

Supervisory visit to assess PQM activities in Ethiopia

Addis Ababa, Ethiopia
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Trip Report

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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 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. 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.

Abstract

The PQM director, Dr. Lukulay, travelled to Ethiopia to review PQM activities with key country partners and USAID and also met with the Food, Medicine and Health Care Administration Control Authority management to review accomplishments in FY 10 and to develop an implementation plan for FY 11 activities funded by PEPFAR and PMI.

At the request of USAID, Dr. Lukulay participated in a meeting at USAID along with SPS senior management to discuss PQM and SPS support to FMHACA and identify synergies and technical areas where the two programs could collaborate more closely to provide a concerted technical assistance to FMHACA.

Dr. Lukulay also met with SCMS staff to finalize the request for Expressions of Interest that PQM prepared to provide technical assistance to local manufacturers of opportunistic infection medicines and Food by Prescription products.

As USP is in the process of registering as an international NGO in Ethiopia PQM director met with officials of the Ministry of Health and Foreign Affairs to brief them about PQM activities in the country and answer any questions they may have about the technical assistance they are providing to FMHACA.

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Key Words

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ACRONYMS

ACT	Artemisinin-based Combination Therapy
FBP	Food By Prescription
DQI	Drug Quality and Information Program
FMHACA	Food, Medicine and Health Care Administration Control Authority of Ethiopia
HIDN	Office of Health Infectious Disease and Nutrition
GMP	Good Manufacturing Practices
NGO	Non-governmental organization
OI	Opportunistic Infection
PFSCM	Partnership for Supply Chain Management
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
SPS	Strengthening Pharmaceutical Systems
USAID	United States Agency for International Development
USP	United States Pharmacopeia

Background

In FY 09, PQM began receiving funding from USAID/Ethiopia to provide technical support to the Food, Medicine and Health Care Administration Control Authority of Ethiopia (FMHACA) to strengthen its regulatory capacity especially in medicines registration and support to the national Quality Control (QC) laboratory to achieve ISO 17025 accreditation.

PQM's support to FMHACA has been primarily focused on the following technical areas:

- Training laboratory staff in basic and advanced quality control procedures
- Developing quality systems in the laboratory and assisting the lab to meet the requirements for ISO accreditation
- Training staff in medicines registration, including dossier review and Good Manufacturing Practices (GMP) inspection
- Establishing a post marketing surveillance system in-country for monitoring medicines quality and detecting counterfeits

In order to ensure continued technical support and proper follow up, PQM staff have been rotating in Ethiopia on a nearly bimonthly basis to ensure that work continues uninterrupted and steady progress is made.

As PQM activities continue to increase in Ethiopia and with the new government proclamation that all non-governmental organizations (NGOs) must register, PQM has been working with a local lawyer to prepare all required documents to allow USP to register in Ethiopia. The Ethiopian Embassy in Washington, D.C. has reviewed all registration documents and positively recommended PQM. Two local staff have been hired to assist PQM's in-country consultant coordinate activities in Ethiopia and follow up on technical assistance provided to FMHACA.

Purpose of Trip

- Meet with USAID and Strengthening Pharmaceutical Systems (SPS) to discuss technical assistance provided to FMHACA by PQM and SPS and explore areas for collaboration and coordination
- Meet with FMHACA management to discuss FY 10 accomplishments and develop an implementation plan for FY 11
- Meet with Ministry officials to brief them about PQM activities and seek their support for registering USP and opening an in-country office.
- Meet with Partnership for Supply Chain Management System (SCMS) staff to finalize a request for Expressions of Interest (EoI) for providing technical assistance to local manufacturers of Food by Prescription products and medicines for opportunistic infections (OI).

Source of Funding

These activities were funded by USAID/Ethiopia, PEPFAR and PMI funds.

