

Meetings with Korean Pharmaceutical Manufacturers and Korean National Tuberculosis Association and Stop-TB Partnership Korea

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Trip Report

Jennifer Derry
Associate GMP Specialist

Promoting the Quality of Medicines

Implemented by U.S. Pharmacopeia

12601 Twinbrook Parkway

Rockville, MD 20852 USA

Tel: (+1) 301-230-3275

Fax: (+1) 301-816-8374

Email: jxd@usp.org

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Author(s) Name: J. Derry

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Executive Summary

Ms. Derry held meetings with seven manufacturers in Korea who were either interested in discussing the process of applying for World Health Organization (WHO) Prequalification (PQ) of second-line anti-tuberculosis medicines and the technical assistance that PQM can provide, or to follow up on their PQ process.

Ms. Derry met with the President of the Korean National Tuberculosis Association and Manager of Stop TB Partnership Korea to explain the assistance that PQM is providing to the pharmaceutical manufacturers in Korea.

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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

DQI	Drug Quality and Information Program
GMP	Good Manufacturing Practices
PQ	Prequalification
PQM	Promoting the Quality of Medicines Program
TB	Tuberculosis
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 each pharmaceutical company that showed interest in the WHO Prequalification program during PQM’s October 2011 visit and to discuss individual products for potential submission to the WHO PQ Program.

Overview of Activities

Ms. Derry visited seven Korean companies to discuss the process of applying for the WHO PQ Program for second-line anti-TB medicines and the technical assistance that PQM can provide along the way. For each company, details were discussed regarding the products to be submitted for WHO PQ, the status of the facility, dossier questions, and bioequivalence testing; no audits were performed.

Company	Meeting Outcome
Chong Kun Dang Pharm	Trying to obtain market analysis on product of interest and approval from management to continue with PQ
Dong-A Pharm	Response to third round of queries from WHO was sent for Cycloserine active pharmaceutical ingredient (API) and finished pharmaceutical product (FPP) dossiers; in the process of finalizing analytical methods for next product for PQ
EnzyChem Lifesciences	Facility tour was done; in the process of modifying the finished product storage area to separate cephalosporin and non-cephalosporin products
Ildong Pharm	No longer interested in pursuing PQ due to potential FPP manufacturer not being interested in purchasing API
Korea United Pharm	Very interested in pursuing PQ; asked a lot of questions to obtain information for management approval
Sinil Pharmaceutical	Interested in PQ but does not have product in proper dosage
Yuhan Corporation	PQM currently reviewing the CDA sent by Yuhan; will be scheduling a baseline GMP audit

Next Steps

- PQM will begin working with companies to obtain questionnaires and initiate the PQ process as quickly as possible. As of the writing of this report, questionnaires have been emailed to representatives from each company for completion.
- Yuhan Corporation and EnzyChem Lifesciences are discussing having baseline GMP audits of their facilities. They will communicate with PQM after decisions are made.
- PQM will contact WHO PQ to see if a review can be performed for Dong-A prior to the July Assessment meeting.

Conclusion

Overall, the companies were very receptive and eager to pursue WHO PQ. Most companies have agreed to meet internally to discuss which product(s) they would like to pursue and to complete the questionnaire. A baseline audit of manufacturing facilities will be scheduled for companies that decide to start their PQ process.