

Meetings with Pharmaceutical Manufacturers in the Greater China Region

November 19-23, 2012

Trip Report

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PROMOTING THE QUALITY OF MEDICINES

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Executive Summary

Dr. Allan Hong held meetings with six pharmaceutical manufacturers in the Greater China Region to discuss their interest in the Original Equipment Manufacturer (OEM)/contract manufacturing business model towards World Health Organization (WHO) Prequalification (PQ) for second-line anti-tuberculosis medicines, as well as the technical assistance that PQM can offer to them.

After the meetings, three pharmaceutical manufacturers were advanced to the next phase of feasibility studies for the OEM/contract manufacturing model.

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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
OEM	Original Equipment Manufacturer
PQ	Prequalification
PQM	Promoting the Quality of Medicines Program
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. All of these PQM activities have been free of charge to the pharmaceutical manufacturers.

Recently, due to the shortage of second-line anti-TB medicines, concerns over the cost of some medicines have been raised by USAID, especially relating to Capreomycin and Kanamycin. PQM was asked to seek pharmaceutical manufacturers who might be interested in an Original Equipment Manufacturer (OEM)/contract manufacturing business model as a potential way to provide lower-cost medicines.

The active pharmaceutical ingredients (APIs) of Capreomycin and Kanamycin are only produced in the Greater China Region. Six manufacturers with stringent regulatory approvals were identified.

Purpose of Trip

The purpose of this trip was to meet with the six identified pharmaceutical companies to discuss their existing idle capacity, potential facility compatibility, potential interest in the OEM/contract manufacturing model, and the technical assistance that PQM can provide.

Overview of Activities

November 19-23, 2012

Dr. Allan Hong held meetings with six pharmaceutical manufacturers in the Greater China Region to discuss their interest in the OEM/contract manufacturing model towards WHO PQ for second-line anti-tuberculosis medicines, as well as the technical assistance that PQM can offer to them. These six pharmaceutical companies were the only ones with stringent regulatory approval status in the Greater China Region. During the meetings, facility compatibility, idle capacity, and potential interest in OEM/contract manufacturing were discussed.

As a result of these meetings, Zhuhao United Pharma and Jiangsi Hengrui Pharma decided they could not participate in the proposed contract manufacturing model due to facility incompatibility. Sino Japanese Pharma could not participate due to a lack of idle capacity.

Baush Pharma Hong Kong, Interpharma Access Hong Kong, and Sagent Hong Kong are all proceeding with internal discussions on the OEM/contract manufacturing model.

Details of the meetings with the individual companies are included in the chart below. For explanations of the acronyms used in the chart, please refer to the master acronym list on page 5.

Company Name	Project	Status	Next Steps
Baush Pharmaceutical Hong Kong Ltd.	Capreomycin FPP	The company has been WHO approved for the FPP of an HIV medicine, it has the idle capacity, and its facility is compatible with Capreomycin FPP.	Baush Pharma will perform an internal assessment to see if the OEM/contract manufacturing model meets their profit expectations for the WHO PQ market.
Interpharma Access Hong Kong	Kanamycin FPP	The company has had a TGA approved FPP for 10 years. They are now doing OEM for Sandoz in Europe and have the idle capacity.	They will do an internal assessment on the Kanamycin OEM model.
Sagent Hong Kong Pharma JV	Capreomycin & Kanamycin FPPs	They are US FDA approved for injectables and have the idle capacity.	The company will perform an internal assessment to see if the OEM/contract manufacturing model meets their profit expectations for the WHO PQ market.
Zhuhai United Pharma, Zhuhai City, Guangdong Province, China	Capreomycin & Kanamycin FPPs	Their US FDA approved facility can only produce penicillin medicine.	Not able to participate due to facility incompatibility.
Jiangsu Hengrui Pharmaceutical Co., Liang Yun Gang City, Jiangsu Province, China	Capreomycin & Kanamycin FPPs	Their US FDA approved facility can only produce cytotoxic medicine.	Not able to participate due to facility incompatibility.
Sino Japanese Pharma Tianjin Co., Tianjin City, Hebei Province, China	Capreomycin & Kanamycin FPPs	Their facility was approved by the Japan Government and they are doing OEM for Japanese companies.	Not able to participate due to lack of capacity.

Conclusion

This visit to the Greater China Region to meet with second-line anti-TB medicine manufacturers who are the potential candidates for PQM's OEM/contract manufacturing model in the region was successful. After the meetings, there are three pharmaceutical manufacturers who are moving into the next stages of feasibility studies.