

**Trainings on Minilab® techniques for basic testing of 2<sup>nd</sup> line anti-tuberculosis and other essential medicines**

**Phnom Penh, Cambodia  
October 18-22, 2010**

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***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 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 and National Health Products Quality Control (NHQC) conducted two Mini-lab trainings. First training for staffs from 12 existing sentinel sites already familiar with Mini-lab was on Basic-Testing of 2<sup>nd</sup> line antituberculosis medicines. The second 'refresher' training, sponsored by FSP Mekong, was for sentinel site staffs new to Mini-lab and a group of police/customs officers. During this period, PQM team also met with key partners in Cambodia.

## **Recommended Citation**

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## **Key Words**

Cambodia, Minilab, Basic testing, Essential medicines, Second-line anti-tuberculosis medicines, National Health Product Quality Control

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## **ACKNOWLEDGEMENTS**

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- The staff of the National Health Products Quality Control (NHQC) center; in particular, Dr. Nam Nivanna for her support and guidance; Mr. Tey Sovannarith, for being a highly committed teacher throughout the trainings; Mr. Prav Cheang Hor, for his hospitality and all the energy that was put in the preparation of this training.
- H.E Sok Pheng, Secretary of State; and H.E Tep Lun, General Directorate for Health, for chairing the Opening and Closing Ceremonies.
- Dr. Heng Bunkiet, Director of Department of Drug and Food (DDF) of the Ministry of Health; and Dr. Chroeung Sokhan, President of Pharmacist Association of Cambodia, for their valuable guidance.
- Le Capitaine de Police Silvain Coué, FSP MEKONG Project, French Embassy, for supporting the refresher training for first-time analysts who will be implementing the medicine quality monitoring program in the field.
- All participants from sentinel sites, DDF, CENAT, CNM and the Ministry of Interior for their efforts and attention during the training.
- Our PQM colleagues for their help and support.
- Tony Boni and Maria Miralles at USAID/Washington, D.C. for their guidance and support.

## **ACRONYMS**

ANEQAM	Asian Network of Excellence in Quality Assurance of Medicines
ASEAN	Association Southeast Asian Nations
CENAT	National Center for Tuberculosis and Leprosy Control
DDF	Department of Drug and Food
DQI	Drug Quality and Information Program
DOTS	Directly Observed Therapy – Short Course
FSP	Fond de Solidarité et Priorité
GMP	Good Manufacturing Practices
GFATM or Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HPLC	High Performance Liquid Chromatography
MOH	Ministry of Health
MQM	Medicines Quality Monitoring
NHQC	National Health Product Quality Control
OPHE	Office of Public Health and Education
PAC	Pharmacist Association of Cambodia
PQM	Promoting the Quality of Medicines Program
PSA	Public Service Announcement
QA	Quality Assurance
QC	Quality Control
RDM/A	USAID Regional Development Mission for Asia
TB	Tuberculosis
TLC	Thin Layer Chromatography
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

## **Background**

The Drug Quality and Information (DQI) Program—and, its successor, the Promoting the Quality of Medicines (PQM) Program—has provided technical assistance to the Cambodian Ministry of Health’s Department of Drugs and Food (DDF), the National Health Product Quality Control Center (NHQC), and national priority diseases programs for malaria and tuberculosis since 2003, in an effort to improve the quality of medicines in Cambodia.

PQM assisted the Cambodian government to establish 12 sentinel sites that collect data on medicines quality. Currently, the medicines quality monitoring (MQM) program is jointly funded by USAID and the Global Fund (GF) and is implemented by the DDF. Substandard and counterfeit medicines in all categories—antimalarial, antibiotic, and antiretroviral—have been found circulating in the Cambodian market. In March 2010, a regional meeting was held to discuss the accomplishments of the past five years, challenges and plans for further activities.

## **Purpose of Trip**

- Facilitate training on basic testing of 2<sup>nd</sup> line anti-tuberculosis medicines using Minilab<sup>®</sup>
- Facilitate refresher training on basic testing of essential medicines using Minilab<sup>®</sup>
- Provide technical assistance to the NHQC laboratory

## **Source of Funding**

This trip was supported with funds from USAID/Cambodia.

