

Good Manufacturing Practices Assessments of Lomus Chlorhexidine 7.1% Gel Manufacturing Activities

Kathmandu, Nepal

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Trip Report

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Promoting the Quality of Medicines

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Executive Summary

Dr. Chibwe and Mr. Toledo traveled to Nepal to perform a Good Manufacturing Practices (GMP) assessment of Lomus Pharmaceutical Pvt. Ltd. The assessment revealed that the firm has the capabilities, facilities, infrastructure, knowledge, and skills necessary to manufacture chlorhexidine products. All the non-compliances and opportunities for improvement observed during the assessment were listed in a separate confidential report sent directly to the manufacturer.

In addition to the assessment, meetings were held with Mrs. Leela Khanal, Project Manager for the Chlorhexidine Navi Care Program, to learn about Nepal's chlorhexidine project implementation, and with Deurali-Janta Pharmaceuticals, to discuss their dossier compilation status regarding levofloxacin.

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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

CAPA	Corrective and Preventive Action
CHX	Chlorhexidine
DQI	Drug Quality and Information Program
DJPL	Deurali-Janta Pharmaceutical Limited
FPP	Finished Pharmaceutical Product
GMP	Good Manufacturing Practices
JSI	John Snow Incorporated
MCH	Maternal and Child Health
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

The United Nations Commission on Life-Saving Commodities for Women and Children was established to focus on 13 essential health commodities to assure that they have the medicines and other supplies needed to achieve the relevant Millennium Development Goals. In support of the UN Commission, PQM will provide technical assistance on Good Manufacturing Practices (GMP) and quality assurance to manufacturers of selected medicines such as: chlorhexidine (CHX), oxytocin, misoprostol, and magnesium sulfate formulations, all of which are priority commodities for the UN Commission.

Tuberculosis (TB) is also 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 Program.

Purpose of Trip

The main purpose of the trip was to evaluate current CHX formulation manufacturing activities at Lomus Pharmaceuticals. Lomus is the only manufacturer that produces CHX 7.1% gel, and other countries are interested in procuring CHX from Lomus. Secondary purposes included meeting with Leela Khanal, Project Manager for CHX Navi Care Program, to discuss CHX rollout in selected African countries, and discussing the project status of levofloxacin, an anti-TB medicine, with Deurali-Janta Pharmaceutical.

Source of Funding

This trip was funded by USAID for Core MCH and TB.

Overview of Activities

Manufacturer	Products	Status	Next Steps
Lomus	Chlorhexidine Gel	The assessment revealed that the firm has the capabilities, facilities, infrastructure, knowledge, and skills necessary to manufacture CHX products.	<ul style="list-style-type: none">• PQM sent a separate confidential report directly to Lomus that includes all the non-compliances and opportunities for improvement observed during the assessment.• Lomus will draft and submit to PQM a corrective and preventive action (CAPA) plan for the observations listed in the confidential report by mid Feb 2013.• Lomus will start implementing the CAPA plan by late Feb 2013.• PQM will visit Lomus to evaluate improvements in Apr/May 2013.
Deurali-Janta (DJPL)	Levofloxacin Finished Pharmaceutical Product	The company has started purchasing active pharmaceutical ingredient from a new vendor (Zhejiang Xinhua	<ul style="list-style-type: none">• DJPL will produce stability batches by the end of Feb 2013.• DJPL will update and submit the dossier by Aug 2013.

		Pharmaceutical) and will start manufacturing new batches for stability and process validation and will update the dossier accordingly.	
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Meeting with Leela Khanal, Project Manager, Chlorhexidine Navi Care Program

In Kathmandu, Dr. Chibwe and Mr. Toledo met with Ms. Leela Khanal, who highlighted the Nepal experience with CHX. She stated that a survey of the newly introduced intervention to reduce infant mortality indicated that immediate application of 4% CHX reduces neonatal mortality by about 23%. The USAID-funded Nepal Family Health Program II has conducted two studies: the first examined the efficacy of CHX lotion versus aqueous preparations, while the second examined the acceptability and ease of the two different formulations.

Ms. Khanal explained that there seem to be good support from the Nepali Government, which has included the CHX program as a component of essential newborn care practices. Part of the success of the CHX roll-out in Nepal seems to stem from the teamwork among non-governmental organizations, the government, and a large pool of volunteer community health workers, who have helped the program to reach women in rural parts of the country.

Ms. Khanal also noted that John Snow Incorporated (JSI) is working to support the initial CHX roll-out in Nigeria and the monitoring and evaluation of the program in Nepal.

Conclusion

The assessment revealed that Lomus needs to strengthen their quality systems as well as their facilities and infrastructure to continue to manufacture CHX gel 7.1% for international supply as part of CHX roll out activities in selected African countries, and others that may be interested. The visit to DJPL was productive as PQM provided support in dossier updating and validation activities. JSI’s involvement and experience in Nepal has demonstrated the potential impact the expected roll-out for CHX might have on Nigeria’s neonatal mortality.