

Meetings with Pharmaceutical Manufacturers in the Greater China Region and South Korea

August 6-31, 2012

Trip Report

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Executive Summary

In order to assess interest in and readiness for the World Health Organization (WHO) Prequalification (PQ) program for second-line anti-tuberculosis medicines, Dr. Allan Hong performed Good Manufacturing Practices (GMP) audits for two companies in South Korea and China, visited five companies in Taiwan and China, and attended the Hong Kong Pharmaceutical Exhibition to meet with three regional pharmaceutical companies.

Table of Contents

<u>Acknowledgements</u>	4
<u>Acronyms</u>	6
<u>Background</u>	7
<u>Purpose of Trip</u>	7
<u>Overview of Activities</u>	7
<u>Conclusion</u>	9

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
GDF	Global Drug Facility
GMP	Good Manufacturing Practices
OEM	Original Equipment Manufacturer
PQ	Prequalification
PQM	Promoting the Quality of Medicines Program
TA	Technical Assistance
TB	Tuberculosis
TGA	Therapeutic Goods Administration (Australia)
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 purposes of this trip were to:

- Meet with Asian pharmaceutical companies in Taiwan, Hong Kong, and China to discuss their interest towards pursuing WHO PQ for second-line anti-tuberculosis medicines as well as the technical assistance that PQM can provide
- Audit Enzychem’s (South Korea) Cycloserine active pharmaceutical ingredient (API) process and Hisun Pharma’s (China) PAS, Cycloserine, and Moxifloxacin API processes
- Attend the Hong Kong Pharmaceutical Exhibition

Overview of Activities

August 6-10, 2012

Dr. Hong introduced the WHO PQ program to Shijiazhuang Pharma Group Company and NPC New Formulation Company to gauge interest in the WHO PQ program and the technical assistance that PQM can provide. Dr. Hong also provided hands-on corrective and preventive action (CAPA) technical assistance to Hebei Shengxue Pharma, NCPC Huasheng Pharma, and Fuzhou Fuxin Pharma based on the findings from earlier inspections carried out by the WHO PQ program.

August 13-17, 2012

Dr. Hong visited Taiwan Peili Pharma to gauge their interest in the WHO PQ program. In addition, Dr. Hong attended the Hong Kong Pharmaceutical Exhibition to meet with Yick-Vic Chemical and Pharma Company, Hong Kong Interpharma Access Company, and Baush Pharma Hong Kong to introduce the WHO PQ program to them.

August 20-24, 2012

Dr. Hong performed a full audit on South Korea’s Enzychem Lifescience Corporation for their Cycloserine API process and provided a gap analysis for potential application to the WHO PQ program.

August 27-31, 2012

Dr. Hong visited Sagent Kong Hong Pharma and Chengdu Shengnuo Biotechnology to gauge interest in the WHO PQ program. Dr. Hong also conducted a mock audit of Zhejiang Hisun for their PAS, Cycloserine, and Moxifloxacin API processes for potential application to the WHO PQ program.

Details of these activities are included in the chart below. 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
Shijiazhuang Pharma Group Company, Shijiazhuang City, Hebei Province, China	Kanamycin FPP	Company made Kanamycin FPP for Vietnam in the past.	They will evaluate participating in WHO PQ for Kanamycin FPP.
Hebei Shengxue Pharma Group Co, Shijiazhuang City, Hebei Province, China	Streptomycin API	CAPA plan based on WHO PQ inspection was reviewed and recommendations made. Critical part of CAPA plan was emphasized.	Once CAPAs are completed, PQM will review the document before it is sent to WHO PQ.
NCPC Huasheng Pharma, Shijiazhuang City, Hebei Province, China	Capreomycin API	CAPA plan was reviewed based on WHO PQ inspection. WHO PQ accepted their GMP status.	PQM will help them complete all CAPAs before the CAPA document is sent to WHO PQ.
NCPC New Formulation Co., Shijiazhuang City, Hebei Province, China	second-line anti-TB medicine	The company has made investments in a new plant. They are interested in WHO PQ.	They will evaluate participating in WHO PQ.
Fuzhou Fuxin Pharma, Fuzhou City, Fujian Province, China	Kanamycin API	They started with a CAPA plan based on WHO PQ inspection.	PQM encouraged them to complete the CAPAs to comply with WHO PQ by providing the TA needed to pass the next WHO PQ inspection.
Taiwan Peili Pharma Co., Taizhong City, Taiwan	Levofloxacin, Cycloserine, Prothionamide, and PAS FPPs	Currently, their facility is approved by Japanese pharma companies by OEM. PQM provided GDF forecasts to them.	This company will assess the possibility of going for WHO PQ for any of their products.
Hong Kong Yick-Vic Chemical & Phama Co., Hong Kong, China	Second-line anti-TB medicine	PQM provided the WHO PQ second-line anti-TB medicine list and GDF forecasts.	This company will assess the possibility of going for WHO PQ for any of their products.
Interpharma Access Hong Kong, Hong Kong, China	Kanamycin FPP	This company has TGA approved process that is OEM for Sandoz.	This company will assess the possibility of going for WHO PQ for any of their products.
Baush Pharma Hong Kong, Hong Kong, China	Capreomycin FPP	This company has a WHO PQ approved process for HIV injectable Gancyclovir.	This company will assess the possibility of going for WHO PQ for any of their products.
Enzychem Lifescience Corp., Yusung-Ku, Taejon City, Korea	Cycloserine API	PQM conducted a full audit of their Cycloserine API process.	The audit report has been issued separately. The company will evaluate participating in WHO PQ.

Sagent Kong Hong Pharma, Chengdu City, Sichuan Province, China	Capreomycin & Kanamycin FPPs	This company has a US FDA approved production line. PQM introduced the WHO PQ program to them.	The company will evaluate participating in WHO PQ.
Chengdu Shengnuo Biotechnology Co., Chengdu City, Sichuan Province, China	Capreomycin & Kanamycin FPPs	This company has a US FDA approved process for peptide API.	The company will evaluate participating in WHO PQ.
Zhejiang Hisun Pharma, Jianjiang City, Zhejiang Province, China	PAS, Cycloserine, & Moxifloxacin APIs	PQM conducted a WHO PQ mock audit in the plant and ask them to pursue API MF filing.	The audit report has been issued separately. They will consider the filings.

Conclusion

During this trip, Dr Hong provided hands-on CAPA technical assistance to three pharmaceutical companies in China, based on WHO PQ inspection findings, and audited two pharmaceutical companies in South Korea and China for four API projects. One project is for potential WHO PQ filing and another three projects are for WHO PQ submissions. Dr. Hong also met with three companies in Hong Kong during the Hong Kong Pharmaceutical Exhibition and had five company visits in Taiwan and China to introduce the WHO PQ program for second- line TB medicines.