## **Overview of Activities**

### **Basic Testing of 2<sup>nd</sup> line anti-tuberculosis medicines using Minilab<sup>®</sup> techniques**

October 18-20, 2010 at NHQC in Phnom Penh

Lead Facilitators: Mr. Tey Sovannarith and Mr. Prav Cheang Hor

PQM Facilitators: Ms. Siv Lang and Dr. Asawin Likhitsup

Participants: Staff from existing 12 sentinel sites, DDF Inspectors, staff from National Center for Tuberculosis and Leprosy Control (CENAT), staff from CNM

Opening remarks were given by Prof. Nam. Nivanna (NHQC Director); Dr. Chantha Chak (Infectious Disease Team Leader, OPHE, USAID Cambodia); and H.E. Dr. Tep Lun (General Directorate for Health, Ministry of Health).

Following an introduction to the elements of basic testing (visual inspection, disintegration and TLC testing), the participants had hands-on training on each method.

Before the end of the training, participants had ample time to discuss their past experiences and provided their input to improve the MQM program.

A discussion with Dr. Chay Sokun from CENAT, who participated in the training, gave more insight into the current status of Cambodia’s National TB Program. A 2006 survey found some multi-drug resistant TB cases that are resistant to Levofloxacin, Kanamycin, Prothionamide and Cycloserine. Now, a new TB treatment guideline called DOTS-plus has been piloted and will soon be used throughout Cambodia.

A general discussion was opened for all participants on the last day of the training. Many issues were raised relating to:

1. Sample collection

- Since antimalarial monotherapy was banned, it is difficult to find on the market, and the group recommended that monotherapies be removed from the testing and collecting list. They also proposed that USP develop monographs for testing combination medicines such as Dihydroartemisinin+Piperaquine, Tetracycline+Nystatin, Ampicillin+Cloxacillin, and an injectable antimalarial like Artemether.
- Samples collected are similar for each quarter so we may want to review and update items for collecting and testing.

2. Feedback and results of confirmatory testing from NHQC

- Provincial staff proposed to central level (both DDF/MoH and NHQC) to let them know the result of confirmatory tests and actions to be taken as soon as possible. They noticed a lag time of more than 6 months, and appropriate actions may not be able to be taken after such a period of time.

3. Materials needed for TLC testing

- At the beginning of TLC testing, the staff were instructed to use 2 TLC plates for 1 sample. More recently, due to a shortage of TLC plates, some provinces have been using only 1 plate for 1 sample. The group wanted to know if it is possible to maintain enough quantity for their consumption and if it is acceptable to use only 1 plate for 1 sample.
- Some UV lamps, glasses, and a dryer need to be replaced.

Closing remarks were given by Dr. Nam Nivanna (Director, NHQC); H. E. Sok Pheng (Secretary of State); and Dr. Asawin Likhitsup. At the end of ceremony, certificates of completion were given to all participants.

**Basic Testing of Essential Medicines using Minilab<sup>®</sup> Techniques**

October 21-22, 2010 at the NHQC in Phnom Penh

Lead Facilitators: Mr. Tey Sovannarith and Mr. Prav Cheang Hor

PQM Facilitators: Ms. Siv Lang and Dr. Asawin Likhitsup

Participants: Silvain Coué (FSP Mekong), NHQC staff, Cambodian police and customs officers, new staff from existing sentinel sites

Opening remarks were given by Mr. Prav Cheang Hor (Deputy Director, NHQC); Capt. Silvain Coué (FSP Mekong); and Prof. Dr. Nam Nivanna (Director, NHQC).

This training was similar to the first one but was provided for participants who are new to Minilab<sup>®</sup>. In addition to the general introduction, a hands-on training on handling pipettes and other basic equipment was given.

**Meetings with key partners**

Meeting with Dr. Nam Nivanna (Director, NHQC)

October 19, 2010

NHQC has a plan to build a new laboratory financed by a loan from the World Bank. Following up from a previous visit by Dr. Patrick Lukulay, PQM Director, the PQM team made two suggestions to their blueprint so that the new laboratory is in line with ISO/IEC 17025 standards.

