

Second-line Anti-tuberculosis Medicines Manufacturers Workshop

Accra, Ghana
May 9-10, 2013

Trip Report

Mr. Edwin Toledo, Senior GMP Specialist

Dr. Patrick Lukulay, Director

Dr. Teferi Bedane, Regulatory Affairs Manager-Ethiopia

Promoting the Quality of Medicines

Implemented by U.S. Pharmacopeia

12601 Twinbrook Parkway

Rockville, MD 20852 USA

Tel: (+1-301-816-8582)

Email: pqm@usp.org and ERT@usp.org

Cooperative Agreement # GHS-A-00-09-00003-00

Funding Source: USAID Core TB

Grantee: Promoting the Quality of Medicines (PQM) Program

Author(s) Name: PQM staff

Language: English

Date of Publication: June 7, 2013



This report is made possible by the generous support of the American people through the United States Agency for International Development (USAID), under Cooperative Agreement No. GHS-A-00-09-00003-00. The contents are the responsibility of the Promoting the Quality of Medicines Program, implemented by the U. S. Pharmacopeia, and do not necessarily reflect the views of USAID or the United States Government.

PROMOTING THE QUALITY OF MEDICINES

Executive Summary

The PQM team traveled to Ghana to convene a two-day workshop for Sub-Saharan African anti-tuberculosis medicine manufacturers about the World Health Organization Prequalification (WHO PQ) Program and the technical assistance PQM can provide.

A total of 24 manufacturers attended the workshop, and seven manufacturers from Ghana, Nigeria, and Ethiopia expressed interest in participating in the WHO PQ Program and in receiving technical assistance from PQM. They completed screening questionnaires and submitted them to PQM.

TABLE OF CONTENTS

<u>Acknowledgements</u>	4
<u>Acronyms</u>	5
<u>Background</u>	6
<u>Purpose of Trip</u>	6
<u>Overview of Activities</u>	6
<u>Annex 1: Workshop Agenda</u>	8
<u>Annex 2: Workshop Participants</u>	10

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.

ACKNOWLEDGEMENTS

I would like to thank:

- Dr. Milan Smid, Dr. Antony Fake, Mr. Deusdedit K. Mubangizi, Mr. Lorenzo Witherspoon, and Dr. Kaspars Lunte for their availability, support, and effective delivery of presentations during the workshop
- Mr. Anthony Boni and Dr. Maria Miralles at USAID/Washington, for their support and advice
- PQM administrative and editorial staff for their support with logistical arrangements and for editing the trip report

ACRONYMS

API	Active Pharmaceutical Ingredient
ATB	Anti-tuberculosis Medicine
DQI	Drug Quality and Information Program
FPP	Finished Pharmaceutical Product
GDF	Global Drug Facility
GMP	Good Manufacturing Practices
PQM	Promoting the Quality of Medicines
TB	Tuberculosis
USAID	United States Agency for International Development
USP	United States Pharmacopeial Convention
WHO	World Health Organization
WHO PQ	World Health Organization Prequalification Programme

Background

Tuberculosis (TB) is a global concern, and PQM has actively contributed to the USAID strategic objective of “increased use of effective interventions to reduce the threat of infectious diseases, including tuberculosis” (P.E.1.2 -TB). PQM assists countries to implement anti-TB (ATB) medicine quality monitoring, and in 2008, began providing technical assistance related to current Good Manufacturing Practices (GMP) to interested companies on the preparation of medicine dossiers they submit to the World Health Organization (WHO) with their "Expressions of Interest" for the WHO Prequalification (PQ) Program.

Purpose of Trip

Introduce the WHO PQ program to ATB manufacturers in Ghana and engage them to actively participate in the process.

Overview of Activities

May 9-10, 2013: Second-Line ATB Medicines Manufacturers' Workshop, Accra, Ghana

With financial support from USAID, a two-day workshop was jointly organized by PQM, UNITAID, Global Drug Facility (GDF), and WHO to inform manufacturers and regulatory personnel about the WHO PQ program, the technical assistance that PQM can provide in the PQ process, and the outlook on the global ATB medicines market.

