United States Government Supply Chain Meeting 2012

Johannesburg, South Africa
May 21-25, 2012

Trip Report

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PROMOTING THE QUALITY OF MEDICINES

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Executive Summary

Dr. Abdelkrim Smine traveled to Johannesburg, South Africa to attend and present at the United States Government (USG) Supply Chain Meeting on behalf of the Promoting the Quality of Medicines (PQM) Program. The meeting was held May 21-25, 2012 and attended by United States Agency for International Development (USAID) staff from Washington, DC, supply chain advisors from selected African countries, Supply Chain Management System (SCMS), Management Sciences for Health (MSH), Systems for Improved Access to Pharmaceuticals and Services (SIAPS), Global Fund, PQM, and others.

The meeting was a great platform for discussing the successes, failures, and challenges in Sub-Saharan Africa (SSA) in order to assist USAID decision makers to better focus future funds and technical support to improve health systems in developing countries.

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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 assistance 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.

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- Mr. Kaleb Brownlow (and the Supply Chain team), Dr. Maria Miralles, and Mr. Anthony Boni from USAID headquarters in Washington, DC for arranging PQM's participation in the USG Supply Chain meeting in Johannesburg and for reviewing PQM's presentations.

- PQM colleagues who reviewed the presentations and this report and assisted with all trip logistics.

ACRONYMS

DQI	Drug Quality and Information Program
MSH	Management Sciences for Health
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President’s Malaria Initiative
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
SCMS	Supply Chain Management System
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SSA	Sub-Saharan Africa
USAID	United States Agency for International Development
USG	United States Government
USP	United States Pharmacopeia
WHO	World Health Organization

Background

The United States Government (USG) spends a considerable amount of foreign aid on the procurement of medicines and diagnostic products. With the implementation of the President's Malaria Initiative (PMI) and the President's Emergency Plan for AIDS Relief (PEPFAR), the United States Agency for International Development (USAID) technical support for supply chain management has increased.

After almost a decade of PMI and PEPFAR presence in many sub-Saharan African (SSA) countries, it was time to conduct an assessment of the successes achieved and challenges faced, as well as to share lessons learned and best practices among SSA countries.

Purpose of Trip

Dr. Abdelkrim Smine traveled to Johannesburg, South Africa to attend and present at the USG Supply Chain Meeting on behalf of Promoting the Quality of Medicines (PQM) Program.

Source of Funding

This was trip was funded by USAID Core Funds for Common Agenda.

Conference Overview

The meeting was held May 21-25, 2012 in Johannesburg, South Africa and attended by USAID staff from Washington, DC, supply chain advisors from selected African countries, Supply Chain Management System (SCMS), Management Sciences for Health (MSH), Systems for Improved Access to Pharmaceuticals and Services (SIAPS), Global Fund, PQM, and others. The first two days of the meeting were held with USAID staff only, the next two days included all participants, and the last day included a visit to a private warehouse used by SCMS. The complete agenda can be found in *Annex 1*.

Introduction: The USAID Supply Chain team organized this meeting in order to share lessons learned in supply chain management in several SSA countries. The meeting offered a platform for presenting successful approaches, major challenges, and discussions about better use of USG support to achieve greater impact on public health in SSA.

Goal: Establish a USG supply chain community to share challenges and lessons learned, identify opportunities for collaboration on supply chain system strengthening, and contribute to policy and strategy to advance country-led and sustainable public health supply chain systems.

Objectives:

- **To provide technical updates and discuss technical areas** through country examples of successes and lessons learned (e.g. government-to-government financing, network design, human resources, and performance measurement) and updates in supply chain systems (e.g. performance-based incentives).

- **To review program and project management strategies** through country examples of managing and coordinating multiple supply chain projects, transitioning and closing-out of central-level projects, integrating supply chain system strengthening into health portfolios, and monitoring project performance.

- **To consult with the field on new policies and guidance** through updates on impact on supply chain programs and dialogue with the field on draft guidance and frameworks (e.g. waste management and performance measurement)

- **To strengthen coordination and collaboration** through identifying key challenges and issues, processes to coordinate and collaborate, and strategies related to procurement and supply chain system strengthening with donor partners (e.g. Global Fund) and implementing partners.

Highlights of the Meeting

Day Three: USAID and partners discussed accountability and transparency within country supply chain, supply chain integrity, and strategic planning. These topics were supported by experience from the field. The participants also discussed human resources issues related to the supply chain. The Global Fund representative gave an update about the funding situation and the expected USG support.

Dr. Smine gave a presentation during the technical panel in the afternoon. The presentation addressed the issue of counterfeit and substandard medicines and what PQM is doing to assist USAID-supported countries deal with the problem. The presentation illustrated PQM's approach of using basic tests to detect counterfeit and substandard medicines. This presentation can be found in *Annex 2*.