1. Rearrangement of some laboratories
2. Installation of a central air circulation unit

The deadline for design modification was September 30, and the bidding process will start soon. However, NHQC withheld the blueprint and there is time for modification. Dr. Nivanna allowed the PQM team to have a copy of the blueprint. Dr. Nivanna is concerned that the estimated cost was over the budget ceiling. The initial cost was estimated at \$300,000 but now the estimate is around \$1,000,000, without taking into account the central air circulation unit.

### **Next steps**

PQM will send a consultant to NHQC in December to help with laboratory design modification.

Meeting with Dr. Heng Bun Kiet (Director, DDF) and H.E. Tep Lun (General Director, MOH)  
October 19, 2010

Dr. Bun Kiet asked if it is possible to support their confirmatory testing at an ISO certified lab abroad (in Thailand or Vietnam) in case they find failed medicine during confirmatory testing at NHQC.

### **Next Steps**

PQM will be able to support testing for a limited amount of samples outside Cambodia and will look to conduct proficiency tests of some products between the NHQC and 1 or 2 ISO accredited labs. However, PQM's long-term focus will be on helping NHQC/DDF achieve ISO accreditation or WHO prequalification.

Meeting with Dr. Chroeng Sokhan (Vice Director, DDF and President, PAC)  
October 20, 2010

Dr. Sokhan said that PAC sponsorship has been cut recently because of the end of the PATH project. Therefore, he requests more support from PQM.

PAC is planning to hold a seminar on the topic of ethical promotion of medicines. The target audience will be sales representatives, manufacturers, owners of pharmaceutical companies, and prescribers. They anticipate requesting PQM and other NGOs for support.

Meeting with Monique Mosolf (OPHE Director) and Dr. Chantha Chak (USAID/Cambodia)  
October 21, 2010 at USAID Cambodia

Dr. Chantha informed the PQM team that, beginning next year, USAID/Cambodia will only handle TB and MCH funding. Malaria funding will be handled by RDM-A.

Dr. Chanta also expressed interest in the analytical method for testing the quality of oxytocin.

Annex: Training Participants

**REGISTRATION LIST**  
**Drug Quality Monitoring 2 lines Anti-TB Using Basic Tests, Sampling Procedure and Drug Quality Data management**  
**Venue : National Health Product Quality Control Center, October 18-20,2010**

N°	Name	Sex	Title	Contact Address	Signature		Others
					Morning	Afternoon	
<b>1 Preah Vihear</b>							
1	KONG SAKAL	M	PHD Preah Vihear	012236416			
2	So lain	M	PHD	012993704			
<b>2 Pursat</b>							
1	KUY VANNY	M	PHD Pursat	012266581			
2	ROS HON SLY	M	PHD/PS	012492088			
<b>3 Koh Kong</b>							
1	Touch Phalk	M	PHD Kc	016611205			
2	PIN-VANNARA	M	PHD Kc	012738267			
<b>4 Battambang</b>							
1	HAS ASSANY	M	PHD BTB	012772656			
2	CHHOUN SENG	M	PHD BTB	012530322			
<b>5 Banteay Mean Chey</b>							
1	PHIKUMBUNNARA	M	PHD. BMC	012832023			
2	YAM-CHAI FOAN	M	PHD BMC	012608834			
<b>6 Oddor Mean Chey</b>							
	HEAN KINSEAT	M	PHD BMC	012983336			
	SUN Channa	M	PHD BMC	092960856			
<b>7 Mondulkiri</b>							
	HUOT RITHYNDRAK	M	PHD BMC	012964905			
	KHONH-KHIM	M	PHD BMC	099620191			
<b>8 Pailin</b>							
	NUTH TITH	M	PHD BMC	017710928			
	Chan. Chhang	M	RH Pailin	0945284043			
<b>9 Kampong Cham</b>							
	TRY RASY	F	PHD Kc	012801992			
	CHHAN-Rachna	F	PHD Kc	011996323			
<b>10 Stung Treng</b>							
	KIM VATHAK	M	PHD ST	012631924			
	THA SOTA	F	PHD ST	0979043074			
<b>11 Rattanakiri</b>							
	Ly channeth	M	Pharmacist	012965981			
	NGOUN BOUKANKANDO	M	Pharmacist	012767786			
<b>12 Kratie</b>							
	Ngov. Sochoh	M	PHD Kratie	012932398			
	NITH SREYTOUCH	F	Labo RH	092284413			