The target audience included representatives from senior management and/or regulatory affairs and representatives from Medicines Regulatory Authorities who are involved in the dossier evaluation of ATB medicines for registration. It was strongly recommended that each company invited send a member from one of those teams in order to gain the most from this experience and make any appropriate decisions on behalf of the company.

The following products were included in the priority list for the workshop:

- Amikacin, solution injection 500mg/2 ml vial, amp; powder for injection 1g vial, amp
- Capreomycin, powder for injection 1g, vial
- Cycloserine, capsule 250mg
- Ethionamide, tablet /capsule 250mg
- Kanamycin, powder for injection 1g, vial
- Kanamycin, powder for injection 500mg, vial
- Levofloxacin, tablet/capsule 250mg, tablet 500mg, tablet 750mg
- Moxifloxacin, tablet /capsule 400mg
- Ofloxacin, tablet /capsule 200mg; 400mg
- Prothionamide, tablet /capsule 250mg
- Para-Aminosalicylic Acid (PAS) sachets, 4g granules
- PAS Sodium 100g jar granules, 4g / 9.2g sachets granules; powder for oral solution sachets
- Terizidone, tablet/capsule, 300mg

Opening Ceremony

Mr. Lorenzo Witherspoon, Supply Advisor from UNITAID, and Dr. Patrick Lukulay, Director of PQM, welcomed the participants. Following the opening remarks Dr. Kaspars Lunte, Team Leader at GDF and the Stop TB Partnership Secretariat, gave an overview of the global TB situation, the need for quality-

assured ATBs, and the anticipated demand for ATBs in the next few years. She also presented GDF's role and current activities.

Mr. Witherspoon presented the "TB Donor Perspective on the Role of PQ on Sustainability, Procurement, and Supply." Dr. Milan Smid, Technical Officer at WHO PQ, presented an overview of the WHO PQ Programme and provided participants with detailed information on the format of the dossiers. Dr. Lukulay discussed the PQM program and its mandates, explaining the types of technical assistance that PQM provides to manufacturers.

On the second day, Mr. Teferi Bedane of PQM presented "WHO PQ: Finished Pharmaceutical Product Dossier Requirements" followed by Dr. Antony Fake of WHO, who presented "Fake Demonstration of Active Pharmaceutical Ingredient Quality for WHO PQP." Mr. Deusededit Mubangizi of WHO then presented "WHO PQP GMP Requirements and Organization of Inspections." After the presentation a Panel Discussions/Round Table Q&A was held with Dr. Paul Lartey from La Gray Pharmaceutical, Mr. Witherspoon from UNITAID, and Dr. Lukulay from PQM to discuss challenges and opportunities for African manufacturers interested in obtaining WHO PQ status for essential medicines.

Workshop Deliberations

Representatives from 24 companies participated. Seven manufacturers expressed interest in pursuing WHO PQ and in receiving technical assistance from PQM for ATBs on the GDF/WHO PQ priority list; each completed a screening questionnaire and submitted it to PQM. Some manufacturers also inquired about other priority medicines, such as those for zinc sulfate and malaria.

Key challenges and obstacles the companies face in achieving WHO PQ include:

- Limited and/or incomplete availability of Master Files from the active pharmaceutical ingredient (API) producers/suppliers. Many API producers/suppliers are reluctant to provide this information to finished pharmaceutical products (FPP) manufacturers, which creates obstacles to compiling and submitting complete dossiers.
- Limited understanding of the process, eligibility, procedures, and requirements of WHO PQ and GDF as well as the process of obtaining technical assistance from PQM.
- Concerns about the capital investment they may have to make in order to improve their facilities and quality systems to comply with WHO GMP requirements.
- Low profit margin for some medicines.
- Low GDF demand for second-line ATB medicines.

See [Annex 1](#) for the conference agenda and [Annex 2](#) for a list of workshop participants and those companies interested in receiving technical assistance from PQM.

Conclusion

The workshop was successful with seven ATB manufacturers expressing interest in the WHO PQ process and in obtaining technical assistance from PQM.

