

Chlorhexidine Gel Manufacturing: Rapid Assessment of Nigerian Manufacturers Submitting Expressions of Interest for PQM Technical Assistance

Lagos, Ilorin, and Abuja, Nigeria

September 9-17, 2013

Trip Report

**Lawrence Evans III, Ph.D., MPH
Global Services and Standards Development Manager**

**Edwin Toledo, ASQ-CQA
Senior GMP Specialist**

**Chimezie Anyakora, Ph.D.
PQM Consultant–Nigeria**

Promoting the Quality of Medicines
Implemented by U.S. Pharmacopeial Convention
12601 Twinbrook Parkway
Rockville, MD 20852 USA
Tel: (+1) 301-816-8389
Fax: (+1) 301-816-8374
Email: le@usp.org

Cooperative Agreement # GHS-A-00-09-00003-00
Funding Source: USAID/Nigeria Maternal and Child Health (MCH)
Grantee: Promoting the Quality of Medicines (PQM) Program
Author(s) Name: PQM staff
Language: English
Date of Publication: November 13, 2013



This report is made possible by the generous support of the American people through the United States Agency for International Development (USAID), under Cooperative Agreement No. GHS-A-00-09-00003-00. The contents are the responsibility of the Promoting the Quality of Medicines Program, implemented by the U. S. Pharmacopeia, and do not necessarily reflect the views of USAID, or the United States Government.

Executive Summary

At the request of the the United States Agency for International Development (USAID)/ Nigeria Mission, and in support of United Nation Commission activities under the Chlorhexidine Working Group (CWG), staff from the Promoting the Quality of Medicines (PQM) program traveled to Nigeria in September 2013 to visit local manufacturers who had submitted expressions of interest (EOIs) for technical assistance to manufacturers of chlorhexidine digluconate gel. Based on the EOIs received and responses to a manufacturers' questionnaire, six of the ten manufacturers submitting EOIs were identified as potentially having the capacity to manufacture the product according to international standards—Morison Industries PLC, Drugfield Pharmaceutical Ltd., Neimeth International Pharmaceutical Plc., Saro Lifecare, Emzor Pharmaceutical, and Tuyil Pharmaceutical Industries Limited. PQM performed rapid assessments of most of these companies' facilities to evaluate their capacity. As part of their CWG activities, staff from the nongovernmental organization PATH accompanied PQM on the site visits to carry out due diligence business assessments (Annex 1) of the manufacturers.

PQM also visited Chi Pharmaceutical and other manufacturers interested in producing zinc sulfate tablets that were not assessed during the previous visit.

As a result of the meetings and rapid assessments conducted, PQM determined that Drugfield, Emzor, and Tuyil each have the equipment and capability to manufacture chlorhexidine gel according to international standards and bring it to market the fastest. The other companies currently do not have either suitable infrastructure or the equipment needed to manufacture chlorhexidine and will require a longer period of time to bring to market; however, with investment and technical assistance, they should be able to produce chlorhexidine within a two- to three-year period.

In addition to the manufacturer visits, PQM traveled to Abuja, Nigeria, to meet with staff from the Family Health Department of the Ministry of Health, the National Agency for Food and Drug Administration and Control (NAFDAC), the Targeted States High Input Project (TSHIP), and USAID/Nigeria to brief them on PQM activities related to maternal and child health pharmaceutical commodities.

TABLE OF CONTENTS

<u>Acknowledgements</u>	4
<u>Acronyms</u>	5
<u>Background</u>	6
<u>Purpose of Trip</u>	6
<u>Source of Funding</u>	6
<u>Overview of Activities</u>	7
<u>Conclusion</u>	10
<u>Next Steps</u>	10
<u>Annex 1: PATH Trip Report: Nigeria</u>	11

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.