Overview of Activities

Meeting at USAID

At the request of the PEPFAR commodity specialist at USAID, PQM and SPS staff met to discuss the technical assistance that the two programs are providing to FMHACA and to explore opportunities for collaboration and coordination. The following points were discussed at the meeting:

- PQM support to FMHACA is mainly in the area of building FMHACA capacity in quality assurance and quality control of medicines and covers four pillars of support
 - Medicines Registration
 - Quality Control
 - Post-Market Surveillance
 - GMP inspection of manufacturing facilities
- SPS support is mainly in the area of pharmaceutical management and development of standards and guidelines for health care practitioners
- The two programs will revisit FMHACA's mandate and identify tangible areas where support is needed without duplicating efforts
- FMHACA's role was conflated with that of the Pharmaceutical Fund and Supply Agency in some areas such as rational use of medicines. The two programs will focus on areas where FMHACA's mandate is clear and unambiguous
- Any guidelines related to drug registration and GMP should be developed by PQM and could receive support from SPS as necessary
- A joint assessment of FMHACA will be conducted by SPS and PQM with involvement of FMHACA to identify areas for improvement for carrying out its regulatory oversight of pharmaceuticals and practitioners

Progress on PQM Objectives

At the meeting between Dr. Lukulay, Dr. Wondemagegnehu (PQM in-country consultant) and FMHACA management, the FY 10 activities in the implementation plan were reviewed in detail. It was clear that PQM has accomplished a majority of the objectives in the plan, including important training provided to FMHACA in registration, dossier review, and GMP as well as basic and advanced laboratory techniques. Significant progress has also been made in meeting requirements for ISO accreditation, and it is expected that the laboratory will receive accreditation in 2012. Several trainings were also funded by PQM for FMHACA staff to train overseas in the areas of ISO accreditation (India) drug inspection (Tanzania) and quality control (Philippines). The activities that were not completed included assisting the laboratory to move to the new building and training staff in Good Clinical Practices and traditional medicines registration. Funding for these activities has been carried forward to FY 11, and the activities will be carried out as soon as the new building is complete and countries are identified where FMHACA staff could go and receive training.



Following discussion, FMHACA management and PQM agreed on FY 11 activities and budget. The new implementation plan for FY 11 was signed by Dr. Lukulay and the Deputy Director of FMHACA.

Dr. Lukulay also took the opportunity to visit the new laboratory building under construction and assessed the progress made. His visit coincided with the visit of the PQM consultant who has provided technical specifications to ensure that the laboratory will comply with ISO 17025 stipulations. They identified certain features in the building that would need to be changed to ensure compliance, such as the location of fume hoods. The main areas of concern are the small width of the doors to the laboratories — which are not adequate for the movement of large equipment — and the fact that laboratory windows are not sealed.



Support to local manufacturers

PQM and the Partnership for Supply Chain Management (PFSCM) have considered partnering to support local manufacturers to improve GMP to supply medicines for OIs and Food by Prescription (FBP) products for HIV/AIDS malnourished patients. A request for EoI for manufacturers has been prepared and shared with USAID for approval.

PFSCM and PQM staff met to discuss the draft request for EoI prepared by PQM to provide technical assistance to local manufacturers of OI and FBP products. It was agreed that PQM will issue the request for EoI to manufacturers by contacting select FBP manufacturers in Ethiopia recommended by PSCM and also advertise in the local newspaper. After responses are received, PQM will conduct GMP audits and make final recommendations about their GMP compliance to PFSCM and USAID.

Meeting with government officials to brief about PQM activities in Ethiopia

Dr. Lukulay, the Director General of FMHACA, and Dr. Wondemagegnehu paid a courtesy call on the Deputy Minister of Health to brief him about PQM activities in Ethiopia. Dr. Lukulay discussed the four pillars of support that PQM is providing to FMHACA and elaborated on planned activities for FY 11. The Director General praised the work of PQM and cited the various support provided by PQM which has improved the performance of FMHACA in drug registration and quality control of medicines. The Deputy Minister thanked PQM and USAID for the support that they have provided to ensure the supply of quality medicines for the Ethiopian people. He indicated that a new committee has been formed to facilitate enforcement action against those who perpetuate substandard and counterfeit medicines. This committee will work with PQM to obtain evidence-based data that can be used to bring about enforcement actions.

Dr. Lukulay also met with officials at the Foreign Affairs Ministry to brief them about PQM activities in-country and to urge them to expedite the registration of PQM in Ethiopia. The Ministry officials praised the work of PQM to combat counterfeit and substandard medicines in

Ethiopia. The official in charge of registration indicated that he will do all he can to ensure that final recommendation for registration is sent to the committee for ratification.