**REGISTRATION LIST**  
**Drug Quality Monitoring 2 lines Anti-TB Using Basic Tests, Sampling Procedure and Drug Quality Data management**  
**Venue : National Health Product Quality Control Center, October 18-20,2010**

Nº	Name	Sex	Title	Contact Address	Signature		Others
					Morning	Afternoon	
<b>1 DDF</b>							
1	Kao Seng	M	DDF	016717562			
2	MOEUY KHA	M	DDF	07793389			
3	Ev Bararath	M	DDF	06883460			
<b>2 EDB</b>							
1	Hun Huong	M	DDF	01287866			
<b>3 CNM</b>							
1	Bam Boravann	F	CNM				
<b>4 TB</b>							
1	CHAY SOKUN	M	Technical officer	012674867			

**REGISTRATION LIST**  
**Drug Quality Monitoring 2 lines Anti-TB Using Basic Tests, Sampling Procedure and Drug Quality Data management**  
**Venue : National Health Product Quality Control Center, October 18-20,2010**

Nº	Name	Sex	Title	Contact Address	Signature		Others
					Morning	Afternoon	
<b>NHQC (National Health Product Quality Control Center )</b>							
1	CHANON	F	Deputy chief of technical Bureau				
2	UNG SOTHAY	F	Chief of technical Bureau				
3	KHUON VILAVANN	F	Deputy chief of NHQC				
4	Ngon Henry	F	Chief of chemical section				
5	Yi SOTHEARY	F	Chemical staff				
6	Tep Keila	M	Deputy director				
7	Tay souannarith	M	Deputy chief of Technical Bureau	012974786			
8	Prav Chheang Vix	M	Deputy Director	012959993			
9	Keo Sathy	F	Chief of Adm Bureau	092695292			
10	YIM TEANG	F	NHQC staff	077553365			

**REGISTRATION LIST**  
**Drug Quality Monitoring 2 lines Anti-TB Using Basic Tests, Sampling Procedure and Drug Quality Data management**  
**Venue : National Health Product Quality Control Center, October 18-20,2010**

Nº	Name	Sex	Title	Contact Address	Signature		Others
					Morning	Afternoon	
<b>Honor Guest</b>							
	ASAWIN	M	TECHNICAL CONSULTANT	PGM BANARUK			
	CHAK	M	ITD Team leader	USAID			
	Heng Nam	M	Director of DDF	DDF (MOH)			
	Nivanna	F	Director of NHQC	NHQC			
	SIV Lang	F	PGM Consultant	PGM			

**REGISTRATION LIST**

Refresh training course on quality of the essential drug using Basic test ( Visual Inspection, Disintegration test, and Thin Layer Chromatography )  
 Venue : National Health Product Quality Control Center, October 21-22,2010

N°	Name	Sex	Title	Contact Address	Signature		Others	
					Morning	Afternoon		
<b>1. Police national</b>								
1	លោក រសេនីយ៍ឯក ខួត វុឌ	Klauth Vuth	M	Chef adjoint dela direction du Bilan et de la Planification et de l'etat Major	012 458 237			
2	លោក រសេនីយ៍ឯក ម៉ៅ ច័ន្ទ មុធីវិទូ	Mao Chanmaithurith	M	Chef adjoint dela direction des affaires Etrangères de l'etat Major	015 888 877			
3	លោក រសេនីយ៍ទោ សួន ណារ៉ា	Suon Nara	M	Chef de Bureau de la Direction de la Police Economique	092523 7777			
4	លោក រសេនីយ៍ត្រី ទួច ដាណារ៉ា	Touch Danara	M	Chef adjoint de Bureau de la Police Economique du Commissariat de Phnom Penh	012 973 973			
5	លោកស្រី ត្រីនូបាលឯក ហេង សុខស៊ី	Heng Sokly	F	Fonctionnaire de la Direction de l'Administration et du Bilan de l'Etat Major	011 683 888 011 685888			