Day Four: The group gave presentations and held discussions about the effectiveness of USAID support in supply chains. Issues of how to measure the performance and impact of USG support and where USG should spend its money to get the most impact were discussed. The SCMS team from South Africa presented a new supply chain assessment tool. The approach of using performance-based incentives was also discussed and examples from Mozambique and Rwanda were presented as models.

Dr. Smine gave a presentation focused on quality assurance (QA) throughout supply chain levels within a session moderated by Dr. Maria Miralles. This presentation can be found in *Annex 3*. SCMS staff presented on their QA activities (qualification of suppliers, procurement, quality control of rapid diagnostic kits, Good Manufacturing Practices audits, etc.), while SIAPS presented on pharmacovigilance.

Day Five: The group visited the warehouse facilities used by SCMS, including the bonded warehouse. Discussions were held on investment rationale, decision-making, system implementation, and human resources.

Conclusion

The USG supply chain meeting was a great platform for discussing the successes, failures, and challenges in SSA in order to assist USAID decision makers to better focus future funds and technical support to improve health systems in developing countries. Many new assessment tools for supply chain performance were presented and discussed together with approaches such as performance-based incentives to improve performance and effectiveness toward better and

sustainable systems. USAID partners shared their lessons learned from different countries with varying successes and challenges.

PQM's presentations were eye-opening to many supply chain managers, as they clearly illustrated the importance of the quality assurance of medicines and diagnostics throughout the distribution levels of the supply chain.

Given all the lessons learned, future USG funds should be linked to performance, focusing on effective activities that lead to sustainable systems to improve public health in USAID-supported countries.

Annex 1

Agenda

Monday May 21 and Tuesday May 22, USG Meeting only

Wednesday May 23	USG and Partners
Morning 8:30 – 9:00	**Morning Review & Recap** **Introductions**
9:00 – 10:15	**Plenary: How to ensure accountability and transparency within country supply chains and between partners & countries**
9:30 - 10:15	**Panel: Experiences from the field and discussion** ● Country examples (e.g. Nigeria and Mozambique) ● Addressing governance and institutional capacity
10:15 – 10:30	*Break*
10:30 - 11:30	**Plenary: Strategic Planning & Strategic Network Design** ● Role of strategic planning and design ● Approach/checklist for strategic planning & network design ● Country-specific approaches (e.g. Liberia, Haiti, Mozambique) ● Disease-specific or system-focus
11:30 - 12:30	**Global Fund Updates & USG-GF Collaboration**
12:30 – 1:30	**Lunch**
Afternoon **1:30 - 2:30**	**Technical Update: Lab Procurement & Harmonization Strategy** ● Demo presentation of the CHAI Laboratory Tool **Technical Update: Supply Chain Integrity (e.g. SLICE, End-Use Verification Tool)** ● Discuss tools to evaluate internal control & accountability ● Discuss pharmaceutical/non-pharmaceutical quality monitoring
2:30 - 3:00	**Plenary: Update on Human Resources**
3:00 - 3:15	*Break*
3:15 - 4:00	**Breakouts: Country presentations on successes and challenges in HR**
4:00 - 5:00	**Open Space** ● Opportunity to discuss issues of interest with other field advisors and topic area "Resource People"
5:00 – 5:15	**Wrap-up from Day 2**

Thursday May 24	**USG and Partners**
Morning 8:30 – 8:45	**Morning Review & Recap**
8:45 – 9:15	**Plenary: Balancing effectiveness and efficiency in the supply chain**
9:15 - 10:30	**Performance Measurement - Strategic to Operational**
10:30 – 10:45	*Break*
10:45 – 12:00	**Plenary: Improving Supply Chain Performance Through Incentives** ● Country examples: Rwanda and Mozambique
12:00 – 1:00	**Lunch**
Afternoon 2:00 – 3:30 *Break 3:30 – 3:45*	**Technical Update: QA and Assuring Patient Safety** ● ● **Technical Update: Integration - Learning from what works** ● Harmonization of data collection/information systems
3:45 – 5:00	**Private Sector - Outsourcing to 3PLs and Flexible Contracting** ● Flexible contracting and activity-based costing for 3PLs ● Decision-making and risk evaluation for outsourcing ● Moderated discussion with private sector clients and/or country representatives and service providers
5:00 – 5:30	**Wrap-Up, Evaluation and Farewell**
6:30 – 8:00	**Farewell Reception**
Friday May 25	**USG and Partners (Half-Day)**
Morning 8:30 - 1:00	**Open Space** ● Opportunity to discuss issues of interest with other field advisors and topic area "Resource People" **One-on-one meetings** **Site Visit: RTT/PHD Centurion Facilities** ● Tour the RTT/PHD warehouse facilities (East and West Building) including the RDC (bonded warehouse) ● Discussion on investment rationale, decision-making, system implementation, and human resources

