

Meetings with Pharmaceutical Manufacturers

China

Feb 25- Mar 8, 2013

Trip Report

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Executive Summary

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

One company would like to participate in PQM's Kanamycin Original Equipment Manufacturer (OEM) project, while a total of four companies are interested in pursuing WHO PQ for several anti-tuberculosis medicines, including Capreomycin, Levofloxacin, Moxifloxacin, and Clofazimine. PQM is assisting the final company in responding to WHO PQ questions on their Prothionamide submission.

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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
DQI	Drug Quality and Information Program
FPP	Finished Pharmaceutical Product
GMP	Good Manufacturing Practices
MF	Master File
OEM	Original Equipment Manufacturer
PQ	Prequalification
PQM	Promoting the Quality of Medicines Program
TB	Tuberculosis
U.S. FDA	United States Food and Drug Administration
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 related to current Good Manufacturing Practices (GMP or cGMP) 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 Ausia Biotech and Shandong Reyoung Pharmaceutical to discuss their interest in submitting Capreomycin Finished Pharmaceutical Product (FPP) to WHO PQ
- Assist HEC Pharmaceutical in submitting Levofloxacin and Moxifloxacin Active Pharmaceutical Ingredient (API) Master Files (MFs) and FPP submissions to WHO PQ within three months
- Visit Shenyang Chengda Biotech, U.S. Food and Drug Administration (U.S. FDA) approved facility, to discuss the possibility of their hosting a Kanamycin FPP Original Equipment Manufacturer (OEM) project
- Visit Nanjing Liye to discuss their interest in submitting Clofazimine API MF and FPP to WHO PQ
- Visit Suzhou Kaiyuan Minsheng Science Tech to discuss their interest in submitting their Prothionamide API MF to WHO PQ

Overview of Activities

February 25-27, 2013

Dr. Hong visited Ausia Biotech Co. Ltd., to discuss their interest in WHO PQ for Capreomycin FPP, and Shenyang Chengda Biotech Company’s U.S. FDA approved injectable solution process line, to discuss their interest in WHO PQ for Kanamycin FPP.

February 28 - March 1, 2013

Dr. Hong visited HEC Pharma to discuss their Levofloxacin and Moxifloxacin API MF and FPP filings for WHO PQ.

March 4-8, 2013

Dr. Hong visited Shandong Reyoung Pharmaceutical Co. Ltd. to discuss their Capreomycin FPP filing process with WHO PQ. He also visited Nanjing Liye Pharmaceutical Co. Ltd. to discuss their Clofazimine FPP project. Lastly, he visited the Suzhou Kaiyuan Minsheng Science Tech Co. Ltd. to assess their Prothionamide API process for WHO PQ.

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

Company Name and Location	Project	Status	Next Steps
Ausia Biotech Co. Ltd. Hangzhou, Zhejiang Province	Capreomycin FPP	This is the first time PQM assessed this company on this project. The cGMP status of the equipment is a concern.	The company is evaluating their cGMP gaps and will discuss their next steps by June 2013.
Shenyang Chengda Biotech Co. Ltd. Shengyang, Liaoning Province	Kanamycin FPP	The U. S. FDA inspected their injectable products in Jan 2013 with minor observations. The company is interested in participating in the Kanamycin OEM project.	The company is waiting for PQM to implement the OEM Kanamycin FPP project.
HEC Pharmaceutical Co. Ltd. Dongguan, Guangdong Province	Levofloxacin API and FPP Moxifloxacin API and FPP	This company submitted Levofloxacin to the U.S. FDA and Moxifloxacin to the European Directorate for the Quality of Medicines and Healthcare.	The company agreed to convert necessary Levofloxacin files for WHO PQ API MF and FPP submissions within 3 months.
Shandong Reyoung Pharmaceutical Co. Ltd. Yiyuan, Shandong Province	Capreomycin FPP	This company currently processes Streptomycin FPP for the export market.	The company is assessing their capabilities for Capreomycin FPP.
Nanjing Liye Pharmaceutical Co. Ltd. Nanjing, Jiangsu Province	Clofazimine API and FPP	This is the only company in China that produces this medicine. The current cGMP is below international standards.	The company is assessing the possibility of submitting to WHO PQ for this medicine.
Suzhou Kaiyuan Minsheng Science and Tech Co. Ltd. Suzhou, Jiangsu Province	Prothionamide API	This company filed their API MF for this product to WHO PQ, and they will need PQM's assistance to respond to WHO questions.	PQM is helping this company address API MF issues with WHO PQ.

Conclusion

This trip was successful, with PQM visiting six companies interested in WHO PQ or PQM's OEM project. One company would like to participate in PQM's Kanamycin OEM project; two companies are interested in pursuing Capreomycin FPP for WHO PQ submission; one company is interested in pursuing Levofloxacin and Moxifloxacin API and FPP; one company is interested in pursuing Clofazimine API and FPP; and lastly, PQM is assisting one company with their Prothionamide API MF.