

Program Partners' Meeting on Engaging Key Stakeholders to Support Quality Assurance and Quality Control Activities for Anti-Tuberculosis Medicines

Jakarta, Indonesia
October 15-19, 2012

Trip Report

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Promoting the Quality of Medicines

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PROMOTING THE QUALITY OF MEDICINES

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Executive Summary

Dr. Souly Phanouvong traveled to Jakarta, Indonesia and teamed up with Musalkazim Ali, the local PQM consultant, to present at a key partners meeting organized by the National Tuberculosis Control Program (NTP). The PQM team gave an overview of the program and discussed the ways forward for effective program implementation in Indonesia, especially in relation to PQM's technical assistance to help Indonesian anti-tuberculosis medicine manufacturers work toward World Health Organization (WHO) Prequalification (PQ). The workshop aimed to discuss what each of the involved agencies can do to strengthen their cooperation for better program implementation. A key outcome of the meeting was the creation of a comprehensive list of action items complete with responsible parties and due dates.

While in Jakarta, Dr. Phanouvong met with staff from the WHO Country Office's TB Program to discuss the possibilities for WHO involvement in engaging local partners in PQM program implementation, especially as it relates to WHO PQ and capacity-building for the National Agency of Food and Drug Control (NA-FDC). The PQM team also met with management staff of local manufacturers Indofarma, Phapros, and Equilab International to follow up on their progress toward WHO PQ, as well as with Sandoz Indonesia, a new candidate participating in the WHO PQ process.

The PQM team also held meetings with management staff at the National Quality Control Laboratory for Drug and Food (NQCL-DF), USAID/Indonesia's Office of Health, and the NTP to discuss program progress and challenges.

In addition, the PQM team visited Indonesia University and met with the Director of the Department of Occupational Medicine to begin discussing the possibility of having a PQM office at the University.

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About PQM

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID’s response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical assistance to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID, PMI or the United States Government. It may be reproduced if credit is given to PQM and USP.

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- Dr. Kendra Chittenden, Senior Infectious Diseases Advisor, USAID/Indonesia
- Dr. H.M. Shubuh, Director of Directorate General Disease Control & Environmental Health, Ministry of Health, Indonesia
- Dr. Syamsudin, Director of NQCLDF of NA- DFC, Indonesia
- Drg. Dyah Erti Mustikawati, Head of Sub-directorate, Tuberculosis Directorate, General Disease Control & Environmental Health, Ministry of Health, Indonesia
- Dr. Nani Sukasediati, WHO Consultant
- Dr. Muhammad Akhtar, WHO TB Program Manager/Medical Officer
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ACRONYMS

ATB	Anti-tuberculosis medicine
BINFAR	Pharmaceutical Product Production and Distribution
CAPA	Corrective and Preventive Action
DQI	Drug Quality and Information Program
FDC	Fixed Dose Combination
GMP	Good Manufacturing Practice
MDR-TB	Multi Drug Resistant Tuberculosis
MOH	Ministry of Health
MQM	Medicine Quality Monitoring
NA-DFC	Indonesia National Agency for Drug and Food Control
NQCL-DF	National Quality Control Lab for Drugs and Food
NTP	National Tuberculosis Program
PQ	Prequalification
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
TB	Tuberculosis
TLC	Thin Layer Chromatography
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Background

Indonesia is considered to be a “high burden” country for tuberculosis (TB) by the World Health Organization (WHO); it ranks ninth out of 22 high burden countries. The situation is compounded by the development of multi-drug resistant tuberculosis (MDR-TB). There is a need to improve the quality assurance system for anti-TB medicines (ATBs) being purchased and used in the National Tuberculosis Program (NTP) and to develop and implement strict regulatory control measures for the sale and supply of anti-TB medicines in the private sector. None of the ATB products produced in Indonesia has achieved WHO prequalification (PQ) status for their quality and efficacy.