PQM Presentation #1

2012 USG Supply Chain Strengthening Meeting
Johannesburg, South Africa ◆ May 21 – 25, 2012

Counterfeit Medicines

Abdelkrim Smine, Ph.D.
PQM Consultant

Counterfeit medicines - 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.*

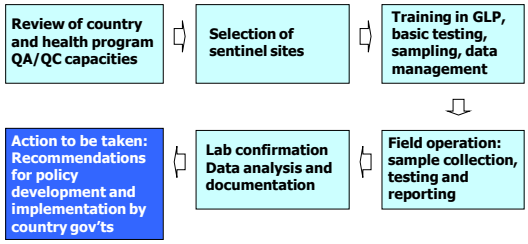
- **Substandard**

  Legal branded or generic product, but does not meet official standards for identity, quality, purity, strength, packaging, and labeling.

Background

- First USAID-PQM work started in 2003-2003 mainly in SEA on antimalarials
- PQM approach was very successful is finding and documenting the first drug Quality data
- Same approach was expanded to other health programs and other medicines
- Drug quality become a priority component of Malaria control in the region
- Same approach was duplicated in many countries in Africa and LAC

PQM methodology



Methodology

Methodology – TLC testing

TLC is a useful analytical tool;

- Verifying the Identification of drug products
- Semi-quantification of tested products
- Detection of impurities and degradation of drug products
- It is a recognized pharmacopeia analytical method

Monitoring the Quality of Medicines (MQM)

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Activities	Level of Testing	Protocol
Sample collection **Basic testing** • Physical/Visual inspection • Simplified disintegration • Thin layer chromatography	① **Sentinel site**	**Test: 100% of samples collected** 1. 100% doubtful samples to QC or designated Lab for verification 2. 100% of failed samples 3. 5-10% of passed samples
Verification • Repeat TLC on all samples • Pharmacopeia specifications • Methods	② **National QC or Designated Lab**	**Test: 100% samples received from sentinel sites** Samples that QC lab cannot test or for second verification in reference lab.
Confirmation • Pharmacopeial specifications or • Mfr validated methods	③ **Reference Laboratory**	**Test: All samples received from National QC Lab or Designated Lab**

MQM Sites in Southeast Asia

Increased # of sites:
2003: 17
2006: 28
2012: 56

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

Leveraged support from GFATM in Laos, Cambodia, and Vietnam

Basic Tests

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Basic tests - Ghana

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Counterfeit

Genuine

Counterfeit Medicines

Hong Kong, 2000

Counterfeit

Genuine

PQM Quality Data

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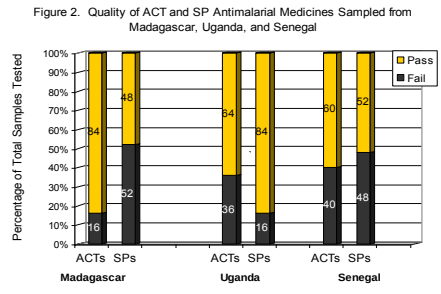

PQM Drug Quality Data

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Countries	Failure rate Domestic	Failure rate Imported	Overall failure rate
Cameron	0	37%	37%
Ethiopia	0	0	0%
Ghana	64%	30%	39%
Kenya	9%	3%	5%
Nigeria	74%	57%	64%
Tanzania	42%	0	11%

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Questions

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Thank You

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President's Malaria Initiative

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PQM Presentation #2

2012 USG Supply Chain Strengthening Meeting
Johannesburg, South Africa ◆ May 21 – 25, 2012

Quality Assurance of Medicines

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Definitions

The Medicine

- The Active Pharmaceutical Ingredient (API)
- The Excipients
- The Package
- The Label
- The Storage Conditions
- The Shelf Life
- The Indications for use

Definitions

Quality Assurance

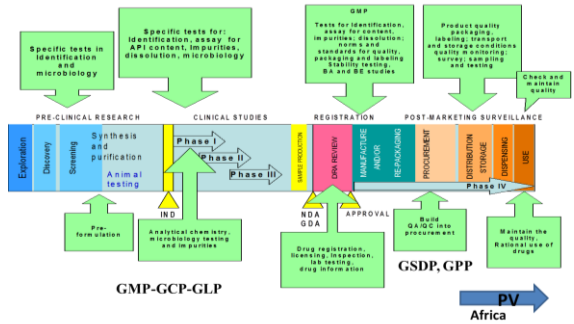
- Quality Assurance (QA) of medicines are all the measures taken to assure the quality of a medicine from the time of its development to its use by the patient.
- In other words:

QA = making sure that a medicine

is FIT for its intended use

Efficacy, safety and quality, storage, and appropriate use

When does QA of Medicines Start? End?



