

Meetings with Pharmaceutical Manufacturers

China

April 21- May 10, 2013

Trip Report

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Executive Summary

Dr. Allan Hong traveled to China in April/May 2013 to provide technical assistance to five anti-tuberculosis medicines manufacturers who are in the process of applying for World Health Organization Prequalification (WHO PQ). Dr. Hong performed Good Manufacturing Practices assessments at two companies and followed up with the other three companies to assist them with their WHO PQ submissions. One company expects to receive WHO PQ status in the coming weeks.

In addition, Dr. Hong interviewed candidates for a PQM consultant position to be based in China and will provide his recommendations to PQM management.

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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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ACRONYMS

API	Active Pharmaceutical Ingredient
CAPA	Corrective and Preventive Action
DQI	Drug Quality and Information Program
FPP	Finished Pharmaceutical Product
GMP	Good Manufacturing Practices
PQ	Prequalification
PQM	Promoting the Quality of Medicines Program
TA	Technical Assistance
TB	Tuberculosis
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

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 medicine quality monitoring, and in 2008, began providing technical assistance (TA) 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

The purposes of this trip were to:

- Assess Shandong Reyoung Pharmaceutical Co. Ltd. for Capreomycin Finished Pharmaceutical Product (FPP)
- Help HEC Pharmaceutical to be ready to submit Levofloxacin and Moxifloxacin Active Pharmaceutical Ingredient (API) Master Files (MF) and FPP submissions to WHO PQ
- Assess Dandong Beiqi Pharmaceutical Co. Ltd for Prothionamide API, for which a WHO PQ APIMF was submitted last year
- Visit NCPC Huasheng to follow up with their Capreomycin API project following a WHO PQ inspection
- Meet with Fuzhou Fuxin on the Kanamycin API project for WHO PQ
- Interview candidates for a PQM consultant on WHO PQ projects in China

Overview of Activities

April 22-26, 2013

Currently, Reyoung Pharma is producing Streptomycin FPP for export, and they are interested in producing Capreomycin FPP for WHO PQ. Dr. Hong conducted a GMP gap analysis assessment, with assistance from PQM consultant, Dr. Andre Van Zyl. The inspection report will be issued separately.

April 29-30, 2013

Dr. Hong visited NCPC Huasheng Pharma to follow up on their Capreomycin API project. A WHO PQ team inspected NCPC Huasheng in July 2012 with minor observations. The company completed their corrective and preventive actions (CAPAs) in early 2013. The WHO PQ inspection report should be ready in a few weeks.

May 2-3, 2013

Dr. Hong visited HEC Pharma to provide TA for their WHO PQ Levofloxacin FPP and Moxifloxacin FPP projects. HEC Pharma is expected to submit the Levofloxacin APIMF and Levofloxacin FPP dossier to WHO PQ by the end of May 2013. Their Moxifloxacin APIMF and FPP dossiers are being prepared and should be submitted by the end of June 2013.

May 6-8, 2013

Dr. Hong assessed Beiqi Pharma for their Prothionamide API WHO PQ project. This company has a good facility and new equipment for this API. There were some observations made in order to prepare for a future WHO PQ inspection. During this visit, some technical issues were addressed for their

Prothionamide APIMF, which was already submitted to WHO PQ. The assessment report will be issued separately.

May 9, 2013

Dr. Hong held a meeting with Fuzhou Fuxin Management to discuss the progress of their Kanamycin APIMF and future WHO PQ inspection. Everything is ready except the filter validation. PQM is in discussions with third party technical experts to address this issue.

May 10-11, 2013

Dr. Hong interviewed several candidates for the China consultant position, and will provide recommendations to PQM management.

Company Name	Project	Status	Next Steps
Reyoung Pharmaceutical Co. Ltd.; Yiyuan City, Shandong Province	Capreomycin FPP	PQM completed a GMP gap analysis.	Reyoung Pharma will complete CAPAs based on the GMP gap analysis.
NCPC Huasheng Pharmaceutical Co. Ltd.; Shijiazhuang, Hebei Province	Capreomycin API	WHO PQ inspection was completed in July 2012; CAPAs were submitted in 2013 Q1.	WHO PQ approval should occur in the coming weeks.
HEC Pharmaceutical Co. Ltd.; Dongguan, Guangdong Province	Levofloxacin API and FPP Moxifloxacin API and FPP	Levofloxacin APIMF and FPP dossier submitted to WHO PQ in May.	Moxifloxacin APIMF and FPP dossier will be submitted to WHO PQ in June 2013.
Liaoning Beiqi Pharmaceutical Co. Ltd.; Dandong, Liaoning Province	Prothionamide API	Prothionamide APIMF submitted to WHO PQ. PQM conducted a GMP assessment.	Prepare for a future WHO PQ inspection.
Fuzhou Fuxin Pharmaceutical Co. Ltd.; Fuzhou, Fujian Province	Kanamycin API	Validation batches for the APIMF submission to WHO PQ completed.	PQM is assisting them to resolve issues with the filter validation.

Conclusion

The trip to China was successful, with Dr. Hong completing GMP assessments for two companies and providing TA for three others who have anti-TB medicine projects in the pipeline. One company is expecting to receive WHO PQ in the coming weeks. In addition, Dr. Hong was able to interview potential candidates for PQM's China consultant position.