ACKNOWLEDGEMENTS

We would like to thank:

- Mrs. Hauwa Keri, Director, Establishment Inspection, NAFDAC
- Dr. Nancy Lowenthal, Director of Health, Population & Nutrition Office
- Ms. Gertrude Odezugo, Program Manager –Maternal and Child Health (MCH), USAID/Nigeria
- Dr. Joseph Monehin, Program Manager–Maternal and Child Health (MCH), USAID/Nigeria
- Dr. Uwem Inyang, Program Manager – Malaria, USAID/Nigeria
- Mr. Steve Onya, CEO/Managing Director, Chi Pharmaceuticals, Ltd.
- Mr. Jonathan Ukwuru, QA/QC Manager, Chi Pharmaceuticals, Ltd.
- Mr. Olajunle Ekundayo, Managing Director, Drugfield
- Ms. Femi Titiloye, General Manager, Morison Industries Plc.
- Mrs. Folasade Olaiya-Segun, Neimeth International Pharmaceuticals Plc.
- Mr. Sola Adedji, Saro Lifecare
- Mr. Ahmed Yusuf Ahmed, Managing Director/CEO, BCN Plc.
- Mr. Gbenga Bambe Technical Director, Tuyil Pharmaceutical
- Mr. Hakeem Oshiyemi, Managing Director, QCAT International
- Dr. Stella Okoli, Managing Director/CEO, Emzor Pharmaceutical Industries, Ltd.
- Mr. Silver Ajalaye, Research and Development Coordinator, Swiss Pharma Nigeria, Ltd.
- Mr. Anthony Boni and Dr. Maria Miralles at USAID Headquarters in Washington, D.C.
- PQM administrative staff and editors

ACRONYMS

CAPA	Corrective Action/Preventive Action
CWG	Chlorhexidine Working Group
CHX	Chlorhexidine Digluconate
DQI	Drug Quality and Information Program
EOI	Expression of Interest
FMOH	Federal Minister of Health
GMP	Good Manufacturing Practices
MCH	Maternal and Child Health
NAFDAC	National Agency for Food and Drug Administration and Control
ORS	Oral Rehydration Salts
PQM	Promoting the Quality of Medicines Program
TSHIP	Targeted States High Impact Project
UN	United Nations
UNoLSC	UN Commission on Life-Saving Commodities for Women and Children
USAID	United States Agency for International Development
USP	U. S. Pharmacopeial Convention
WHO	World Health Organization

Background

The United States Agency for International Development (USAID)/Nigeria Mission selected the Promoting the Quality of Medicines (PQM) program, implemented by the U.S. Pharmacopeial Convention, to support strengthening the capacity of select Nigerian manufacturers that produce zinc sulfate tablets, chlorhexidine digluconate gel, and other maternal and child health (MCH) priority commodities for the United Nations (UN) Commission on Life-Saving Commodities for Women and Children.

The UN Commission on Life-Saving Commodities for Women and Children (UNoLSC) was established in April 2012 to improve affordable access to medicines and supplies essential to the health and welfare of women, newborns, and children under the age of five—populations that most often die of preventable causes. The UNoLSC has recommended 13 essential health commodities for women and children that it considers will have the greatest impact on achieving health-related UN Millennium Development Goals, among them, zinc supplements and oral rehydration salts for the treatment of diarrhea, and chlorhexidine for post-natal cord care.

In support of the UN Commission's goals, USAID/Nigeria is working to increase the availability of relevant MCH medicines in the country. Toward that end, PQM will provide technical assistance on Good Manufacturing Practices (GMP) and quality assurance to local medicines manufacturers in collaboration with the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC).

At the request of the USAID/Nigeria, PQM solicited local Nigerian manufacturers to submit expressions of interest (EOIs) to receive technical assistance for the manufacture of chlorhexidine digluconate gel. Based on the EOIs received and responses to a manufacturer questionnaire, Morison Industries Plc., Drugfield Pharmaceutical Ltd., Neimeth International Pharmaceutical Plc., Saro Lifecare, Emzor Pharmaceutical, and Tuyil Pharmaceutical Industries Limited were selected to visit.