Purpose of Trip

The main objective of the trip was to present at a key partners meeting organized by the NTP to discuss ways forward for effective program implementation in Indonesia, especially in relation to PQM’s technical assistance to help ATB medicine manufacturers work toward WHO PQ.

Overview of Activities

Meeting with Dr. Muhammad Akhtar, WHO TB Program Manager: October 15, 2012

Dr. Akhtar was very interested in the work PQM has been doing in Indonesia in support of the NTP to help tackle MDR-TB from a medicines quality perspective. He will engage his colleague, Dr. Nani Sukasediati, who is well aware of the WHO PQ program and involved in obtaining technical support from the PQ team to strengthen the Indonesia National Agency for Drug and Food Control (NA-DFC) staff’s knowledge. Dr. Akhtar has strong experience with ATB supply management and is tasked to help the NTP improve pharmaceutical management of ATBs in Indonesia. He stated that he would need assistance from PQM in building strong quality assurance/quality control (QA/QC) systems for ATBs and that the PQM-supported Medicines Quality Monitoring (MQM) program can play a big role in this regard. Dr. Akhtar stated that he will attend the partners’ workshop at the NTP on October 18 where PQM will be presenting.

Action Items:

- WHO and PQM will keep each other informed on future progress and challenges.

Meeting with Indofarma to review and discuss progress: October 15, 2012

Dr. Kosasih, Production Director, updated PQM that Indofarma has received the government budget for building a new facility dedicated to ATB solid dosage forms. Indofarma submitted a master plant design to NA-FDC on October 8 for approval, which may take 3-4 months. The bidding process for selection of a construction company has begun. Indofarma will share the blueprint of the plant with PQM for comment once it develops from the master plan design approved by NA-FDC. Dr. Kosaish also informed PQM that Indofarma staff participated in a NA-DFC workshop on WHO PQ requirements for documentation and Good Manufacturing Practices (GMP) compliance in May, which deepened their understanding of the PQ process.

Action items:

- Indofarma will keep PQM informed of the status of its application to NA-FDC.
- Indofarma will send the plant blueprint (when it is available) to PQM for comment and involve PQM as early as possible to ensure compliance with GMP requirements.

Meeting with Phapros to review and discuss progress: October 16, 2012

Ibu Rosa presented on the implementation status of the remaining corrective and preventive actions (CAPAs) since the last update in July 2012. The majority of the CAPAs will be completed by the end of November 2012, including a) equipment and facility cleaning validation; b) material coding system; c) reformulation to reduce overage of rifampicin; and d) documentation from a GMP perspective. To increase GMP compliance, Phapros has been renovating some areas of its facility and installing new equipment. Phapros is conducting a pilot bioequivalence (BE) study with Equilab International before the full BE studies of its 4 and 2 fixed-dose combinations (FDCs). Phapros also continues to conduct dissolution profile testing of its products against the comparator products provided by PQM. The following are to be completed January-June 2013:

- External pre-audit - PQM
- Production of Biobatch (4-FDC)
 - Process optimization (Jan 2013)
 - Production of biobatch (2 batch) (March-April 2013)
 - IVD test of biobatch (April-May 2013)
 - Pilot BE study (Equilab) (April-June 2013)
 - Accelerated stability study (at least 6 months for PQ submission)
 - Real-time stability study (at least 6 months for PQ submission)
- BE Study
 - BE Study (with Accutest and/or Equilab) (July-October 2013)
 - Dossier final preparation/submission to PQM for final review (July 2013)
 - Dossier submission to WHO (August 2013)

Meeting with National Quality Control Laboratory for Drugs & Food (NQCL-DF): October 17, 2012

Mr. Syamsudin, the head of NQCL-DF, informed the PQM team that the Minilabs[®] were scheduled to be transported to sentinel sites by a service provider, PT Tricor, at the end of October 2012. In addition, a bank account is being opened for PQM-supported programs; this should be completed by early November 2012.