Conclusion

PQM has provided significant support to FMHACA to strengthen their regulatory capacity and build their capacity in registration, quality control, GMP and post-market surveillance of the quality of medicines.

Work toward achieving ISO 17025 accreditation of the laboratory continues on track for 2012. PQM plans to have a mock audit of the lab in 2011 to assess its readiness for a formal audit by an ISO 17025 accrediting body.

FY 11 implementation plans involve continued technical assistance in developing guidelines for medicines regulation, developing procedures for registration of traditional medicines and medical devices, and reducing backlog dossiers by conducting dossier review campaigns with FMHACA staff.

Next Steps

- PQM and SPS to conduct an assessment of FMHACA at the request of USAID
- Follow up progress on work identified in the FY 11 implementation plan
- Follow up on receiving final approval papers from the Ministry of Foreign Affairs on PQM registration in Ethiopia
- Open PQM office in Ethiopia



PQM Pillars of Support to FMHACA of Ethiopia

PROMOTING THE QUALITY OF MEDICINES

QUALITY ASSURANCE OF MEDICINES

REGISTRATION

- ▶ Dossier Assessment
- ▶ Update Registration guidelines
- ▶ Reduce backlog

QUALITY CONTROL

- ▶ Quality control
- ▶ GLP compliance
- ▶ ISO and WHO Accreditation

POSTMARKET SURVEILLANCE

- ▶ ARVs
- ▶ Antimalarials
- ▶ Ols
- ▶ Provide reagents and chemicals
- ▶ Equipment maintenance

GMP INSPECTION

- ▶ Update GMP guidelines
- ▶ GMP training
- ▶ Mfr assessment
- ▶ WHO prequal

Build Capacity of FMHACA staff

PQM COP 2011 Work Plan-Strengthening FMHACA Capacity

Main activity/ tasks	Responsible	Timeline		Indicators	Means of verification
Objective 1: Get baseline information on the regulatory activities of FMHACAC, identify gaps and make recommendations					
Review regulatory and quality assurance capacity of FMHACA using assessment tool <ul style="list-style-type: none"> • Get consent from concerned body on the assessment • Develop tool for assessment • Identify assessors • Conduct assessment • Write report with recommendations • Discuss report with key stakeholders • Prepare action plan 	PQM and FMHACA	Dec 2010 – February 2011		<ul style="list-style-type: none"> • Assessment report with gaps and recommendations • Work plan developed 	<ul style="list-style-type: none"> • Report of assessment
Objective 2: Establish operational PQM office in Ethiopia					
<ul style="list-style-type: none"> • Support PQM consultants • Provide office supplies 				Office registered Office operational and supporting FMHACA	Feedback from FMHACA and reports generated
Objective 3: Improve/strengthen medicine registration and licensing system to ensure that medicines approved by FMHACA are of good quality, safe and efficacious					
2.1 Improve capacity and skills of new staff <ul style="list-style-type: none"> • Identify trainees • Identify trainers 	PQM and Product Registration	Dec 2010- Feb 2011-		<ul style="list-style-type: none"> • At least 15 new staff trained 	<ul style="list-style-type: none"> • Report on training

<ul style="list-style-type: none"> • Develop training materials • Identify training place • Provide training 	and Licensing Directorate (PRLD)				
<p>2.2 Improve capacity and skills of existing staff</p> <ul style="list-style-type: none"> • Identify trainees • Identify trainers • Develop training materials • Identify training place • Provide training 	PQM and PRLD	December 2010-March 2011		<ul style="list-style-type: none"> • 20 X 2 staff trained in advanced medicine registration • 2 trainings on advance medicine registration organized • Dossier assessment time reduced from one year to three months • No of dossiers in backlog reduced to below 20 at any given time. 	<ul style="list-style-type: none"> • Report of training • Audit report on assessment time and dossiers in backlog
<p>2.3 Review and up date existing registration and licensing guidelines and procedures</p> <ul style="list-style-type: none"> • Make copies of all existing guidelines • Review and update the guidelines • Discuss updated guidelines with stakeholders • Incorporate comments and prepare final guidelines • Disseminate final guidelines to clients/customers and load them on website 	PQM and PRLD	March - May 2011		<ul style="list-style-type: none"> • At least 9 existing guidelines and procedures reviewed and updated • At least 2 consultative workshop on guidelines organized 	<ul style="list-style-type: none"> • Copies of updated and printed old guidelines and procedures
<p>2.4 Develop new guidelines and procedures for medicine registration and licensing</p> <ul style="list-style-type: none"> • Make inventory of missing guidelines • Draft missing guidelines • Discuss guidelines with stakeholders • Incorporate comments 	PQM and PRLD	March –May 2011		<ul style="list-style-type: none"> • At least 5 new guidelines developed • At least 1 consultative workshops organized to finalize the guidelines 	<ul style="list-style-type: none"> • Copies of printed and disseminated new guidelines

