World Health Organization Prequalification Workshop and Meetings with Anti-Tuberculosis Medicines Manufacturers

China

June 20- June 27, 2013

Trip Report

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Executive Summary

Dr. Allan Hong traveled to China in June to participate in the CPhI World Health Organization (WHO) Prequalification (PQ) workshop, meet with and provide technical assistance (TA) to medicine manufacturers regarding the development of their WHO PQ projects, and identify Chinese manufacturers for potential neglected tropical diseases (NTD) projects for WHO PQ.

The CPhI workshop was well attended, and Dr. Hong was able to discuss the TA that PQM can provide to manufacturers pursuing WHO PQ. In addition, Dr. Hong was able to identify two Chinese manufacturers for potential NTD projects and provide TA to several other manufacturers on their current WHO PQ projects.

Of particular note is that one company, Hebei Shengxue Dacheng Pharmaceutical Co. Ltd., has received Spanish Government approval for their Streptomycin active pharmaceutical ingredient (API) following PQM technical assistance.

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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
NTD	Neglected Tropical Diseases
PQ	Prequalification
PQM	Promoting the Quality of Medicines Program
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 (TA) related to current Good Manufacturing Practices (GMP) to interested companies on the preparation of the 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:

1. Participate in the CPhI WHO PQ workshop in Shanghai
2. Meet with and provide TA to manufacturers regarding the development of their WHO PQ projects
3. Identify Chinese manufacturers for neglected tropical diseases (NTD) projects for WHO PQ

Overview of Activities

June 20-21, 2013
Dr. Hong visited Beijing Yabao Pharmaceutical Co. Ltd to discuss their Ofloxacin finished pharmaceutical product (FPP) project for WHO PQ. Some technical issues related to the formulations were discussed, and dissolution studies between pre-formulation samples and comparator products were reviewed. During this meeting, some immediate tasks to speed up formulation development were identified.

June 25-26, 2013
Dr. Hong participated in a WHO PQ workshop hosted by CPhI. Approximately 80 people attended the workshop that covered medicines for HIV/AIDS, malaria, TB, reproductive health, and NTDs. This workshop introduced the WHO PQ Program's requirements and processes for registration and site inspection. PQM's ability to provide TA to manufacturers who are pursuing WHO PQ was also discussed. Dr. Hong answered several technical questions on registration and inspections. During the conference, Dr. Hong identified two Chinese manufacturers for potential NTD projects.

June 27, 2013
Dr. Hong met with:

- Hebei Shengxue Dacheng Pharma to discuss Spanish Government approval for their Streptomycin API, based on PQM's suggestions for corrective and preventive actions (CAPAs) for their WHO PQ inspection.
- Reyoung Pharmaceutical Co. Ltd. to discuss their Capreomycin FPP project, which is in the preparation stage.
- Jiangsu Yabao Pharmaceutical Co. Ltd.'s General Manager to discuss PQM's potential mock audit on their Mebendazole API for WHO PQ inspection in September 2013.
- Nanjing Pharmaceutical Co. Ltd. to discuss potential help from PQM on their Albendazole API and FPP for WHO PQ.

Company Name and Location	Project	Status	Next Steps
Reyoung Pharmaceutical Co. Ltd.; Yiyuan City, Shandong Province	Capreomycin FPP	Based on a PQM GMP gap analysis, Reyoung Pharma is nearing completion of their CAPAs.	The company is in the process of completing media fill simulation. Registration batches are planned for August 2013.
Hebei Shengxue Dacheng Pharmaceutical Co. Ltd.; Shijiazhuang, Hebei Province	Streptomycin API	Obtained Spanish Government approval on their Streptomycin API.	PQM will coordinate with WHO PQ on the API Master File dossier requirements for the company and assess if another inspection is needed from WHO PQ.
Beijing Yabao Pharmaceutical Co. Ltd.; Beijing	Ofloxacin FPP	This company is in the product development stage.	A registration batch is planned for December 2013.
Jiangsu Yabang Pharmaceutical Co. Ltd.; Dandong, Liaoning Province	Mebendazole API	This company is expecting WHO PQ inspection in September 2013.	PQM may provide a potential mock inspection to Jiangsu Yabang Pharma.
Nanjing Pharmaceutical Co. Ltd.; Nanjing	Albendazole API and FPP	The company recently developed API and FPP processes for Albendazole.	PQM will monitor this project and provide TA to the company if NTD funds materialize.

Conclusion

The trip to China was a success. The CPhI workshop was well attended, and Dr. Hong had an opportunity to discuss the TA that can be provided to companies pursuing WHO PQ. In addition, Dr. Hong was able to identify Chinese manufacturers for potential NTD projects and provide TA to several manufacturers on their current WHO PQ projects.