

Supervisory visit to assess PQM activities in Ethiopia and finalize one-year plan for PQM assistance to Food, Medicines and Health Administration and Control Authority

**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 Promoting the Quality of Medicines (PQM) Program Director traveled to Kenya as an invited speaker at the Malaria Initiative Conference November 2-4 and took the opportunity to travel to Ethiopia November 4-8 to meet with USAID and other partners to discuss the progress of PQM work in Ethiopia. The PQM Director also followed up on a recent laboratory training and met with Food, Medicines and Health Administration and Control Authority (FMHACA) – formerly known as the Drug Administration and Control Authority (DACA) – management to discuss a one-year plan for PQM technical assistance to FMHACA using President's Emergency Plan for AIDS Relief (PEPFAR) FY 09 funds.

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Key Words

Drug Administration Control Authority (FMHACA), sentinel sites, Quality Control, ISO 17025

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ACRONYMS

| | |
|--------|---|
| AIDS | Acquired Immunodeficiency Syndrome |
| ARV | Antiretroviral |
| DACA | Drug Administration and Control Authority |
| FMHACA | Food, Medicines and Health Administration and Control Authority |
| GLP | Good Laboratory Practices |
| GMP | Good Manufacturing Practices |
| MOH | Ministry of Health |
| MOU | Memorandum of Understanding |
| MSH | Management Sciences for Health |
| PEPFAR | President's Emergency Plan for AIDS Relief |
| PFSA | Pharmaceutical Fund and Supply Agency |
| PMI | President's Malaria Initiative |
| PQM | Promoting the Quality of Medicines Program |
| QA | Quality Assurance |
| QC | Quality Control |
| QMS | Quality Management System |
| SPS | Strengthening Pharmaceutical Systems |
| USAID | United States Agency for International Development |
| USP | United States Pharmacopeia |
| WHO | World Health Organization |

Background

In FY 09, PQM was selected by the USAID/Ethiopia President's Emergency Plan for AIDS Relief (PEPFAR) team to provide technical assistance to Food, Medicines and Health Administration and Control Authority (FMHACA) laboratory – formerly known as Drug Administration and Control Authority (DACA) – to strengthen their quality control capabilities for antiretrovirals (ARVs) in particular and for pharmaceuticals in general. PQM, in collaboration with FMHACA management, developed an implementation plan to enable the FMHACA laboratory to obtain ISO 17025 accreditation. In this respect, PQM developed a training curriculum to train laboratory staff in Good Laboratory Practices (GLP) and laboratory Quality Management Systems (QMS). In addition to strengthening the laboratory, assistance is also being provided to improve drug registration practices and incorporate ARVs into the established drug quality monitoring program, which is currently focused on antimalarials. The proposed activities have been discussed with FMHACA management and discussions continue regarding timelines, priorities, and specific objectives.

Purpose of Trip

The purpose of the trip was to conduct a supervisory visit to Ethiopia to review the PQM supported drug quality monitoring program, discuss the implementation plan for accreditation of the FMHACA laboratory, and develop a mechanism for coordinating PQM and Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS) activities, as necessary.

Source of Funding

This trip was supported with funds from PEPFAR through USAID/Ethiopia.

Overview of Activities

Review of PEPFAR-funded activities

As indicated in the background statement above, PQM PEPFAR-funded activities started in FY 09 with the focus on providing technical assistance in the following areas:

- Strengthening FMHACA laboratory capacity for quality control of ARVs and good laboratory practices leading to ISO 17025 accreditation
- Strengthening drug registration practices at FMHACA including GMP inspections
- Post-market surveillance of ARVs to assess product quality

Dr. Lukulay met with Jamie Browder, PEPFAR coordinator in Ethiopia, and Negussu Mekonnen, SPS Chief of Party, to discuss PQM and SPS activities under PEPFAR and to look for opportunities to synergize activities. The following agreements were made:

- MSH/SPS and PQM will develop a joint workplan for PEPFAR funded activities
- PQM will develop a Memorandum of Understanding (MoU) with FMHACA about PQM supported activities in FY 09
- PQM will develop a “training of trainers” program to take over basic laboratory and Minilab[®] training activities in a few years
- PQM and SPS will develop a transition plan for FMHACA to take over most training activities in approximately three years.

Review of PQM PMI-funded activities

In FY 08, PQM worked with FMHACA, Ethiopia Ministry of Health, SPS, and the World Health Organization (WHO) to establish a post-marketing surveillance program for antimalarials. One round of sampling was conducted at four sentinel sites, and Minilabs[®] were used to screen the quality of the medicines. Confirmatory testing was delayed because the analytical equipment in the FMHACA laboratory were non-functional and out of calibration. The equipments have since been serviced, leveraging PEPFAR funding provided through SPS. Confirmatory testing has now been completed and the results communicated with USAID. The failure rate for the antimalarials was about 10% and several medicines in circulation were found to be unregistered.