<ul style="list-style-type: none"> • Prepare final guidelines and disseminate to customers 					
<p>2.5 Campaign assessment of dossiers in backlog</p> <ul style="list-style-type: none"> • Make inventory of applications in backlog • Select staff who will do the campaign assessment • Develop strategy for assessment • Organize the assessment • Notify applicants the results of assessments • Incentives for Registration staff for backlog dossier campaign 	PQM and PRLD	Nov 2010-May 2011		<ul style="list-style-type: none"> • No of dossiers in backlog reduced to below 20 at any given time. • At least 560 dossiers assessed and decision made 	<ul style="list-style-type: none"> • Action plan for assessment of dossiers in backlog and new applications • Final report of Campaign assessment •
<p>Objective 4: Strengthen GMP and GCP inspection system to improve the quality of medicines</p>					
<p>3.1 Review and update GMP, GCP guidelines and inspection templates</p> <ul style="list-style-type: none"> • Identify existing/new guidelines • Review guidelines • Circulate for comments • Conduct consultative meetings with customers • Incorporate comments • Finalize and disseminate to stakeholders 	PQM and PRLD	April -June		<ul style="list-style-type: none"> • 5 guidelines developed and/or reviewed and updated 	<ul style="list-style-type: none"> • Copies of guidelines and procedures developed
<p>3.2 Train staff on GMP inspection</p> <ul style="list-style-type: none"> • Identify trainee • Identify trainers • Prepare training materials • Identify training site • Conduct training 	PQM and PRLD	April -June		<ul style="list-style-type: none"> • 2x20 staff trained on GMP • 2 GMP trainings • 100% GMP inspection carried out on local manufacturers 	<ul style="list-style-type: none"> • Report of training on GMP • Copy of training material developed • GMP inspection report on local manufacturers

3.3 Train staff in GCP inspection <ul style="list-style-type: none"> Identify trainees Identify trainers Prepare training materials Identify training place Conduct training 	PQM and PRLD	July-September		<ul style="list-style-type: none"> 5 staff trained in GCP inspection 100% GCP inspection for authorized clinical trials 	<ul style="list-style-type: none"> Report of training on GCP Reports of clinical inspections carried
3.4 Train in registration of traditional medicines <ul style="list-style-type: none"> Identify trainees Identify training location Conduct training 				20 Experts trained by experts from abroad or Conduct TOT	
3.5 Train in registration of medical device <ul style="list-style-type: none"> Identify training location Identify trainees Conduct training 				20 Experts trained by experts from abroad or Conduct TOT	
3.6 Develop guidelines and train staff in food registration <ul style="list-style-type: none"> Develop guidelines Training in food registration 					
Objective 5: Strengthen the Quality Control laboratory of FMHACA to make it WHO prequalified and ISO17025 Accredited					
4.1 Develop SOPs and guidelines <ul style="list-style-type: none"> Identify SOPs and other procedures/tools to be developed Develop SOPS and procedures/tools Circulate SOPs and procedures/tools for comments Incorporate comments Finalize and approve SOPs and procedures 	PQM and Quality Control Laboratory (QCL)	October 2010-March 2011		<ul style="list-style-type: none"> At least 100 procedures developed and approved At least two audits conducted by PQM 	<ul style="list-style-type: none"> Copies of approved procedures Audit reports
4.2 Train QC lab analysts	PQM and QCL	January-March		<ul style="list-style-type: none"> At least three trainings 	<ul style="list-style-type: none"> Report of trainings