Purpose of Trip

The purpose of this trip was to:

- Conduct assessments of several manufacturers who submitted expressions of interests for technical assistance to produce chlorhexidine (CHX) digluconate gel;
- Visit Chi Pharmaceuticals to follow up on PQM's initial assessment and provide assistance with the Corrective Actions/Preventive Actions (CAPA); and,
- Meet with USAID/Nigeria, staff from the Family Health Department of the Ministry of Health, the National Agency for Food and Drug Administration and Control (NAFDAC), and the Targeted States High Input Project (TSHIP) to provide an update on discussions with manufacturers.

Source of Funding

This trip was funded by USAID/Nigeria–Maternal and Child Health program.

Overview of Activities

Meetings with Nigerian manufacturers submitting EOIs—September 9-13, 2013

Mr. Toledo and Drs. Anyakora and Evans met with eight Nigerian companies to further discuss the PQM technical assistance described in the request for EOIs to determine the status of each regarding the manufacture of chlorhexidine digluconate gel or zinc sulfate tablets. Highlights of the individual meetings are provided below.

Meetings in Lagos and Ilorin, Nigeria: September 9-13, 2013	
Company	Meeting Highlights
Chi	<ul style="list-style-type: none"> Completed zinc sulfate tablets palatability study for World Health Organization (WHO) Prequalification (PQ) Programme; data under review. Packing machinery for oral rehydration salts (ORS) will be transferred to ORS line in good manufacturing practices (GMP) part facility by the end of the year. Conducted follow-up walkthrough of zinc sulfate tablet manufacturing line, indicating the company has begun implementing CAPAs from previous PQM assessment.
Emzor	<ul style="list-style-type: none"> Currently developing a CHX gel. Requested advice on a new facility. They will have their own CHX gel formulation in approximately three weeks. A prototype of the tube and secondary packaging has been developed and a product name (Emxidine® gel) has been registered. Production capacity: Will be able to produce from 3g to 25g tube sizes with a capacity of 16,800 tubes per day. A new facility is under construction that will focus on CHX, zinc, and ORS products; it will be ready to produce production batches in the next six to nine months. The company also produces “Mama Kits” containing basic medical items used to help women deliver babies at home.
Morison	<ul style="list-style-type: none"> Manufactures antiseptics in liquid form used in hospitals and household applications. The company has a new gel filling machine that is not yet in use; however, a walkthrough of the facility revealed the need for capital investment to upgrade the premises and utilities in order to manufacture a good quality CHX product. The company is planning to upgrade their facility in the next four to five months.
Drugfield	<ul style="list-style-type: none"> The facility appeared to be well maintained. Current capacity includes three gel filling machines that can produce 3g to 25g CHX tube sizes with a capacity of 50,000 tubes per day. Currently developing its own CHX gel formula. It has shared with PQM the

	<p>art work of the secondary packaging for Chlorxy-G[®] Gel, the brand name registered with NAFDAC.</p> <ul style="list-style-type: none"> • CHX raw material for product development has been purchased and was in country customs at the time of this visit. • The company has significant experience in manufacturing gel products. • Samples of the first batch will be sent to PQM for analysis by end of October 2013.
Neimeth	<ul style="list-style-type: none"> • Currently, has an older gel filling machine but has indicated it will be procuring a new gel filler. • The walkthrough revealed the need for capital investment to upgrade the premises and utilities in order to manufacture good quality products. • The facility is older than most of the others being considered and will need considerable investment to comply with current GMP requirements. An upgrade of the facility is planned between December 2013 and March 2014.
Saro	<ul style="list-style-type: none"> • Visited the commercial office only. • The company currently produces antiseptics. • Other public health products it makes include the “Mama and Midwife Kits” for home baby deliveries. • They are open to license CHX from Lomus.
BCN	<ul style="list-style-type: none"> • Interested in manufacturing zinc sulfate tablets. • Met with PQM; however, PQM did not visit manufacturing site. • No existing formulation available at this time. • Requesting technical assistance for formulation development, zinc manufacturing, and sourcing of active pharmaceutical ingredient.
Swiss Pharma Nigeria Ltd	<ul style="list-style-type: none"> • Has a zinc product currently in development, awaiting delivery of raw materials from a supplier. • Short tour of the facility revealed that the facility is well maintained. • Company requested support for zinc palatability studies in order to pursue WHO PQ. • Timeline for zinc project is nine months, with local regulating authorities requiring six months of stability data.
Tuyil	<ul style="list-style-type: none"> • Has a new facility under construction dedicated to CHX gel. • CHX gel production is awaiting installation and subsequent validation/qualification of a air handling system. • Company has been working to develop their own CHX gel formulation.