PQM and NQCL-DF discussed a potential supervisory and monitoring trip with USAID/Indonesia to visit 1-2 sentinel sites and follow up on sample collection and Minilab[®] testing. PQM and NQCL-DF also planned for a meeting to be held in March 2013 convening all five sentinel sites—Medan (QCL & Field), Makassar, Surabaya, Serang, and Mataram—to discuss and share their experiences, lessons learned, and results from Round One sample collection and testing.

There are some budget gaps based on the estimated figures included in the Letter of Collaboration between PQM and NQCL-DF for MQM in Indonesia for 2012-2013. The PQM team advised NQCL-DF to carry out the MQM activities as planned, with some budget adjustments, and that all sentinel sites should be able to perform their activities. PQM can make some budget amendments, if necessary, and with the approval of USAID/Indonesia.

Action Items:

- NQCL-DF will ensure the Minilabs[®] are shipped to the field by the end of October 2012
- NQCL-DF will ensure that the bank account is opened by the beginning of November 2012
- PQM will wire funds within 2-3 weeks after the bank account is open.

Meeting with NTP: October 17, 2012

PQM updated Dr. Dyah Erti Mustikawati, the head of NTP, about the status of PQM's technical assistance to Phapros and Indofarma towards WHO PQ. Bottlenecks and challenges the manufacturers and PQM have been facing were discussed and possible solutions include: a) high level government involvement and support in the process; b) increased responsiveness and open communication between the companies; and c) the presence of a PQM technical representative in Jakarta to be available for consultation and assistance. The October 18th face-to-face meeting among key stakeholders will also be a positive step toward addressing challenges.

The Indonesia Ministry of Health (MOH) has engaged a private company, Sandoz Indonesia, to participate in the WHO PQ process. Dr. Dyah Erti Mustikawati urged PQM to work with Sandoz.

Meeting with USAID/Indonesia: October 17, 2012

Despite challenges, as described earlier, both PQM and the Mission remain optimistic. The good news is that Phapros and Indofarma have consistently put serious investment into building and/or renovating their ATB production facilities to achieve full compliance with international standards. It is only a question of time needed to help them to achieve PQ status. The Mission is pleased to hear that the MOH has engaged Sandoz to take part in the PQ process and asked PQM to start working with Sandoz as soon as possible.

Partners Meeting on Engaging Key Stakeholders to Support QA/QC Activities for Anti-TB Medicines to Help NTP and NA-FDC Tackle MDR-TB in Indonesia: October 18, 2012

The meeting objectives included:

- Overview of the PQM program
- Overview of the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM) requirements and findings from recent QA/QC assessments in selected provinces
- Discussions on key stakeholder involvement and support for QA/QC activities to improve the quality of ATBs in Indonesia

Opening Statements

The importance of the problem of MDR-TB and medicines quality in Indonesia—in terms of their potential impact on treatment outcomes, antimicrobial resistance, and the public's trust in health systems—was highlighted. In addition, participants were encouraged to increase their efforts to support the NTP program in its target of treating 1 million TB patients and diagnosing and treating 5,100 MDR-TB patients by 2014.

Highlights of the Meeting

The Meeting, attended by 24 representatives from 11 institutions/organizations, was opened by the MOH Representative, Mr. H.M. Subuh (Director of the Directorate of Directly Transmitted Diseases, Directorate General of Disease and Environmental Health, Indonesia), and the meeting proceeded in accordance to the agenda. Please see the agenda in *Annex 1* and the list of participants in *Annex 2*.

Dr. Phanouvong's presentation covered PQM program elements with the main focus on Indonesian activities and challenges. He also discussed ways forward for effective program implementation and sustainability. The MQM program—introduced by PQM to strengthen post-marketing surveillance by the NA-FDC, provincial health authorities, and NTP—was among the top discussion topics of the meeting. Dr. Phanouvong's presentation can be obtained by contacting him directly at sxp@usp.org.