Monitoring the Quality of Medicines (MQM)

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Confirmation •Pharmacopeial specifications or •Mfr validated methods	③ **Reference Laboratory**	**Test: All samples received from National QC Lab or Designated Lab**

Quality Control of Medicines

Critical Attributes for Testing Medicines

Identity ◆ purity ◆ quality ◆ strength ◆ packaging ◆ labeling

Identity	*confirmation of API*
Assay / Dosage	*amount of active ingredient on the label*
Disintegration	*prerequisite for bioavailability*
Dissolution	*higher level of assurance of bioavailability*
Impurities	*generally related to API → toxicity*
Uniformity	*uniformity of content/dosage, GMP*
Sterility	*injectable solutions*
Package / Label	
Others	*medicine-specific*

MQM Sites in West Africa

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

MQM Sites in East Africa

ETHIOPIA
1. East Shoa
2. West Wollega
3. Jimma
4. Borena
5. Hararge

KENYA
1. Eldoret
2. Kakamega
3. Kisumu
4. Mombasa
5. Nairobi

PQM Program in Africa – Liberia (starting from Zero)

- PQM assessed QA/QC capacities
- Priority action: support MRC to draft a legislation establishing a medicines regulatory authority (MRA)
- Legislation finalized, signed President in Oct 2010
- Supporting newly established MRA drafting priority regulations
- Building QC capacity – staffing, facility, equipment, training

Medicines Quality Monitoring – Liberia (2011)

Medicines	Passed	Doubtful	Failed	Total
Artemether	0	4	0	4
Artemether/Lumefantrine	0	1	0	1
Amodiaquine	2	6	4	12
Artesunate	1	1	2	4
Artesunate/Amodiaquine	12	15	5	32
Artesunate/Sulfamethoxypyrazine/ Pyrimitamine	1	0	0	1
Chloroquine	3	6	1	10
Sulfadoxine/Pyrimethamine	7	2	0	9
Quinine Sulphate	1	2	13	16
Ciprofloxacin	3	2	0	5
Paracetamol	1	0	0	1
Total	31	39	26	95

Medicines Quality Monitoring – Ghana (2011)

- PQM supports PMI objectives in Ghana
- PQM focuses mainly on MQM using Minilabs® at sentinel sites
- Confirmatory testing carried out by National QC labs according to PQM protocol and guidelines
- Pharmaceutical markets are better controlled
- Well-functioning Medicines Regulatory Authorities
- Active National QC Laboratories
- Medicines quality monitoring limited mainly to health programs

Medicines Quality Monitoring – Ghana (2011)

Medicines	Total	Passed	Failed	Doubtful
Artesunate	6	4	1	1
Amodiaquine	3	2	1	0
Artesunate/Amodiaquine	11	7	2	2
Artemether/ α-β Arteether	11	9	0	2
Artemether/Lumefantrine	7	4	1	2
Sulphadoxine/Pyrimethamine	6	0	5	1
Quinine	5	0	4	1
Quinine Sulphate	4	2	0	2
Chloroquine	1	0	1	0
Dihydroartemisinin	9	0	5	4
Dihydroartemisinin/ Piperaquine	16	9	1	6
Sulphamethoxypyrazine/Pyrimethamine	5	3	1	1
Halofantrine	4	4	0	0
Artesunate-Sulphamethoxypyrazine/Pyperimethamine	1	0	1	0
Total	89	44	23	22

Regional Initiative

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National Medicines Control Labs (NAMCOL)

- Created in 2009
  Ghana, Senegal, Ethiopia, Mali, Kenya, Uganda & Mozambique
- PQM support includes; *Proficiency testing, expert reviewing, USP training, regional collaboration and regional harmonization*
- Other countries in Africa are interested to join NAMCOL Network
- NAMCOL will be established as a professional scientific association with charter to be reviewed in July 2012.

Support to Manufacturers

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- There is a shortage of manufacturers able to produce priority quality assured finished products and API
  - Second line TB medicines
  - Selected MCH products
  - Selected products for HIV programs
- "Most promising" manufacturers identified through EOI
- Assistance includes:
  GMP assessment and improvement plan, minor equipment, support for dossier preparation for submission to WHO prequalification or other SRA.

Five Key Take Away Messages

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- For some essential products there is a shortage of manufacturers able to produce QA products
- Good procurement practices (esp. product specifications) are critical
- Supply chain systems must maintain the quality and safety of medicines throughout their shelf life
  - Monitoring the Quality of Medicines must be conducted at all levels of supply chain
- Don't forget to budget for 8 to10 % of medicines cost to be allocated to quality assurance for GFATM procurement
- Access alone is not enough; Patients need access to safe and efficacious medicines of assured quality

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