Meetings with TSHIP, NAFDAC, USAID/Nigeria, and the Family Health Department— Abuja, Nigeria, September 15–17, 2013

Dr. Evans, Dr. Anyakora, and Mrs. Mutsumi Metzler of PATH (“the Team”) traveled to Abuja to meet with TSHIP, NAFDAC, USAID/Nigeria, and the Family Health Department in the Ministry of Health to provide updates on the rapid assessment of CHX manufacturers. Mrs. Metzler accompanied PQM to carry out due diligence business assessments (Annex 1) of the manufacturers as part of PATH’s CWG activities. Highlights of the meetings follow:

Meeting with TSHIP

- The Team met with TSHIP management.
- Nosa Orobato gave an update on TSHIP CHX activities with Nigerian manufacturers.
- TSHIP is hiring a focal person in Abuja to facilitate CHX policy efforts in Nigeria.
- TSHIP would like to support PQM–PATH efforts pertaining to technology transfer between manufacturers in Nepal and Nigeria.

Meeting with NAFDAC

- The Team met with Dr. Paul Orhii, Director General, and Mrs. Hauwa Keri, Director of Establishment Inspection of NAFDAC to update them on the manufacturer assessments conducted the prior week.
- NAFDAC indicated that CHX solution already has over-the-counter (OTC) status in Nigeria.
- Manufacturers using the LOMUS formulation are likely to undergo an abridged review; new CHX gel formulations may require efficacy and safety studies. The Director of Registration and Regulation will be consulted on this matter.
- CHX gel importation policy was discussed, as was the potential for including CHX gel on the list of products prohibited from importation. This could occur only after local production has been developed and becomes sustaining.
- PQM will share with NAFDAC roadmaps to support product development and registration for selected CHX gel manufacturers.

Meetings with USAID/Nigeria

Meeting 1: PQM and USAID

- PQM staff met with Ms. Gertrude Odezugo (MCH) and Dr. Uwem Inyang (Malaria) at the USAID/Nigeria Mission and briefed them on the rapid assessments performed of potential CHX gel manufacturers and on the follow-up meetings with zinc and ORS producers.
- The mission asked that PQM work more closely with the Clinton Health Access Initiative to assist their efforts with local manufacturers.
- USAID/Nigeria requested a draft of the combined FY13 work plan (Malaria and MCH) that includes support to build NAFDAC capacity to ensure quality of MCH commodities.

Meeting 2: PQM, PATH, and USAID

- The Team met with Ms. Gertrude Odezugo (MCH), Dr. Joseph Moneheim (MCH), and Dr. Nancy Lowenthal, Director of Health, Population & Nutrition Office at the USAID mission.
- The mission informed PQM that amoxicillin dispersible tablets are a priority commodity and that future activities should support this area.
- DELIVER will procure zinc from a local manufacturer as part of a pilot study. The mission will provide PQM with the contact information of the DELIVER partners responsible for zinc procurement so PQM can implement quality control batch testing of zinc sulfate tablets.