Mr. Syamsuddin, Director of the NQCL-DF, informed the meeting participants that the NA-DFC has been conducting pre- and post-market surveillance for essential medicines circulating in Indonesia, and samples have been tested at his lab, which is ISO/IEC 17025 accredited, as well as at its network of 31 QC labs at provincial levels. PQM conducted hand-on training workshops for key ATB medicines for the NQCL-DF and selected provincial QC labs in June 2012. The challenge the NQCL-DF is facing now is the acquisition of reference standards for many products.

Dr. Nani, WHO consultant, pointed out that there is a need for more coordination among the NA-DFC, the MOH Pharmaceutical Product Production and Distribution (BINFAR), and the Pharmaceutical Access and Pharmacy Service Department in efforts to improve the quality, safety, and rational use of medicines, especially ATBs. She also indicated that, in Indonesia, to reach international GMP compliance, companies need capital investment to upgrade their facilities and improve documentation. There are still many companies who do not meet these standards. With the help of PQM and support from WHO, some companies would be able to achieve PQ status in the near future. According Dr. Nani, John Snow Inc. has started to work with BINFAR to provide and develop standard operating procedures (SOPs) for Good Storage Practices. It would make sense to work collectively to avoid duplication of efforts.

Dr. Phanouvong led the discussion on ways forward to engage key stakeholders to provide support to help tackle the MDR-TB situation in Indonesia from a QA/QC of medicines standpoint. A key outcome of the meeting is a comprehensive list of action items, included in *Annex 3*.

Meeting with Sandoz Indonesia: October 18, 2012

PQM met with key technical and business staff from Sandoz at NTP's offices and provided information on the WHO PQ process and the technical assistance PQM can provide. Sandoz informed PQM that the ATB products they currently produce are all branded generics. They are interested in WHO PQ for several adult and pediatric FDCs.

Challenges include the fact that no BE studies have been done on the products in accordance with PQ requirements. In addition, the product dossiers are not in the required format, and are in Bahasa language (general SOPs are in English and Bahasa). However, Sandoz has in-house resources to translate the dossiers into English. The Sandoz team anticipates potential investments to upgrade their facilities, and they are pleased and excited about the opportunity to work with and receive technical assistance from PQM.

Action Items:

- Sandoz will report the outcomes of this meeting to upper management
- Sandoz will submit a complete questionnaire to PQM by the end of October 2012

Meeting with Equilab International: October 19, 2012

Equilab is working to secure a contract with an insurance service provider to ensure full compliance with WHO requirements for the subjects enrolled in the BA/BE studies as recommended by PQM consultant, Dr. Andre Vanzyl. Discussion also touched on the BE study protocol that Equilab should prepare. The PQM team requested that Equilab send the draft protocol to PQM for input.

Equilab also informed PQM that a WHO consultant and NA-FDC will conduct a training audit at Equilab's facilities for NA-FDC auditors.

Action Items:

- Equilab will submit its BE study protocol for PQM input by November 2012
- Equilab will notify PQM once an insurance service provider is contracted
- Equilab will notify PQM on the outcomes of the audit training

Meeting at Indonesia University: October 19, 2012

PQM met with Dr. Muchtarudin Mansyur (Head of Occupational Medicine Residency Program, Department of Community Medicine, and Vice Chairman of Health Research Ethics Committee) to discuss possible collaboration in improving the quality of medicines at the point of dispensing and use and the possibility of having a PQM office at the University. In order to have an office at the University, a joint research project should be established. Three areas surrounding medicines quality were discussed, which could potentially contribute to MDR-TB control efforts in Indonesia: improved access to high quality ATBs in mining areas; awareness-raising on the dangers of using poor-quality ATBs; and improved curriculum of medical and pharmacy students on QA/QC principles. Dr. Muchtaruddin Mansyur then showed the PQM team two rooms which might be appropriate for a PQM office of 2-3 people.

