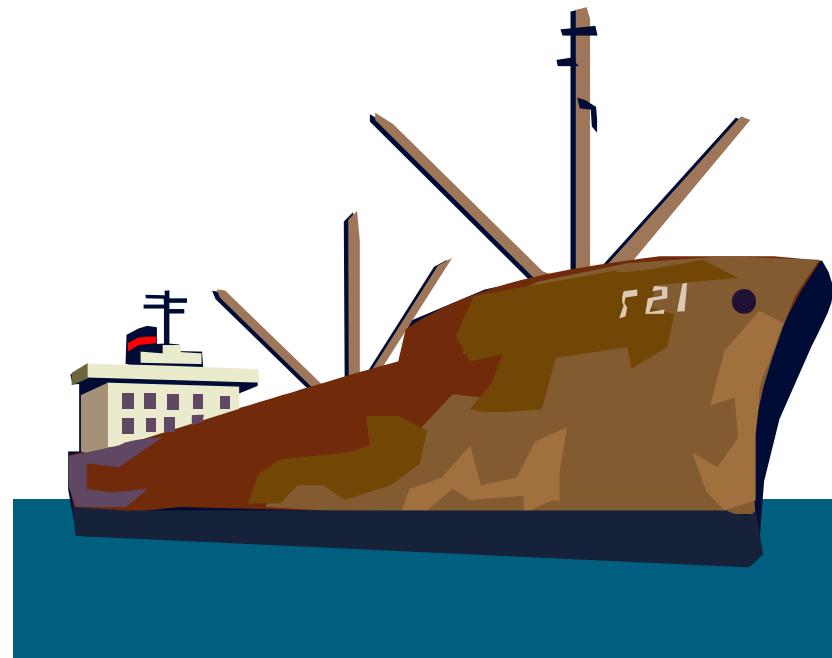
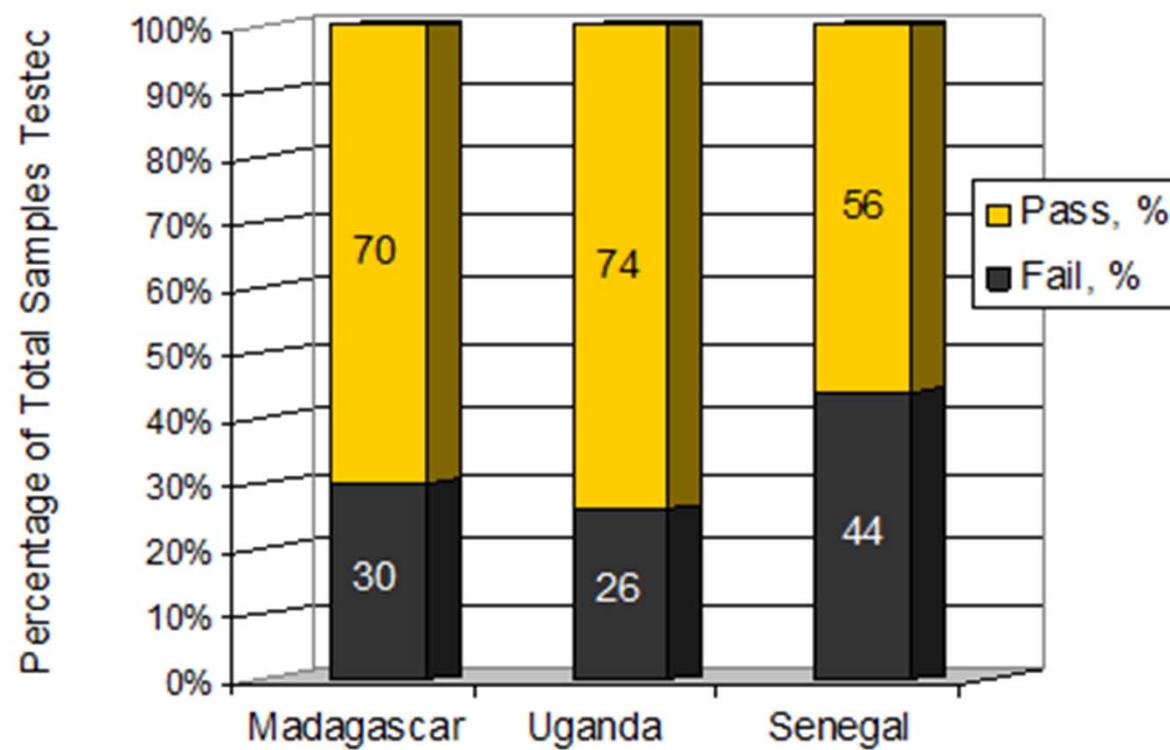


Figure 1. Quality of Antimalarial Medicines Sampled from Madagascar, Uganda, and Senegal