Plans are now underway for the next round of sampling. Prior to the launch of the next round, a refresher Minilab[®] training will be conducted to train new sentinel site staff. Because the lab equipments are now fully functional, confirmatory testing will be done expeditiously following the initial screening by Minilabs[®].

The PQM director briefed Richard Reithinger, the PMI Malaria Advisor, about progress on confirmatory testing. Dr. Reithinger asked to be informed about the timing for the next round of sampling so that his staff could accompany PQM staff. At Dr. Reithinger's request, Dr. Lukulay sent the results of the second round of testing upon returning to the U.S.

Meeting with FMHACA management

Participants: Bikila Bayissa, Head of FMHACA Lab; Mengisteab Woldearegay, Deputy Director FMHACA; Eshetu Wondemagegnehu, Consultant, PQM

The PQM Director met with FMHACA management to finalize discussions on all PQM supported activities in FY 09. See *Annex 1* for the proposed workplan. The PQM Director discussed all planned program activities, asked for FMHACA feedback, and informed them about the outcomes of the meeting with SPS and USAID.

The following agreements were reached:

- FMHACA will appoint at least one FMHACA lab staff to be part of the sentinel site team for better oversight. This will address some lapses that were observed during the last round of sampling and testing.
- The PQM consultant will create terms of reference for a consultant to develop specifications for laboratory furniture. This has now been completed.
- The PQM consultant will create terms of reference for a WHO consultant to conduct training of FMHACA staff in drug registration. This has now been completed.

See *Annex 2* for minutes of the meeting.

Next steps

- Develop an MoU with FMHACA indicating agreed-upon activities for FY 10
- In view of the large number of unregistered medicines identified during the last round of MQM, confirm the registration status of various antimalarials
- Finalize a joint PEPFAR workplan with SPS

- Meet with the National Malaria Control Program to integrate their Global Fund and Ministry of Health funded medicine quality monitoring activities into PQM's
- Meet with Supply Chain Management System director to discuss joint funding of drug registration training for FMHACA staff
- Meet with Pharmaceutical Fund and Supply Agency (PFSA) to discuss integrating post-marketing surveillance activities with PQM and FMHACA

PQM Work Plan – PEPFAR Program in Ethiopia FY10 Activities

| Technical Assistance Area | Budget Item | Activities | Description | Outcomes |
|---|-------------|---|--|--|
| (1) Strengthen FMHACA quality control lab capacities | 1 | Rotate USP staff every 2-3 weeks to follow up and assist FMHACA lab staff in their daily work and to implement good practices | One USP staff member will spend 2-3 weeks, every other month for six months – USP staff will work with QA to establish an internal audit program | – Close follow-up on PQM activities – Accelerate implementation of ISO 17025 guidelines – Increase effectiveness of PQM trainings |
| | 2 | Provide FMHACA lab with power generator, 200 KVA | – Identify the right generator for the current and new facilities – Purchase and install the generator | The power generator will be used in the current facility and moved to the new FMHACA lab |
| | 3 | Training on analytical methods and quality systems | PQM will conduct at least two lab trainings in FY10 based on identified needs | – Gaps on analytical capacity filled – Quality system in place by end of FY10 |
| | 4 | Service of all analytical equipment in the lab | – Make sure all analytical equipment defects are identified and that all equipment is functional at all times – Train FMHACA lab staff on preventive maintenance | – FMHACA lab makes use of all existing equipment – Lab staff are better trained on proper use and maintenance of lab equipment |
| | 5 | Support FMHACA with furniture specifications for the new lab | – Visit the new facility and provide guidance on furniture specifications to comply with ISO 17025 – Get expert advice | The new FMHACA lab complies with ISO 17025 |
| | 6 | Apply the implementation plan to get FMHACA lab up to ISO 17025 standards | Implement PQM strengthening plan and consolidate each step before moving to the next | – By the end of 2010, FMHACA lab quality system must be in place – FMHACA lab staff are trained on all compendial methods |
| | 7 | Assist FMHACA lab in move to the new facility <i>Based on moving dates</i> | – PQM will assist FMHACA lab in moving to the new facility – PQM will assist with installation and qualification of equipment after the move – PQM will assist FMHACA lab adapt its quality system to the new lab facilities | – All lab equipment qualified four months after the move to the new facility – Quality system finalized within six months of moving to the new facility |
| (2) Strengthen drug registration | 8 | Assess FMHACA capacities for Drug Registration | – Check the existing system and practices – Benchmark with WHO standard on | – Gaps identified – Plan to address gaps established and approved |