Meeting with staff of Federal Minister of Health (FMOH)–Family Health Department, TSHIP, and PATH (September 17, 2013)

- The FMOH staff was updated on PQM’s rapid assessment of CHX gel manufacturers.

- PQM was asked to share in the decision-making process to select which manufacturers will receive technical assistance.
- The FMOH is interested in the 20g tube presentation of CHX gel. Although larger than the typical 3g tube, the 20g would be applied to a single child. Use on a single child is also consistent with the New Cord Care Policy being implemented of “1 Tube, 1 Baby.”

Conclusion

Overall, the companies were very receptive to PQM’s offer of technical assistance and eager to begin local manufacturing of quality-assured chlorhexidine digluconate gel. Some manufacturers have advanced to developing their own chlorhexidine digluconate gel formulations that, potentially, would not require technical transfer. PQM will begin to outline individual plans for selected manufacturers as a roadmap to manufacturing quality chlorhexidine digluconate gel.

Next Steps

- PQM will schedule a gap analysis GMP audit of Drugfield, Tuyil, and Emzor. (October 2013 –March 2014)
- PQM will develop individual implementation plans for technical assistance to be provided to selected CHX gel manufacturers: Drugfield, Emzor, and Tuyil. (Following gap analysis)
- PQM will follow up with selected manufacturers regarding technical transfer. (November 2013)
- PQM will continue to support CHI pharmaceuticals on the zinc project. (Ongoing)
- PQM will test the ORS samples collected from CHI during this visit. (October 2013)
- PQM will begin working with Swiss Pharma to develop a specific roadmap for the company to manufacture zinc sulfate tablets according to GMP.

Trip report: Nigeria

Meeting with stakeholders for 7.1%
chlorhexidine digluconate for
umbilical cord care

September 8-18, 2013
Submitted to USAID

November 6, 2013

MAILING ADDRESS

PO Box 900922
Seattle, WA 98109
USA

ADDRESS

2201 Westlake Avenue
Suite 200
Seattle, WA 98121
USA

TEL: 206.285.3500

FAX: 206.285.6619

www.path.org



USAID
FROM THE AMERICAN PEOPLE



Support for this project is made possible by the generous support of the American people through the United States Agency for International Development (USAID) under the terms of the HealthTech Cooperative Agreement # GPH-A-00-01-00005-00. The contents are the responsibility of PATH and do not necessarily reflect the views of USAID or the US Government.

This report was prepared by PATH for the USAID and distributed to:

- Neal Brandes, USAID
- Unja Hays, USAID
- David Milestone, USAID
- Nosa Orobato, John Snow, Inc./Targeted States High Impact Project
- Lawrence Evans, “Promoting the Quality of Medicines in Developing Countries” Program of the US Pharmacopeial Convention (PQM/USP)
- Edwin Toledo, PQM/USP
- Chlorhexidine Working Group members upon request

Contents

Objectives	1
Key Outputs	1
1. Meeting with National Agency for Food and Drug Administration and Control	1
2. Meeting with the Federal Ministry of Health	2
3. Meeting with the USAID Mission	2
4. Meetings with John Snow, Inc./Targeted States High Impact Project.....	3
5. Key Relevant Information Obtained from Pharmaceutical Companies.....	4
Next Steps	5
Appendix 1: Trip Schedule	6
Appendix 2: Meeting Participants.....	7

Objectives

The main objectives of this trip were to:

- Assess a short-list of six pharmaceutical manufacturers for their ability to produce 7.1% chlorhexidine digluconate for umbilical cord care (the Chlorhexidine Product) in Nigeria in collaboration with the “Promoting the Quality of Medicines” Program of the US Pharmacopeial Convention (PQM/USP).
- Update the National Agency for Food and Drug Administration and Control (NAFDAC), the Federal Ministry of Health (FMOH), the US Agency for International Development (USAID) Mission in Nigeria, and other partners about the progress of manufacturer selection, market research, and demand projection currently being undertaken by the Chlorhexidine Working Group (CWG), and create synergy with the planned activities of the FMOH to move ahead with the Chlorhexidine Product.