<ul style="list-style-type: none"> • Train in advanced analytical techniques • Training on microbiological techniques • Training on condom test • Train in Food analysis • Training on lab equipment maintenance • Identify trainees • Identify training place • Conduct training 		2011		carried out on advanced analytical methods	conducted
<p>4.3 Preventive maintenance and servicing of laboratory equipment</p> <ul style="list-style-type: none"> • Conduct one preventive maintenance activity per year • Conduct 1-2 scheduled instrument service per year • Recruit and train one technician for equipment maintenance 	PQM and FMHACA				
<p>4.4 Assist the QC lab move to the new facility and make operational</p> <ul style="list-style-type: none"> • List lab instruments/equipment that should be moved to the new site • Identify company capable of reinstalling and qualifying the lab instruments/equipment • Identify company that can pack and transport the lab instruments/equipment to the new building • Move instruments/equipment to the new lab • Install lab instruments/equipment and maintain those that need maintenance • Qualify the analytical instruments/ equipments (IQ, DQ/PQ) • Calibrate analytical equipment Adopt the quality system, equipment qualification, change controls to the new facility 	PQM and QCL	April – June 2011		<ul style="list-style-type: none"> • List of equipment/instruments moved • All lab instruments/equipment installed, maintained, qualified and calibrated 	<ul style="list-style-type: none"> • Report on movement of lab. • Report of equipment qualified according to ISO 17025 • QC lab operational in the new facility

<p>4.5 Provide supplies and reference materials</p> <ul style="list-style-type: none"> Identify and quantify needs Submit request for purchase Purchase supplies and reference materials and send 	PQM and QCL	January – March		<ul style="list-style-type: none"> Number of reference materials purchased Types and quantity of supplies provided 	<ul style="list-style-type: none"> Supplies and reference materials provided
<p>Objective 6: Post-marketing surveillance of ARVs, Ois medicines</p>					
<p>5.1 Review and update sampling and quality control protocols for ARVs and Ois</p> <ul style="list-style-type: none"> Establish working group Review and update protocol Circulate for comments Incorporate comments Finalize protocol 	PQM, Inspection Directorate, QCL, Disease Program	October – December 2010		<ul style="list-style-type: none"> A national working group established Protocol developed ARVs and Ois 	<ul style="list-style-type: none"> Copy of protocols for ARV and Ois
<p>5.2 Train people who will collect and test ARVs and Ois</p> <ul style="list-style-type: none"> Identify trainees Develop training materials Organize training based on need 	PQM and QCL, Inspection Directorate	January – February 2011		At least one training carried out for samples collectors and those who test ARVs and Ois	<ul style="list-style-type: none"> Report of training
<p>5.3 Collect samples of ARVs and Ois</p> <ul style="list-style-type: none"> Provide budget to samples collectors Provide transport Collect samples 	PQM, QCL, Inspection Directorate	March-April 2011		<ul style="list-style-type: none"> 50 ARV and 30 OI samples collected 	<ul style="list-style-type: none"> List of samples collected
<p>5.4 Supervise PMS activities</p> <ul style="list-style-type: none"> Select PQM team who will supervise the PMS activities Provide TOR Conduct supervision 	PQM, Inspection directorate and QCL	April 2010		<ul style="list-style-type: none"> At least two supervisions by PQM –during collection and testing of samples 	<ul style="list-style-type: none"> Report of supervision
<p>5.5 Carry out tests as per the protocol</p> <ul style="list-style-type: none"> Identify analysts Provide test and analysis procedure Provide budget for testing Conduct tests Submit certificate of analysis 	QCL	May 2011 – June		<ul style="list-style-type: none"> 50 ARV and 30 OI samples tested and analyzed 	<ul style="list-style-type: none"> Report of testing