**2. Gendarmerie Royale Khmère**

1	លោក រសេនីយ៍ត្រី ប៉ៅ វណ្ណវិទូ	Por Vanarith	M	Chef adjoint de Bureau de la Santé au Commissariat de Phnom Penh	012559690			
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**3. Douanes**

1	លោក ម៉ក់ វិសាល	Mak Visal	M	Fonctionnaire de la direction de planification, de Technique et des affaires Etrangères	012 59115			
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**4. Cooperation Police Française**

1	លោក កូអេ ស៊ីវាំង	COUE Silvain	M	Capitaine de Police, Assistant Technique project FSP MEKONG	092 971 261			
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**REGISTRATION LIST**

Refresh training course on quality of the essential drug using Basic test ( Visual Inspection, Disintegration test, and Thin Layer Chromatography )

Venue : National Health Product Quality Control Center, October 21-22,2010

N°	Name	Sex	Title	Contact Address	Signature		Others	
					Morning	Afternoon		
<b>1 DDF</b>								
1	ឥន្ទ្រ គុណណា	PANSOUKONNA	M	inspector DDF	0128561901			
2	សំសាន់ សំណាង	Som SamNang	M	inspector DDF	0128312686			
3	ស៊ីង - សំណាង	Hfleang Sameth	M	Inspector DDF	012 989 552			

**REGISTRATION LIST**

Refresh training course on quality of the essential drug using Basic test ( Visual Inspection, Disintegration test, and Thin Layer Chromatography )  
Venue : National Health Product Quality Control Center, October 21-22,2010

1 Battambang							
1	ឈ្មោះ លេង	Chhoun Seng	M	PHD Battambang	012 530 327		
7 Monduliri							
1	ឧត្ត យីម	Khonh Khim	M	មន្ត្រីស្ថិតិ	099 620 191		
9 Kampong Cham							
1	ចាន់ រចនា	Chan Rachna	F	PHD Kampong Cham	011 996 323		
10 Stung Treng							
1	ថា សុផា	Tha Sota	F	PHD Stung Treng	097 904 3071		
12 Kratie							
1	ញី ស្រីម៉ូច	Nhen Sreythouch	F	Labo RH	092 284 413		

**REGISTRATION LIST**

Refresh training course on quality of the essential drug using Basic test ( Visual Inspection, Disintegration test, and Thin Layer Chromatography )  
Venue : National Health Product Quality Control Center, October 21-22,2010

N°	Name	Sex	Title	Contact Address	Signature		Others
					Morning	Afternoon	
1	ASAVIN LIKHITSUP	M	Technical Consultant	PQM Bangkok			
2	SIV LANG	F	PQM Consultant	PQM Cambodia			

**REGISTRATION LIST**

Refresh training course on quality of the essential drug using Basic test ( Visual Inspection, Disintegration test, and Thin Layer Chromatography )  
Venue : National Health Product Quality Control Center, October 21-22,2010

N°	Name	Sex	Title	Contact Address	Signature		Others
					Morning	Afternoon	
NHQC (National Health Product Quality Control Center)							
1	ប្អូន វិធាវណ្ណ	F	Deputy chief of NHQC	016 911 196			
2	ប្រាវ ឈាងហិ	M	Deputy chief of NHQC	012 959 993			
3	ទេព កីឡា	M	Deputy chief of NHQC	012 231 391			
4	អ៊ុង សុផាវី	F	Chief of technical Bureau	011 634 228			
5	ជួន ចន្ទោភាស	F	Deputy chief of technical Bureau	011 861 827			
6	តី សុវណ្ណារិទ្ធ	M	Deputy chief of technical Bureau	012 974 786			
7	កែវ សុទ្ធី	F	Chief of Admin. Bureau	092 695 798			
8	ហ្គួន ហង់រី	F	Chief of technical section	011 865 680			
9	យី សុទេរី	F	Chemical staff	NHQC			
10	យីម ទៀង	F	Chemical staff	NHQC			