This trip report primarily focuses on the second objective. In addition, it provides information obtained from the pharmaceutical companies that is not directly related to the manufacturer assessment. The information directly related to the manufacturer assessment will be included in the joint assessment report by PATH and PQM/USP. The detailed trip schedule and the names of the major individuals with whom PQM/USP and PATH representatives met are provided in Appendices 1 and 2.

Key Outputs

1. Meeting with National Agency for Food and Drug Administration and Control

- PQM/USP and PATH reported that three pharmaceutical manufacturers were selected to receive technical assistance from USP and PATH for production of 7.1% chlorhexidine digluconate out of the six that we visited. NAFDAC was pleased with our efforts and results. PQM/USP will share roadmaps with NAFDAC to support product development and registration of the selected manufacturers.
- We discovered that Gongoni Company Ltd., which imports 7.1% chlorhexidine digluconate for the state of Sokoto, is a pesticide manufacturer. Therefore, prevention of cross-contamination with the Chlorhexidine Product would become a significant issue if that company were to manufacture the Chlorhexidine Product.
- NAFDAC indicated that the chlorhexidine solution already has over-the-counter status in Nigeria and that registration of the Chlorhexidine Product would be expedited.
- We confirmed that efficacy and safety studies would be required if pharmaceutical manufacturers in Nigeria decide to develop a chlorhexidine gel formulation, rather than using Lomus Pharmaceuticals’ gel formulation. All three selected pharmaceutical manufacturers are interested in developing their own formulation; however, the requirement for efficacy and safety studies will very likely sway their decision to utilize the Lomus formulation.

- We discussed the importance of protecting local manufacturers once their products are commercialized in Nigeria. In this regard, importation of the Chlorhexidine Product should cease once the locally produced Chlorhexidine Product is commercialized. Including the Chlorhexidine Product on the list of products prohibited from importation could be explored.

2. Meeting with the Federal Ministry of Health

- PQM/USP and PATH updated the FMOH on our manufacturer assessment. The FMOH confirmed that local production of the Chlorhexidine Product is a priority and that they do not intend to purchase imported Chlorhexidine Product once local production is established.
- The FMOH had a meeting with manufacturers in August which was supported by John Snow, Inc./Targeted States High Impact Project (JSI/TSHIP). NAFDAC, Gongoni, and six manufacturers (not the same ones that were visited during this trip) attended. PQM/USP joined the meeting by phone, although the connection was not optimal. During the meeting, the FMOH indicated that the price for the Chlorhexidine Product would be between NR50 and NR110, but no purchase quantity was mentioned.
- The FMOH plans to have a second meeting with manufacturers. We agreed that only the three manufacturers that PQM/USP and PATH believe are capable of manufacturing the Chlorhexidine Product (Drugfield Pharmaceuticals Ltd., Emzor Pharmaceutical Industries Ltd., and Tuyil Pharmaceutical Industries Ltd.) should be invited to the second meeting. In order to justify inviting only these three manufacturers, PQM/USP and PATH were asked to provide an assessment report.
- The FMOH decided to use a multiple-day application of the Chlorhexidine Product instead of a single-day application, and to provide the Chlorhexidine Product in a 20g tube for both home and facility births. This decision was made on the premise that using the Chlorhexidine Product for multiple days will likely dissuade users from reverting to unhygienic cord practices, as they might do after only a single application. There was also discussion around whether to use a large tube for multiple babies. However, it was decided to use one tube per baby to avoid cross-contamination. The policy document is currently being developed.
- We informed the FMOH that manufacturers said they could not locally source small (5g) aluminum tubes but could locally source larger aluminum tubes. Therefore, multiple applications of the Chlorhexidine Product that require use of a larger tube will actually alleviate issues with procurement of the primary container.
- All the participants acknowledged that demand generation would be key to Chlorhexidine Product scale-up. The Nigerian government will take the lead in this important activity. Various avenues should be utilized to create demand; for example, including the Chlorhexidine Product in Mama Kits and providing them during Maternal and Child Health Weeks.
- NAFDAC has also been involved from the beginning and is responsible for both quality assurance and post-market surveillance.
- In order to effectively demonstrate the outcomes of the Chlorhexidine Product introduction/scale-up, the FMOH is interested in studies to assess lives saved and cost effectiveness.