Thin layer chromatography (TLC)-based kit Colorimetric detection-based kit



Visual Inspection - Uniformity of Color



West Africa Sentinel Sites



SENEGAL

1. Dakar
2. Kaolack
3. Kedougou
4. Louga
5. Matam
6. Richard Toll
7. Touba
8. Vélingara
9. Ziguinchor

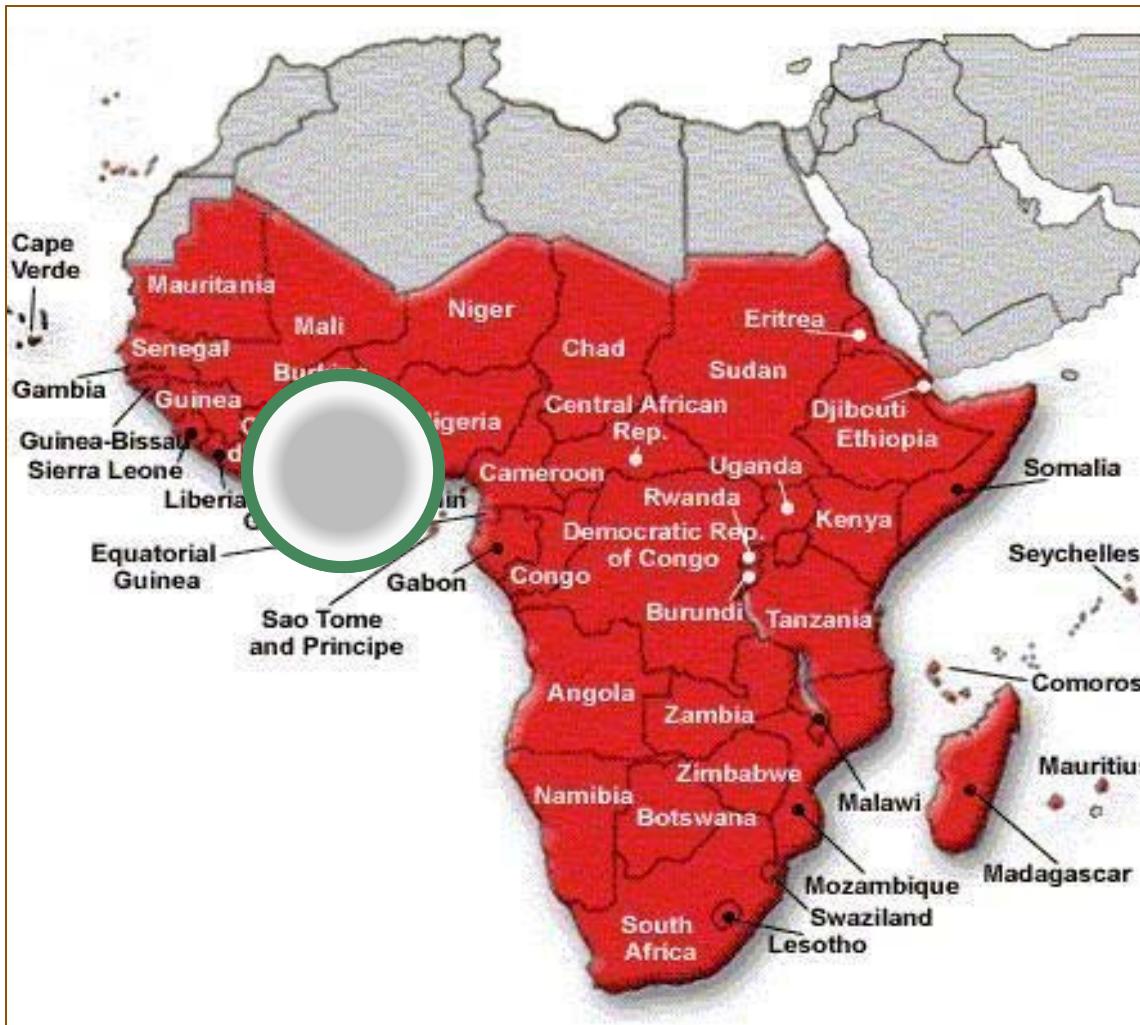
GHANA

1. Bolgatanga
2. Kumasi
3. Ho
4. Tema
5. Tarkwa

MALI

1. Gao
2. Kayes
3. Koulikou
4. Mopti
5. Ségou
6. Sikasso
7. Tombouktou

Map of Africa (SSA in red)



May 13, 2013 Inauguration



Ergonomic Classrooms





QC Labs

- Lab testing
- Technical trainings
- Quality management system
- Equipment calibration
- Lab accreditation

Regulators

- Drug registration
- Dossier evaluation
- BE and stability data review
- GMP audit training
- Post-market surveillance

Manufacturers

- GMP training
- WHO prequalification
- Supplier audits
- BE and stability studies

Dossier Evaluation (Session 1) - Closing Ceremony



- Good regulation is good for business - invites investors in pharmaceutical manufacturing
- Good for economic development
- Good regulation is good for the patient - better quality medicines
- Local manufacturing is vital for economic development and public health
- Interventions must be geared toward sustainable capacity development and country ownership



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Questions



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Thank You

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