Next Steps

- PQM will evaluate the questionnaires of the interested manufacturers and will respond by the end of May
- PQM will visit Juhel Nigeria Ltd. by the end of June



PROMOTING THE QUALITY OF MEDICINES

2nd Line TB Medicines Manufacturers Workshop
May 9-10, 2013 ♦ La Palm Royal Beach Hotel
Accra, Ghana

AGENDA

DAY 1 – Thursday, May 9, 2013

Time	Topic	Presenter/Speaker
09:00-09:30	Opening Remarks	PQM; Ghana FDB
09:30-10:00	Introduction of the workshop Introduction of participants	PQM
10:00-10:45	GDF Quality Assurance Policy and Processes and Demand for 2 nd Line TB medicines*	GDF (Dr. Kaspars Lunte)
10:45-11:15	Coffee/Tea Break	ALL
11:15-11:45	TB Donor Perspective on the Role of PQ on Sustainability, Procurement, and Supply	UNITAID (Mr. Lorenzo Witherspoon)
11:45-13:30	Lunch	ALL
13:30-14:15	PQM Technical Assistance for 2 nd Line TB Medicine Manufacturers and CePAT	PQM (Dr. Patrick Lukulay)
14:15-14:45	Principles and Procedures of PQP (video presentation)	WHO (Dr. Milan Smid)
15:00-15:30	Coffee/Tea Break	ALL
15:30-16:30	WHO Pre-Qualification: FPP Dossier Requirements	PQM (Mr. Teferi Bedane)
16:30-17:00	Day One Wrap up	PQM

*Webcast presentations

DAY 2 – Friday, May 10, 2013

Time	Topic	Presenter/Speaker
09:00-09:30	Summary of Day 1	PQM
09:30-10:30	Demonstration of API Quality for WHO PQP*	WHO (Dr. Antony Fake)
10:30-11:00	Coffee/Tea Break	ALL
11:00-12:00	WHO PQP GMP Requirements and Organization of Inspections*	WHO (Mr. Deusdedit Mubangizi)
12:00-13:30	Lunch	ALL
13:30-14:30	WHO Pre-Qualification: FPP Dossier Requirements	PQM (Mr. Teferi Bedane)
14:30-15:30	Panel Discussions/Round Table Q&A - continued	PQM, UNITAID, GDF, WHO
15:30-16:00	Coffee/Tea Break	ALL
16:00-16:30	Interest in receiving Technical Assistance (TA) from PQM (to fill out the preliminary questionnaire)	Manufacturers
16:30-17:00	Next Steps and Closing	PQM
	All interested companies may stay and speak with members of PQM, WHO PQ or GDF	

*Webcast presentations



**2nd Line TB Medicines Manufacturers Workshop
May 9-10, 2013 ♦ La Palm Royal Beach Hotel
Accra, Ghana**

Workshop Participants

Companies Attending the Workshop	Companies Interested in Receiving PQM Technical Assistance
Dannex Ltd.	Addis Pharmaceutical Factory (Ethiopia)
LaGray Chemical Company	Amponsah Efah Pharma Ltd.(Ghana)
Phyto-Riker Pharma	CHI Pharmaceutical (Nigeria)
Amponsah Efah Pharma Ltd.	Dannex Ltd. (Ghana)
Ernest Chemist	Juhel Nigeria Ltd. (Nigeria)
Entrance Industries	LaGray Pharmaceutical (Ghana)
Danadams Ltd.	Swiss Pharmaceutical (Nigeria)
Unichem	
Letap Pharma	
Starwin Ltd.	
Pharma Nova Ltd.	
Perfect Pharmaceuticals	
African Global Pharma	
Cadila Pharma Ethiopia	
Addis Pharmaceutical Factory	
Juhel Nigeria Ltd.	
CHI Pharmaceutical	
Diz Pharm	
Swiss Pharmaceutical	
Emzor Pharma	
Nigerian German Chemical	
Africal Global Pharma	
Trade Winds Chemist	
Shalina Heathcare	