3. Meeting with the USAID Mission

- PQM/USP and PATH provided updates from the manufacturing assessment and other activities being undertaken by the CWG. We also provided a synopsis of planned activities in Nigeria, such as market research and demand forecasting.
- The USAID Mission informed us that JSI/TSHIP is conducting forecasting for the Chlorhexidine Product. We need to obtain more detailed information from JSI in order to avoid replication with the demand forecasting that PATH plans to perform.
- The USAID Mission informed us that the USAID DELIVER Project (implemented by JSI) has purchased \$200,000 worth of the Chlorhexidine Product from Lomus Pharmaceuticals as a buffer.

4. Meetings with John Snow, Inc./Targeted States High Impact Project

- PQM/USP and PATH met with Mr. Nosa Orobato twice, once prior to the meeting with the FMOH to provide updates from the manufacturer assessment and once after the meeting with the FMOH to discuss next steps.
- JSI/TSHIP is currently conducting a quantification assessment for the Chlorhexidine Product in Nigeria. According to Nosa, the assessment is focused more on the public and nonprofit sectors. He will share the results after it becomes available.
- PATH explained the market research and demand forecasting that we plan to conduct in Nigeria soon. These activities will focus not only on the public and nonprofit sectors but also on the private sector. Furthermore, demand forecasting will incorporate users' and service providers' perspectives. Nosa said that we should not underestimate the power of the private sector. For example, even in Bauchi state, people living in the city will purchase medicines from pharmacies.
- Bauchi state will soon introduce the Chlorhexidine Product, following Sokoto state. Nosa is preparing a press release. His near-term target is to start the introduction of the Chlorhexidine Product in six states.
- JSI/TSHIP is in the process of hiring a person who can dedicate 100% time to introduction/scale-up of the Chlorhexidine Product.
- JSI/TSHIP is writing a proposal to the Bill & Melinda Gates Foundation to request funding to support some activities, including technology transfer of the gel formulation from Lomus Pharmaceuticals to the Nigerian pharmaceutical companies. If funded, TSHIP will be able to support travel expenses so that Lomus can visit Nigeria to work directly with the recipients of their formulation. We provided more detailed information such as frequency of travel and duration of stay required to complete the transfer of the gel formulation, to help TSHIP in budgeting for this proposal.
- We confirmed our continued collaboration with JSI/TSHIP in order to scale up the Chlorhexidine Product in Nigeria. Especially in regard to the transfer of Lomus' formulation, PQM/USP, JSI/TSHIP, and PATH will need to work closely. Once PQM/USP creates a roadmap for formulation transfer, it will be shared with PATH and JSI/TSHIP.

5. Key Relevant Information Obtained from Pharmaceutical Companies

(Please refer to the report on the manufacturer assessment for information on their capacity and capability to produce the Chlorhexidine Product.)