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| | | | drug registration – Identify gaps and ways to address them | |
| | 9 | Provide training and necessary material support to increase drug registration capacities | Provide a training on drug registration in collaboration with WHO Provide FMHACA with software and computerized tools to facilitate drug registration | FMHACA registration unit trained New software and computerized tools installed and being used |
| | 10 | Provide technical assistance on bioequivalence/bioavailability (BE/BA) | Provide FMHACA with TA on how to evaluate BE/BA data | FMHACA trained on evaluation of BE/BA data in medicines dossiers. |
| | 11 | Monitoring and evaluation | Follow up on the transition from old to new systems and provide support FMHACA needs | Transition to the new system |
| (3) Medicine quality monitoring program | 12 | Establish a pilot MQM program on ARVs in Addis Ababa | Work with FMHACA and other USAID partners to establish a pilot program to monitor the quality of ARVs in Addis Ababa | Pilot MQM program established and functional – At least two ARV data reports are made available in FY10 – Data report shared |
| | | | Sample and test ARVs according to MQM plan | |
| | | | Share data with key stakeholders | |
| 13 | Integrate ARVs and Antimalarial medicine quality monitoring in Ethiopia | Make use of existing antimalarial MQM to expand monitoring the quality of ARVs | Good leverage of PMI and PEPFAR funds | |
| (4) Promote enforcement action by FMHACA | 14 | Promote law enforcement by FMHACA | – Use evidence-based data to promote appropriate action – Collaborate with SEA PQM team to produce awareness-raising material based on MQM data PSA, DOC, FILMS | – Increased awareness of poor-quality medicines – Enforcement actions taken by FMHACA |

Minutes of Meeting with FMHACA management

Meetings were held between Dr Patrick Lukulay, Director, PQM; Mr. Mengisteab Woldearegay, Deputy DG of the Food, Medicines and Health Administration and Control Authority; Mr Bikilla Bayissa, Head Drug Quality Control Laboratory (DQCL); and Dr. Eshetu Wondemagegnehu, PQM Consultant, on November 5-6, 2009. The meetings discussed the following issues:

1. Results and final report of the antimalarial drugs post-marketing quality monitoring carried out in the Oromia Region
2. PQM workplan for PEPFAR in Ethiopia FY09 and workplan for antimalarial quality monitoring (rounds 1 & 2) FY09/10
3. Furnishing the new quality control laboratories

Dr. Lukulay was briefed that a partial analysis of the data generated through the post-marketing quality monitoring had been done and what is remaining is to complete the analysis and prepare a synthesis report. It was also noted that DQCL have reviewed part of the two implementation plans (PEPFAR and PMI) dealing with quality issues and made some minor adjustments. The section dealing with strengthening medicine registration and enforcement of laws has not been reviewed. It was agreed that this part will be reviewed by the Authority and incorporated into the final PEPFAR workplan. With regard to furnishing the new quality control laboratory, it was made clear that some work has been done regarding the preparation of specifications, but a consultant is needed with appropriate expertise to visit the laboratories and prepare detailed designs and technical specifications for furnishing of the laboratories. The final designs and specifications will be used to call international tender.

During the meeting, it was agreed that there should be quarterly monitoring and evaluation of the implementation of workplans. The following actions are also recommended:

| | Actions | Responsible | Timeframe |
|---|--|--------------------|------------------|
| 1 | Prepare TOR for the consultant who will design and develop specifications for furnishing the new drug quality control laboratories and submit to PQM | Mr. Eshetu | Before Nov 20 |
| 2 | Review the two implementation plans (PEPFAR and PMI) and submit final approved workplans to PQM | FMHACA/DQ CL | Before Nov 13 |
| 3 | Prepare TOR for consultants who will assess FMHACA (Food, Medicines and Health Administration and Control Authority) and submit to PQM | Mr. Eshetu | Before Nov 20 |
| 4 | To prepare TOR for consultants who will train personnel in medicine and registration and submit to USP-PQM | Mr. Eshetu | Before Nov 20 |
| 5 | Prepare a short (5-7 pages) report on the results of the post-marketing surveillance carried out in the five sentinel sites and submit the report to PQM | Mr. Bikilla | Before Nov 13 |
| 6 | Prepare specifications for standby generator and | Mr. Bikilla | Before Nov 30 |

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| | submit to PQM | | |
| 7 | Identify people who will collect and test samples at five sentinel sites and provide the list to PQM. | DQCL | Before Nov 15 |
| 8 | Organize a two-day workshop for the personnel who will collect and test samples at sentinel sites (Round I) The actual date and site of workshop will be communicated to participants and PQM | DQCL | Dec 15-20 |
| 9 | Identify chemicals and other items needed to undertake first round of PMS and submit the list to PQM | DQCL | Before Nov 30 |
| 10 | Buy needed chemicals and other items for round I and ship them to DQCL | PQM | Before Dec 20 |
| 11 | Budget for first round PMS to be prepared and submitted to PQM. | DQCL | Before Nov 20 |
| 12 | Collect and test samples at sentinel sites | DQCL and sentinel sites | Dec 14 – Jan 15 |