

Meetings with Pharmaceutical Manufacturers

Hong Kong and China

March 25-29, 2013

Trip Report

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

USAID Funding: Core TB

Grantee: Promoting the Quality of Medicines (PQM) Program

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Language: English

Date of Publication: April 17, 2013



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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 number GHS-A-00-09-00003-00. The contents are the responsibility of the Promoting the Quality of Medicines Program and do not necessarily reflect the views of the United States Government.

Executive Summary

Dr. Allan Hong traveled to China to visit three pharmaceutical manufacturers and assess their interest in—or progress toward—World Health Organization (WHO) prequalification (PQ).

This trip was successful, with PQM starting new projects with two companies, for Ofloxacin and Prothionamide Finished Pharmaceutical Products (FPP). Discussions continue with the third company regarding PQM's Kanamycin FPP Original Equipment Manufacturer (OEM) project.

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>Conclusion</u>	6

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

The author of this report would like to express sincere thanks to:

- Personnel from Yabao Pharmaceutical Co. Ltd., Beijing, China
 - Jingping XIE, President
- Personnel from HEC Pharmaceutical Co. Ltd. Dongguan, Guangdong Province
 - Zhongneng ZHANG, Chairman of the Board
 - Richard TANG, Head of R&D
 - David WANG, Head of RA
 - Gary CHEN, Vice Director of R&D
 - Steven ZHANG, General Manager, Manufacturing Plant
 - Tin CHENG, Production Director
 - Langou TU, Director Global Business Director
- Personnel from Interpharma Access Ltd., Hong Kong
 - Chris LIU, Vice President
- PQM administrative staff and editors for their assistance with logistics and editing this report
- Anthony Boni, Maria Miralles, Cheri Vincent, and Thomas Chiang at USAID headquarters, for their support and advice

ACRONYMS

API	Active Pharmaceutical Ingredient
DQI	Drug Quality and Information Program
FPP	Finished Pharmaceutical Product
OEM	Original Equipment Manufacturer
PQ	Prequalification
PQM	Promoting the Quality of Medicines Program
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Background

Tuberculosis 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 medicine quality monitoring, and in 2008, began providing technical assistance related to current Good Manufacturing Practices 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

The purposes of this trip were to meet with:

- HEC Pharmaceutical on their Prothionamide Finished Pharmaceutical Product (FPP) submissions to WHO PQ
- Interpharma on Kanamycin the FPP Original Equipment Manufacturer (OEM) project
- Yabao Pharmaceutical on their new Ofloxacin FPP project for WHO PQ submission

Overview of Activities

March 25, 2013: Dr. Hong met with the president of Yabao Pharmaceutical in Shenyang to discuss their interest in WHO PQ for their Ofloxacin FPP project.

March 26-27, 2013: Dr. Hong visited Interpharma Hong Kong to discuss their implantation plan for the Kanamycin OEM project, for procurement by WHO PQ and the Global Drug Facility.

March 28-29, 2013: Dr. Hong visited HEC Pharmaceutical to discuss the Prothionamide FPP project for WHO PQ and their concerns regarding the Prothionamide active pharmaceutical ingredient (API) supply.

The following chart contains details on each company’s project status and proposed next steps.

Company Name and Location	Project	Status	Next Steps
Yabao Pharmaceutical Beijing	Ofloxacin FPP	PQM met with this company to discuss how to proceed with WHO PQ on this project	The company is committed to start this project for WHO PQ. PQM will begin providing sample products to them for research and development.
Interpharma Access Hong Kong	Kanamycin FPP	The implementation plan was discussed.	Waiting for PQM to implement the Kanamycin FPP OEM project with them as soon as possible.
HEC Pharmaceutical Dongguan, Guangdong Province	Prothionamide FPP	This company wants to start this project for WHO PQ.	The company has requested PQM assistance with recommendations of possible API sources for this project.

Conclusion

This trip was successful, with PQM starting new projects with Yabao Pharmaceutical (Ofloxacin FPP) and HEC Pharmaceutical (Prothionamide FPP) for WHO PQ. Discussions continue with Interpharma for the Kanamycin FPP OEM project.