- Mama Kits are procured by states through tenders. Strengthening Health Outcomes through the Private Sector (SHOPS) has procured them as well. Contents of the kits are mandated by tender documents, which differ from tender to tender. Two of the companies we met (Emzor and Saro Lifecare Ltd.) are assembling and providing the Mama Kits in the following approximate annual quantities:

	Saro Lifecare	Emzor
States	~100,000 kits	1,000-2,000 kits
SHOPS	~50,000 kits	N/A

- A few companies mentioned that smaller aluminum tubes, such as the one used by Lomus Pharmaceuticals, are not produced locally and would have to be sourced from India or somewhere else; however, aluminum tubes larger than 15g can be sourced locally. One company mentioned that 80% of the cost of goods sold is due to packaging. Importing the smaller tube would likely further increase the already high packaging cost for the Chlorhexidine Product.
- Half of the companies that we met described how difficult it is to enter markets in Francophone African countries due to language differences plus those countries' bias toward purchasing products made in France. Export agencies in Nigeria are currently trying to find better ways to enter those markets. In addition, one company mentioned an emerging idea that Nigerian and Ghanaian companies collaborate to capture the Francophone African markets.
- Nigerian pharmaceutical manufacturers are allowed to have a 40% profit margin when they sell products to the government sector. They typically provide a 50% discount when selling their products to distributors in the private sector; however, the multi-layer structure in the private-sector distribution channel makes the prices of products actually higher in the private sector than in the government sector.
- A few companies said that government tenders are monetarily large, but infrequently issued. Their sales to the private sector compensate for periods in which there are no government tenders, which helps to even out their sales. As a result, sales to the private sector represent a larger portion of their total sales quantity.
- None of the Nigerian pharmaceutical companies currently have received World Health Organization prequalification; therefore, they cannot participate in international tenders/procurements. However, recently, greater focus is being placed on strengthening local production capabilities.
- The Nigerian government intends to establish mega-distribution centers to streamline the otherwise complex distribution channels in the country; however, this idea has not yet materialized.

Next Steps

- PQM/USP and PATH to develop a report on the manufacturer assessment and provide it to the FMOH.
- PQM/USP, JSI/TSHIP, and PATH to continue to closely work together to enable selected manufacturers to produce and register a quality Chlorhexidine Product in a timely manner.
- JSI/TSHIP to share the results of the USAID DELIVER Project's forecasting once it is complete.
- PATH to implement market research and demand forecasting in Nigeria and continue to update JSI/TSHIP on our progress and results to gain their input.

Appendix 1: Trip Schedule

	Monday	Tuesday	Wednesday	Thursday	Friday
	9/9	9/10	9/11	9/12	9/13
AM		Morison Industries Plc.	Drugfield Pharmaceuticals Ltd.	Saro Lifecare Ltd.	Move to Ilorin
PM	Arrive in Lagos	Neimeth International Pharmaceuticals Plc.		Emzor Pharmaceutical Industries Ltd.	Tuyil Pharmaceutical Industries Ltd.
	9/16	9/17			
AM	Meeting with NAFDAC	Meeting with FMOH			
PM	Pre-meeting with JSI/TSHIP	Meeting with USAID Mission Recap meeting with JSI/TSHIP			

Appendix 2: Meeting Participants

(In alphabetical order of their respective organizations)

Federal Ministry of Health

- Dr. Kayode Afolabi, Head, Child Health Division
- Dr. Joy Ufere, Child Health Division

John Snow, Inc./Targeted States High Impact Project

- Mr. Nosa Orobaton, Chief of Party
- Nomtai Kadun
- Dr. Kamil Shoretire, Senior Maternal and Newborn Health Advisor

National Agency for Food and Drug Administration and Control

- Dr. Paul B. Orhill, Director General
- Mrs. H. J. Keri, Director, Drug Evaluation and Research

National Primary Health Care Development Agency

- Dr. Nnenna N. Ihebuzor, Director, Primary Health Care System Development

Save the Children

- Dr. William Abimbola, Senior Maternal & Newborn Health Manager

US Agency for International Development Nigeria Mission

- Ms. Gertrude Odezugo, Maternal and Child Health
- Dr. Joseph Moneheim, Program Manager, Maternal and Child Health
- Dr. Nancy Lowenthal, Director, Health, Population and Nutrition Office