Action Items:

- PQM will share meeting minutes with Dr. Muchtaruddin Mansyur by mid-November 2012
- Dr. Muchtaruddin Mansyur will work with the human resources department to find out specific details for arranging a PQM office, including work permit, visas, taxes, etc. and will notify PQM on progress by November 2012

Conclusion

The PQM trip to Indonesia was fruitful, with a successful partners' meeting resulting in the creation of a comprehensive list of action items complete with responsible parties and due dates. In addition, the PQM team was able to meet with several in-country partners (including local manufacturers, WHO, USAID/Indonesia, and NTP) and potential partners (Indonesia University), helping to move program activities forward.

AGENDA
HIGH LEVEL MEETING & WORKSHOP ON NEXT STEPS OF QUALITY ASSURANCE
AND QUALITY CONTROL PROCESS AND SYSTEM FOR ATB MEDICINE NATIONAL
PROGRAM
JAKARTA, 18TH OCTOBER 2012

TIME	ACTIVITIES	PIC
08.30-09.00	Opening & Speech	DG P2PL
09.00-09.30	Presentation on overview of current PQM Program Activities, progress & challenges and the forward	Souly Phanouvong
09.30- 10.00	SOP QC OAT Draft Presentation at Province Level and District/Town	Abdelkrim Smine
10.00-10.15	Break Coffee	Committee
10.15-12.00	Discussion on what can each of the responsible/involved agencies may do to strengthen the cooperation and support for better program implementation)	NTP Manager/Souly/Karim
12.00-13.00	Break, Praying & Lunch	Committee
13.00-14.30	Next Steps Planning	NTP Manager / USP
14.30-15.00	Meeting Summary	NTP Manager

ANNEX 2

PARTICIPANT LIST
PARTNERS MEETING ON NEXT STEPS OF QUALITY ASSURANCE AND QUALITY CONTROL PROCESS AND
SYSTEM FOR ATB MEDICINE NATIONAL PROGRAM
JAKARTA, 18TH OCTOBER 2012

Name	Organization
1. Desinatri	Indofarma
2. Sya Indradewi	Indofarma
3. Iswanto	Phapros
4. Rokhmi Fitna E	Phapros
5. Muhammad Akhtar	WHO-Indonesia
6. Kosasih	Indofarma
7. Hamid Salim	KNCV
8. Christopher Raymond	
9. Souly Phanouvong	USP PQM
10. Abdelkrim Smine	MSH Consultant
11. Nani Sukasediati	WHO Indonesia
12. Kendra Chittenden	USAID-Washington
13. Rudy Hutagalume	NTP
14. Musalkazim Ali	USP PQM
15. Triya N Dinihari	NTP
16. Tiar S	KCNV
17. Ariesita	KNCV
18. Dyah Erti M	NTP
19. HM Subuh	Dir P2ML
20. Syamsudin	PPOMN
21. Mirawati S.	PPOMN
22. Andy Marsden	MSH TB Care
23. Russ Vogel	JSI Deliver
24. Yudhi P	NTP

ANNEX 3

Action Items Identified and Agreed On at the Partners Meeting at NTP 18-October-2012			
Next Steps	Timeframe	Responsible	Remarks
1. Face-to-face meeting between key stakeholders including BPOM, NTP, BINFAR, PPOMN, TB Care, and PQM to come to agreement on urgent matters under item #4 below.	Before end of 2012	NTP convenes meeting to be held at BPOM facilities (to be determined)	
2. Sharing info on activities that BPOM is currently undertaking on QA/QC specific to TB medicines with NTP	Official request drafted and submitted by NTP to BPOM by end of November, 2012	Ditwas Produksi Produk Terapeutik & PKRT under Deputy 1 -Ms. Rumondang	Information sharing on post-marketing surveillance data; sharing BPOM's Annual Reports—looking at TB medicines; will be helpful under GFATM audit, etc. PQM will provide to NTP a draft of background/rationale on why this information is needed. <i>NTP needs to officially request this information from BPOM</i>
3. 3a. NTP will get current registration status of all TB medicines from BPOM (website) 3b. Fast-track registration requirements for Phapros and Indofarma	By end of November, 2012	Dit Penilaian Obat under Deputy 1 -Ms. Endang Woro	
4. 4a. NTP to provide list of 2 nd line ATBs used in national program to BPOM. 4b. Samples that will be collected after January, 2013 to be provided by NTP to PPOMN lab for analysis.	4a. By end of October, 2012 4b. January-June, 2013	NTP (Leading) TB Care PPOMN	Prior to testing, PPOMN will work on method validation and testing procedures. Samples to be collected from selected Central-level warehouse where 2 nd Line ATBs are stored in Jakarta. After receiving the list, the PPOMN lab will identify which products that it can currently analyze & what supplies/resources are needed. <i>Must determine mechanism for funding</i>

