

Good Manufacturing Practices Technical Assistance for Manufacturers of Zinc Sulfate Formulations

Tanzania

May 24-28, 2010

Trip Report

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Promoting the Quality of Medicines Program

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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 to the Drug Quality and Information program (DQI) 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 leadership 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.

Abstract

PQM visited Shelys Pharmaceuticals Ltd. to provide technical assistance on Good Manufacturing Practices corrective action implementation and Zenufa Laboratories Ltd. to learn about their zinc syrup launch.

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Key Words

Shelys Pharmaceuticals Limited (SPL), Zenufa Laboratories Limited (ZLL), Good Manufacturing Practices, Dossier, Zinc Sulfate, Prequalification

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Acronyms

AED	Academy for Educational Development
CAPA	Corrective and Preventive Action Plan
DQI	Drug Quality and Information Program
GMP	Good Manufacturing Practices
POUZN	Point-Of-Use Water Disinfection and Zinc Treatment
PQM	Promoting the Quality of Medicines Program
SPL	Shelys Pharmaceutical Limited
TA	Technical Assistance
UNICEF	United Nations Children Fund
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization
ZLL	Zenufa Laboratories Limited

Background

Since 2007, DQI/PQM has been working with Tanzania manufacturers, Shelys Pharmaceuticals Limited (SPL) and Zenufa Laboratories Limited (ZLL), in support of the Academy for Educational Development (AED) Point-Of-Use Water Disinfection and Zinc Treatment (POUZN) project to increase the availability of good quality zinc products. In 2008, UNICEF requested the World Health Organization (WHO) to add zinc tablets and oral solutions to the Prequalification Program. WHO issued a request for Expressions of Interest inviting interested manufacturers to apply for prequalification. To date, there is no prequalified manufacturer for zinc products.

SPL submitted a dossier that was accepted in September 2009 for assessment and assigned the WHO reference number DI001, the first zinc product accepted for assessment in the WHO Prequalification Program. In January 2010, a WHO Good Manufacturing Practices (GMP) team visited SPL and inspected the facility, finding “not critical” deviations. PQM is currently working with SPL to address dossier and GMP deficiencies in order to help them obtain prequalification status.

PQM has also been working with ZLL on their zinc syrup formulation by providing technical assistance (TA) on GMP and testing their product at the USP laboratory. ZLL zinc syrup complies with the USP monograph for zinc sulfate oral solutions. In 2009, ZLL was granted product registration by the Tanzania Food and Drugs Authority (TFDA) and scheduled the launch of their syrup for June 2010.

Purpose of Trip

- Evaluate SPL’s corrective action implementation, provide recommendations, and review their response to WHO queries stemming from the GMP inspection in January 2010 in order to expedite the process for prequalification
- Visit ZLL and discuss activities related to the upcoming launch of zinc syrup
- Meet with USAID/Tanzania and AED

Source of Funding

This trip was supported by USAID Program Element 3.1.6. Maternal and Child Health.

Overview of Activities

Please see *Annex 1* for the visit agenda.

May 26 –27, 2010

Meeting with Shelys Pharmaceutical Limited (SPL)

Mr. Toledo visited SPL and performed a facility walkthrough to evaluate the Corrective Actions implementation put in place as a result of the January 2010 WHO GMP inspection findings. SPL has invested around \$200,000 in equipment, consultants, and validation activities. The facilities looked to be in a good state of cleanliness and repair: the exterior corridors are being paved to minimize dust, warehouses are being remodeled to ease cleaning and maintenance, interior corridors and doors are being painted and repaired, and new manufacturing and utility equipment was acquired and scheduled for calibration.

SPL’s corrective action plan should be fully implemented by September 2010. The first status report was sent to WHO in March 2010 with a corrective plan and timeline for implementation. Most of the standing issues were acknowledged by WHO in their May 18 response to SPL, but more evidence of corrective actions was requested. SPL is drafting a

second status report to be sent to WHO by June 18, 2010. Mr. Toledo reviewed SPL's draft report and provided recommendations on corrective action implementation, to include a risk analysis evaluation and report.

SPL is in the middle of a restructuring activity as part of plans from Aspen Pharmaceutical, the company that acquired SPL in May 2008. These activities will include implementing a quality culture in line with Aspen corporate quality systems.

May 27, 2010

Meeting with AED

Mr. Toledo met with Mr. Bongo Mgeni, Country Coordinator for the AED-POUZN Project in Tanzania, to discuss the status of Tanzania manufacturers. Mr. Toledo provided details of the TA that PQM is providing to SPL and ZLL. Mr. Mgeni informed Mr. Toledo that the Tanzania AED-POUZN Project will be ending by September 2010 and inquired about SPL's prequalification status. Mr. Toledo explained that SPL should be in good position for prequalification by September 2010.

Meeting at USAID

Mr. Toledo and Mr. Mgeni visited USAID/Tanzania to debrief Dr. Raz Stevenson on the activities with zinc manufacturers in Tanzania and the plans to help SPL become prequalified. Dr. Stevenson was very interested in SPL's GMP prequalification status because the Mission would like to roll out zinc in Tanzania from a prequalified source. Mr. Toledo briefly explained the WHO prequalification program and informed him that SPL has been proactive in implementing WHO's recommended corrective actions, which are scheduled to be fully implemented by September 2010.

May 28, 2010

Meeting with Zenufa Laboratories Limited (ZLL)

Mr. Toledo visited ZLL's manufacturing site to discuss the upcoming zinc sulfate syrup launch. ZLL was granted registration for zinc in December 2009, and the product launch is scheduled for June 2010. Mr. Toledo discovered that ZLL has entered into an agreement with Nutriset to manufacture and distribute zinc tablets in Tanzania through technology transfer, and the zinc tablet launch is scheduled for January 2011. Technology transfer activities were initiated May 27-28, 2010 with a visit from Nutriset technical staff.

ZLL management informed Mr. Toledo that they are willing to pursue prequalification for zinc sulfate syrup formulation, following the launch.

Conclusion

PQM objectives for the trip were met. PQM provided recommendations to SPL for their upcoming WHO report, and the ZLL zinc syrup launch continues as planned for June 2010.

Next Steps

- Ensure that SPL submits the WHO report by June 18
- Perform compendial testing on SPL zinc tablets and ZLL zinc syrup at USP lab
- Continue providing TA to SPL and ZLL toward WHO prequalification

PQM Visit Agenda | May26-28, 2010

Date	Visit	Contact
May 26 (Wednesday)	Shelys	Ashok Gupta
May 27 (Thursday)	Shelys	Ashok Gupta
May 27 (Thursday)	AED	Bongo Mgeni
May 27 (Thursday)	USAID	Raz Stevenson
May 28 (Friday)	Zenufa	Krishor Athalye