

Second-Line Anti-Tuberculosis Medicines Manufacturers Workshop and Meetings

Sao Paulo, Brazil
August 5-8, 2013

Conference Report

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Executive Summary

PQM staff traveled to Sao Paulo, Brazil to host a workshop for second-line anti-tuberculosis (ATB) medicines manufacturers August 8, 2013 during a seminar conducted by CPhI South America. The ATB workshop was jointly hosted by PQM and the Global Drug Facility (GDF) to inform manufacturers and regulatory personnel about the World Health Organization (WHO) Prequalification (PQ) program, the technical assistance that PQM can provide during the PQ process, and the global ATBs market outlook.

During the trip to Brazil, PQM staff also met with representatives of Fiocruz, Farmanguinhos, USP Brazil, and SINDUSFARMA to discuss current projects and future collaboration.

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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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- Dr. Joel Keravec for his availability, support, and effective delivery of the presentation during the seminar
- Each of the participants from the companies for their participation
- Staff from Farmanguinhos for hosting the meeting
- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report
- Mr. Anthony Boni and Dr. Maria Miralles at USAID/Washington for their support and advice

ACRONYMS

ANVISA	Brazilian Health Surveillance Agency
ATB	Anti-Tuberculosis Medicines
DQI	Drug Quality and Information Program
GDF	Global TB Drug Facility
GLC	Green Light Committee
GMP	Good Manufacturing Practices
INCQS	National Quality Control Institute of Brazil
MDR-TB	Multi-Drug Resistant Tuberculosis
PQ	Prequalification
PQM	Promoting the Quality of Medicines Program
TB	Tuberculosis
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Background

Despite efforts by the World Health Organization (WHO) Prequalification (PQ) program, Global TB Drug Facility (GDF), and the Green Light Committee (GLC) to increase access to essential anti-tuberculosis medicines (ATBs), there are not enough WHO-prequalified second-line ATBs and an inadequate supply of products to treat patients with multi-drug resistant TB (MDR-TB).

To assist in this effort, in 2008 PQM began providing technical assistance related to current Good Manufacturing Practices (GMP or cGMP) to interested medicines manufacturers on the preparation of medicine dossiers they submit to WHO for the WHO PQ Program.

Purpose of workshop

A half-day workshop for second-line ATBs manufacturers was held in Sao Paulo, Brazil on August 8, 2013 as part of a CPhI South America conference. The ATB seminar was jointly hosted by PQM and GDF to inform manufacturers and regulatory personnel about the WHO PQ program, the technical assistance that PQM can provide during the PQ process, and the global ATBs market outlook.

The target audience for this workshop included representatives from senior management and/or regulatory affairs and representatives from medicines regulatory authorities who are involved in the dossier evaluation of ATBs for registration. It was strongly recommended that each invited company 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.

Conference Deliberations

See *Annex 1* for the complete conference agenda.

USP Brazil set up a booth at the CPhI conference, and PQM was able to include an informational poster, translated into Portuguese. There were also more than 100 manufacturers from China, India, Korea, Brazil, and other countries that set up booths. PQM staff toured these exhibits and spoke directly to relevant manufacturers.

Ms. Jenny Derry spoke with representatives from two Korean pharmaceutical companies and made connections to discuss WHO PQ for their existing ATB products.



To open the ATB seminar, Dr. Allan Hong welcomed the participants and provided an overview of what the participants could expect. Following the opening remarks, Dr. Joel Keravec, Manager at GDF, gave an overview of the global TB situation, the need for quality-assured ATBs, and the projected demand for ATBs in the next few years. He also presented GDF's role and current activities. Mr. Teferi Bedane presented an overview of the WHO Dossier Prequalification Process. He also provided the participants with detailed information on the

format of the dossiers. Dr. Hong presented the PQM program and emphasized the type of technical assistance that PQM provides to manufacturers during the WHO PQ process.

Additional Activities

While in Brazil, Mr. Edwin Toledo and Ms. Laura Krech traveled to Rio de Janeiro to meet with Dr. Jorge Bermudez, Vice President of Production and Innovation at Fiocruz, to provide an update on the technical assistance that PQM is providing to Farmanguinhos. Mr. Toledo and Ms. Krech also met with the staff at Farmanguinhos to discuss the timeline and steps involved in submitting Farmanguinhos' Ethionamide project to WHO. In addition, Mr. Toledo and Ms. Krech re-visited the warehouse to go over some changes that will be implemented and reviewed the blueprints.

During the trip, Ms. Krech met with staff from USP Brazil. She discussed the PQM GMP technical assistance work, with a focus on Brazil. USP Brazil staff provided feedback and ideas to better engage manufacturers.

Ms. Krech also met with Dr. Lauro Moretto, Vice President of the Association of Pharmaceutical Companies in the State of Sao Paulo (SINDUSFARMA). Dr. Moretto agreed to introduce PQM to some of the bigger pharmaceutical companies in Brazil, including Blau (Kanamycin), Eurofarma (Levofloxacin and Moxifloxacin), Grupo EMS (Levofloxacin and Moxifloxacin), and others.

Conclusion

Overall, the trip was successful, and PQM staff members were able to reach out to pharmaceutical manufacturers through the CPhI expo. Dr. Keravec is interested in PQM conducting more seminars in Brazil with the aid of the National TB Program and the Brazilian Health Surveillance Agency (ANVISA).

Next Steps

- PQM will send information regarding U.S. Food and Drug Administration approved coloring agents for coating to the Farmanguinhos Ethionamide team – sent August 13
- Ms. Derry will follow up with the Korean manufacturers (Daewoong Pharmaceutical and Hankook Korus) to provide detailed information regarding WHO PQ and PQM's technical assistance – by end of September
- Ms. Krech will send informational materials describing PQM's technical assistance to Dr. Moretto to send to pharmaceutical manufacturers in Brazil – sent August 9



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ANNEX 1

PROMOTING THE QUALITY OF MEDICINES

CPhI Brazil Information Seminar on WHO Prequalification
August 8, 2013 ♦ Expo Center Norte
Sao Paulo, Brazil

AGENDA

Time	Topic	Presenter/Speaker
08:30-08:45	Opening Remarks; Introduction of seminar	Dr. Allan Hong, PQM
08:45-09:30	GDF Quality Assurance Policy and Processes and Demand for 2 nd Line TB medicines	Dr. Joel Keravec, GDF
09:30-10:00	WHO Dossier Prequalification Process	Mr. Teferi Bedane, PQM
10:00-10:30	Break	ALL
10:30-11:00	WHO Dossier Prequalification Process (Continued)	Mr. Teferi Bedane, PQM
11:00-11:45	USP PQM Technical Assistance Towards WHO PQ for TB Medicine Manufacturers	Dr. Allan Hong, PQM
11:45-12:30	Question and Answer Session	ALL