Meetings with Pharmaceutical Manufacturers in China

China

April 5-30, 2012

Trip Report

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PROMOTING THE QUALITY OF MEDICINES

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Executive Summary

Dr. Allan Hong held meetings with fourteen manufacturers in China to discuss their interest in and progress toward World Health Organization (WHO) Prequalification (PQ) for second-line anti-tuberculosis medicines, as well as the technical assistance that PQM can offer to them.

With PQM assistance, three of those companies expect to reach WHO PQ in the near future, and PQM is prepared to assist the others attain the same goal.

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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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    - Jiaofeng HONG, Site General Manager
    - Qi CHANGQING, President Office
    - Martha HUANG, Quality Director
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ACRONYMS

API	Active Pharmaceutical Ingredient
ARV	Antiretroviral
CAPA	Corrective and Preventive Action
DQI	Drug Quality and Information Program
EDQM	European Directorate for the Quality of Medicines and Healthcare
FPP	Finished Pharmaceutical Product
GMP	Good Manufacturing Practices
PQ	Prequalification
PQM	Promoting the Quality of Medicines Program
SOP	Standard Operating Procedure
TA	Technical Assistance
TB	Tuberculosis
US 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 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 purpose of this trip was to meet with fourteen pharmaceutical companies to discuss their interest in and progress toward WHO PQ for second-line anti-tuberculosis medicines, as well as the technical assistance (TA) that PQM can offer to them.

Overview of Activities

April 5-30, 2012

Dr. Hong met with staff from fourteen pharmaceutical companies to discuss the process of applying for the WHO PQ Program for second-line anti-tuberculosis medicines and the technical assistance that PQM can provide along the way. For each interested company, details were discussed regarding the products to be submitted for WHO PQ, the status of the facility, dossier questions, and bioequivalence testing. For the companies who are already in the process of applying for WHO PQ, the project status and milestone deliverables were reviewed. No formal audits were performed.

For explanations of the acronyms used in the chart, please refer to the master acronym list on page 6.

Company Name	Project	Status	Next Steps
Zhejiang Second Pharma	Isoniazid API	WHO PQ inspection was conducted April 18-20.	PQM will visit May 28-29 to help with CAPAs.
NCPC Huasheng Pharma	Capreomycin API	WHO PQ inspection will be conducted July 9.	PQM will visit May 24-25 to perform a mock audit.
Fuzhou Fuxin Pharma	Kanamycin API	Based on WHO's observations, PQM helped the company create a CAPA plan.	PQM will provide CAPAs help by early June and will schedule a follow-up visit later in the year.
Zhejiang Hisun Pharma	Capreomycin FPP	PQM reviewed their new facility/equipment qualifications & other SOPs.	PQM will visit May 21-23 to perform a mock audit.
Shangyu Jinxin Pharma	Levofloxacin API	The company is preparing for an EDQM inspection.	The company will complete the WHO PQ dossier and submit by July 30.
Zhejiang Xinhua Pharma	Levofloxacin API	The company just passed a U.S. FDA inspection on ARVs. PQM helped them to begin the WHO PQ process for Levofloxacin API.	PQM will continue to provide TA on dossier preparation. Submission is scheduled for August 31.

Zhejiang Yongning Pharma	Amikacin API, Ofloxacin API	This company has 6 sterilized APIs approved by U.S. FDA. PQM signed a WHO PQ agreement with them in Feb.	WHO PQ dossier preparation is in progress. Submission is scheduled for September 30.
Zhejiang Dankong Pharma	Moxifloxacin API	This company has a U.S. FDA approved API. PQM helped with their 3 validation batches' stability studies.	PQM will visit in July to perform a mock audit. Submission is scheduled for August 31.
Shanghai Fosun Pharma/Guilin Pharma	Prothionamide API, FPP	This company has WHO PQ for antimalarials. PQM helped them with comparator product and new site transfer qualification.	The company needs to separate API from FPP for WHO PQ; waiting for WHO PQ's input on new site qualification.
Shandong Qilu Pharma	Amikacin FPP	PQM completed TA on pre-dossier assembly. The production batch was completed.	Within the next few weeks, the company will decide when to start dossier preparation.
Shanghai Hefeng Pharma	Amikacin FPP	PQM provided TA on pre-dossier assembly.	This company will decide when to start bio-batch for dossier preparation.
Yichang Humanwell Pharma	Amikacin FPP	PQM made a preliminary assessment on their facility/equipment and quality system during this visit.	This company is evaluating whether to proceed for WHO PQ on this product.
Zhejinag Starry Pharma	Moxifloxacin API	This company has Levofloxacin already approved by Japanese regulatory authority.	This company is evaluating whether to proceed for WHO PQ on this product.
Hebei Shengxue Dacheng Pharma	Streptomycin API	At WHO PQ's request, PQM helped this company on post-WHO PQ inspection.	Further TA will be provided based on their inquiry.

Conclusion

This visit to China to meet with second-line anti-TB medicine manufacturers was successful in introducing PQM's technical assistance to fourteen companies. With PQM assistance, three of those companies expect to reach WHO PQ in the near future, and PQM is prepared to assist the others attain the same goal.