5.6 Write report on PMS <ul style="list-style-type: none"> Identify people who will write the report Analyze data generated Write synthesis report 	PQM, Inspection Directorate and QCL	July 2011		<ul style="list-style-type: none"> Report of PMS 	<ul style="list-style-type: none"> Report of PMS
Objective7: Improve capacities and skills of local OI and food-by- prescription (FBP) manufacturers to ensure that their products and the respective manufacturing sites comply with GMP and HACCP					
6.1 Conduct assessment/audit of local OI and food- by- prescription manufacturers <ul style="list-style-type: none"> Send expression of interest to manufacturers of OI medicines and foods- by-prescription List of manufacturers expressing interest Identify assessors Develop assessment tool Conduct assessment Identify gaps Write assessment report with recommendations 	PQM and PRLD	December 2010- February2011		<ul style="list-style-type: none"> Number of plants ready for inspection Number of successful external audits 	Report of audit
6.2 Provide technical support <ul style="list-style-type: none"> Identify technical needs Provide technical support based on needs identified 	PQM and PRLD	March 2011		<ul style="list-style-type: none"> No of plants that received technical support 	<ul style="list-style-type: none"> Report of technical support
6.3 Train manufacturers and FMHACA staffs on GMP and HACCP where needed <ul style="list-style-type: none"> Identify training needs Identify trainees Identify trainers Prepare training materials Conduct training 	PQM and PRLD	May 2011		<ul style="list-style-type: none"> Number of people trained 	<ul style="list-style-type: none"> Report of training
6.4 Develop tools where needed <ul style="list-style-type: none"> Identify procedure/tools needed Develop procedures/ tools Discuss tools with manufacturers 	PQM and PRLD	June-July 2011		<ul style="list-style-type: none"> Number and types of procedures/tools developed 	<ul style="list-style-type: none"> Copies of tools and procedures developed

• Finalize tools					
Main activity /tasks	Responsible	Timeline	Budget	Indicators	Means of verification
Objective 8 Improve evidence base decision of FMHACA leadership					
8.1 Strengthen /establish data management and information system					
8.1.1 Strengthen /establish data management and information system for registration and licensing					
<ul style="list-style-type: none"> • Provide supplies and infrastructure • Test and familiarize system • Procurement of 10 desk top and 4 lab top computer • Upload data and information • Train data entry clerk and assessors 					
8.1.2 Establish/strengthen Laboratory data management and information system					
<ul style="list-style-type: none"> • Procurement of some laboratory equipments, required for lab accreditation project (computers, lab tops...) • Establish net working and software's for sample mgt, lab supplies stock mgt and laboratory information ,management system • Train data entry clerk and analysts 					
8.2 Experience sharing from other food and medicine regulatory bodies 6 management staffs					
• Identify management staff					
• Preparation of tools					

• Experience sharing					
• Report writing					
• Designing and implementing strategies					
Total Budget					
				•	•
Objective 9: Monitoring and Evaluation					
7.1: Conduct a monitoring and evaluation workshop.					
• to assess how FY 11 work went, lessons learned and areas for improvement					
8.1: Enforcement Action					
• FMHACA will take enforcement action to inform the public about counterfeit and substandard medicines found in the PMS activity					
• FMHACA will convene a meeting of manufacturers whose products are substandard and seek improvement in their GMP compliance					
Total:					
Grand Total:					



Invitation to manufacturers of opportunistic infectious (OI) disease medicines and Foods by Prescription (FBP) products for HIV and related diseases to submit an Expression of Interest (EOI) to supply OI and FBP products to procurement organizations

To support national efforts to increase access to HIV/AIDS-related care and treatment, The United States Pharmacopeia (USP)-Promoting the Quality of Medicines (PQM) program is inviting manufacturers of selected opportunistic infectious disease (OI) medicines and foods-by- prescription products (FBP) to submit Expressions of Interest (EOIs) for the supply of these products. Interested organizations will be assessed for compliance with good manufacturing practices (GMP) and the application of the principles and practices of a Hazard Analysis Critical Control Point (HACCP).

Manufacturers which are found to comply with the above requirements will be recommended to procurement agencies who will then verify compliance with their quality assurance policies and will make final decision about procurement. Manufacturers of the following products are encouraged to submit their expressions of interest:

FBP product

- Ready-To-Use-Therapeutic Food, Plumpy nut of 92 gram
- Fortified Blended Food (FBF)

OI products

Co-trimoxazole

Interested manufacturers are therefore encouraged to submit their Expression of Interest together with the list of OI/FBP products they are currently producing.

The assessment procedure to be followed will include the following:

- assessment of the manufacturing site's adherence to GMP, HACCP and its consistency in production and quality control of starting materials, with specific emphasis on active ingredients, and finished product;
- Testing of OI and FP products supplied.

Interested manufacturers can send their Expression of Interest to the following address:

Unites States Pharmacopeia - Promoting the Quality of Medicines
 P.O. Box 100151
 Addis Ababa, Ethiopia
 Email: ert@usp.org



www.usp.org

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