			<p><i>sources for testing prior to sampling—NTP to reprogram funds?</i></p> <p><i>Agreement must be made on payment terms & scheduling</i></p> <p><i>Need face-to-face meeting between NTP, TB Care, BPOM, & PPOMN Lab</i></p>
<p>5. Capacity strengthening QA/QC systems by PQM should include training of trainers to ensure sustainability</p>	<p>PQM will include these activities in the FY13 work plan for the remaining priority 2nd Line ATBs: PAS, Levofloxacin, Moxifloxacin, Kanamycin</p>	<p>USP PQM PPOMN</p>	<p>Central Level analysts capable of training at peripheral level</p> <p>Note: Already completed for all 1st Line ATBs and for two 2nd Line ATBs in Indonesia (FY12)</p>
<p>6. ‘Special Access Scheme’ currently applied by BPOM includes priority TB medicines; NTP should take lead on designing a “sticker” (label) to designate SAS products so they are not rejected during PMS with no reg. number</p>	<p>By end of 2012</p>	<p>TB care NTP</p>	<p>Sticker designed by NTP and TB Care and submitted to PPOMN</p>
<p>7. 7a. Creation of Working Group on WHO-PQ by identifying partners.</p> <p>7b. TOR and Draft ‘Joint Action Plan’ of the Working Group will be drafted and circulated for input and endorsement by partners.</p> <p>7c. Face-to-face meeting of Working Group to ratify TOR and ‘Joint Action Plan’</p>	<p>7a. By end of January, 2013</p> <p>7b. Jan-Mar, 2013: TOR draft circulated and feedback incorporated</p> <p>7c. meeting in March, 2013</p>	<p>PQM in collaboration with: NTP, WHO (TB and Medicines), TB Care, PPOMN, BPOM, BINFAR, JSI, MSH, local manufacturers, USAID, professional organizations: Indonesia Pharmacists’ Association (IAI) Pulmonologists’ Association of Indonesia (PDPI) Pediatricians’ Association of Indonesia (IDAI) Internists’ Association of Indonesia</p>	<p>High level officials will be notified of meeting outcomes on an ad hoc basis.</p> <p>Subsets of Working Group can meet as needed; every 6 months face-to-face update meetings; for urgent issues needing to be addressed, meetings may be scheduled between involved partners on the specific topic of the Working Group as needed</p> <p>NTP to provide contact persons for each organization</p>

		(PAPDI)	
8. NTP, in collaboration with BPOM, will coordinate, with assistance by PQM, follow-up “Working Group” meetings on partnering for QA/QC for TB medicines	Beginning in every 6 months face-to-face meetings, with other ad hoc meetings as necessary	PQM NTP	See item #7
9. Capacity building of the Warehouses	October, 2012- January, 2013: Assessments at 10 TB Care provinces Jan-July, 2013: Develop, agree, and implement performance improvement plans	TB Care (Leading) Supporting partners: People That Deliver JSI WHO BINFAR NTP	Followed up by ‘People That Deliver (PTD)’, including USAID Deliver (JSI), and TB Care