

Dossier Presentation and Review at JSC Kievmedpreparat (Arterium Corporation)

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Trip Report

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Promoting the Quality of Medicines

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Executive Summary

Ms. Derry, Mr. Burimski, and Ms. Morozova traveled to Ukraine to visit Arterium Corporation, where Ms. Derry gave a presentation on common deficiencies in dossier submissions for World Health Organization Prequalification.

Following the presentation, the Capreomycin and Streptomycin dossiers were reviewed. The Capreomycin dossier was submitted to WHO and has been accepted for review, and the Streptomycin dossier is in process. PQM will make a return trip in January 2013 to conduct a mock inspection in preparation for the WHO inspection in February 2013.

While in country, PQM also met with USAID/Ukraine to debrief them on Arterium's progress and discuss possible future collaboration. In addition, PQM met with the State Administration of Ukraine on Medicinal Products. The State Administration is happy to support PQM activities in Ukraine and will assist in identifying other second-line anti-TB medicine manufacturers in Ukraine. The State Administration is hopeful that USAID/Ukraine will provide funding for PQM to combat poor quality medicines in Ukraine.

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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

PQM staff traveled to Ukraine to give a presentation on the most common deficiencies observed in dossiers submitted to the WHO PQ Program and to review the Capreomycin dossier from JSC Kievmedpreparat for submission to WHO.

Overview of Activities

Ms. Derry gave a presentation on common dossier deficiencies to participants from JSC Kievmedpreparat, JSC Halychpharm, and Arterium Corporation (Arterium is the parent organization and Kievmedpreparat and Halychpharm are sister companies). Following the presentation, the Capreomycin and Streptomycin dossiers were reviewed.

The Capreomycin dossier was submitted to WHO and has been accepted for review. PQM will provide technical assistance in responding to WHO’s queries once they are received by Arterium. The WHO inspection for Capreomycin has been confirmed for February 11-15, 2013. In preparation for the inspection, PQM will return to Arterium to perform a mock inspection in January 2013.

Once internal comments are addressed on the Streptomycin dossier, Arterium will send the draft to PQM for review.

Additional Meetings

PQM staff met with the staff of the USAID/Ukraine Office of Health and Social Transition on November 29 to brief them about the visit to Arterium and to describe the type of support provided by PQM in this and other regions:

- Providing technical assistance to manufacturers of second-line anti-TB medicines in reaching WHO PQ
- Establishing medicines quality monitoring programs with Minilabs[®] as part of post-marketing surveillance
- Collaboration with medicine regulatory authorities, including conducting laboratory training courses for the staff of central and regional medicines quality control laboratories and providing technical assistance to the laboratories in reaching WHO PQ and ISO 17025 accreditation

PQM can carry out similar activities in Ukraine if there is an interest and the funds are provided by USAID/Ukraine. USAID/Ukraine staff responded that they will take this into consideration. In addition, USAID/Ukraine staff requested information on Minilab[®] projects.

A meeting was also held at the office of the State Administration of Ukraine on Medicinal Products. PQM staff briefed them about the purpose of the current trip and the status of the project with Arterium. The staff of the State Administration was happy to hear that Arterium is close to prequalification on one

of its medicines and wishes that other local manufacturers would join the program as well. They have agreed to support PQM in identifying other Ukrainian second-line anti-TB medicine manufacturers which could benefit from receiving technical assistance from PQM.

PQM also informed the State Administration staff about its meeting with USAID/Ukraine. The Administration staff expressed hope that PQM will get funding from USAID/Ukraine so that projects to combat poor quality medicines could be carried out in the country. They also informed PQM that the head of the State Administration, Dr. Oleksiy Solovyov, recently sent a letter to the head of USAID/Ukraine requesting support for PQM's work in Ukraine (see *Annex I*).

Next Steps

- PQM will provide technical assistance to Arterium in responding to any WHO queries on the Capreomycin dossier
- PQM will assign a team to perform a mock inspection at Arterium in January 2013
- Once internal comments have been made, Arterium will send the Streptomycin dossier to PQM for review, prior to submission to WHO
- PQM will visit USAID/Ukraine and the State Administration during the upcoming January 2013 trip to continue discussions regarding the possibility of conducting activities related to improving medicine quality
- PQM will provide information on Minilab[®] projects to USAID/Ukraine

Conclusion

The PQ process for Capreomycin from JSC Kievmedpreparat is proceeding well, and the company is awaiting queries from WHO. In the meantime, the company is preparing the dossier for Streptomycin.

The State Administration would like to support PQM activities in Ukraine and hopes that PQM will receive funding from USAID/Ukraine so that projects to combat poor quality medicines can be carried out in Ukraine.