

Second-line Anti-TB Medicines for WHO PQP Workshop, MQM Follow-up, GMP Assessments, and PQM Technical Assistance to Indonesia

**Jakarta, Indonesia
March 18-April 2, 2013**

Trip Report

**Dr. Allan Hong, Manager, GMP Manager, PQM
Dr. Souly Phanouvong, Manager, Asia Programs, PQM
Mr. Chris Raymond, Chief of Party, PQM Indonesia
Mr. Edwin Toledo, Senior GMP Specialist, PQM
Dr. Karim Smine, PQM Consultant, USP**

Promoting the Quality of Medicines

Implemented by U.S. Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852 USA
Tel: (+1-301-816-8582)

Email: pqm@usp.org and jxd@usp.org and sxp@usp.org

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Author(s) Name: Christopher Raymond, Jenny Derry

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Executive Summary

The PQM team traveled to Indonesia during March 18-April 2 to conduct follow-up GMP assessments at local public and private manufacturing sites for anti-tuberculosis (TB) medicines (Phapros in Semarang, Sandoz in Jakarta, Sanbe Farma in Bandung) as part of the process towards application for WHO Prequalification. In addition, the team visited the contract research organization (CRO), SAN-CLIN-EQ Bioequivalence Laboratory, to assess progress on implementing corrective action and preventative action (CAPA) recommendations from 2011 and 2012 inspections by PQM and WHO.

The team also convened a seminar about the WHO Prequalification Programme for local manufacturers during the CPhI Southeast Asia Expo on March 22, and met with representatives of manufacturers that expressed interest in receiving further technical assistance from PQM towards WHO Prequalification. In addition, the team convened a Prequalification Coordination Meeting with the National TB Control Program, BADAN POM Regulatory Authority, public manufacturers, and partner nongovernmental organizations (NGOs) to discuss progress made, challenges encountered, and the way forward.

PQM conducted a supervisory field trip to Makassar, Sulawesi, to follow up on progress made during the first round of sampling and testing being conducted at five provincial sites around the country. In addition, the team discussed the plan to assist the BADAN POM central quality control laboratory in Jakarta to strengthen its ISO 17025 accreditation (moving from product-based to method-based processes) and the training of selected provincial quality control laboratories.

Recommendations from the trip include encouraging the establishment of a Technical Working Group for WHO Prequalification; further support by PQM to coordinate and assist in communications and technical guidance on fast-tracking registration of new anti-TB products under consideration for WHO Prequalification; and increased supervision and oversight during medicine quality monitoring as these activities increase in Indonesia.

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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 or the United States Government. It may be reproduced if credit is given to PQM and USP.

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- Dr. Slamet, Director, Directorate, General Disease Control and Environmental Health, Ministry of Health, Republic Indonesia
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ACRONYMS

ANEQAM	Asian Network of Excellence in Quality Assurance of Medicines
API	Active Pharmaceutical Ingredient
ASEAN	Association of Southeast Asian Nations
ATB	Anti-tuberculosis Medicines
AWGPD	ASEAN Working Group on Pharmaceuticals Development
BA/BE	Bioavailability/Bioequivalence
BADAN POM or BPOM	Badan Pengawas Obat dan Makanan (National Agency of Drug and Food Control, the Indonesian Regulatory Authority)
BBPOM	Provincial BADAN POM Laboratory
BREMERE	Building Regional Expertise in Medicines Regulation/Enforcement
ASEAN	Association of Southeast Asian Nations
CTD	Common Technical Document
CPHI	Convention on Pharmaceutical Ingredients
CRO	Contract Research Organization
DQI	Drug Quality and Information Program, predecessor to PQM
FPP	Finished Pharmaceutical Product
GCP	Good Clinical Practices
GFATM	Global Fund for AIDS, Tuberculosis and Malaria
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GDF	Global TB Drug Facility
GLC	Green Light Committee
GPHF	Global Pharma Health Fund
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
KNCV	Koninklijke Nederlandse Centrale Vereniging
MDR-TB	Multidrug-resistant Tuberculosis
MOH	Ministry of Health
MQM	Medicines Quality Monitoring
MSH	Management Sciences for Health
NOMCOL	Network of Medicines Control Laboratories
NTP	Indonesian National Tuberculosis Control Program
PMDT	Programmatic Management of Drug-resistant Tuberculosis
PMI	President's Malaria Initiative
PPOMN	Indonesian National Quality Control Laboratory of Food and Drugs
PPWG	Product Working Group on Pharmaceuticals
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
TB	Tuberculosis
USAID	United States Agency for International Development
USP	United States Pharmacopeial Convention
WHO	World Health Organization
WHO PQ	World Health Organization Prequalification Programme

Background

Despite efforts by the World Health Organization (WHO) Prequalification (PQ) Programme, Global TB Drug Facility (GDF), and the Green Light Committee (GLC) to increase access to essential anti-tuberculosis medicines (ATBs), there are not enough WHO-prequalified second-line ATBs and an inadequate supply of products to treat patients with multidrug-resistant tuberculosis (MDR-TB).

Indonesia is considered a high-burden tuberculosis (TB) country by WHO; it has been among the top five of the 22 high-burden TB countries for years. The situation is compounded by development of multidrug-resistant tuberculosis (MDR-TB) which is generated primarily due to the large numbers of TB patients who are inadequately treated. There is a need to improve the quality assurance system for TB medicines being purchased and used in the TB control program, and to develop and implement strict regulatory control and measures for the sale and supply of TB Medicines in the private sector, which challenges government effort to control MDR-TB. None of the ATB products produced in Indonesia has achieved WHO Prequalification status for quality or efficacy.

With financial support from the United States Agency for International Development (USAID)/Indonesia Mission, PQM has been providing technical assistance to Indonesia on the following:

1. Strengthening the post-marketing surveillance capacity of the National Agency of Drug and Food Control (Badan Pengawas Obat dan Makanan (BPOM)) by establishing medicines quality monitoring (MQM) of anti-tuberculosis (ATBs) in close collaboration with the National Quality Control Laboratory of Drug and Food (PPOMN);
2. Conducting workshops with WHO and GDF to inform manufacturers and NA-DFC about the WHO Prequalification (WHO PQ) Programme and the technical assistance PQM provides;
3. Providing technical assistance directly to selected local manufacturers to improve their good manufacturing practices (GMP) and product dossier compliance, working toward WHO Prequalification. PQM is also providing support to capacitate two contract research organizations (CRO) for conducting bioavailability and bioequivalence (BA/BE) studies for ATBs according to Good Clinical Practices (GCP) and Good Laboratory Practices (GLP) for acceptance into WHO PQP; and,
4. Conducting research and surveys to determine medicines quality in the marketplace.

Purpose of Trip

- Meet with the Indonesian National Tuberculosis Control Program (NTP) and agree on activities to be carried out by the Indonesian National Tuberculosis Control Program (BPOM) to begin implementing the quality assurance (QA) policy of TB medicines in line with the national post-marketing surveillance program;
- Meet with BPOM to determine priority areas in need of technical support and plan for PQM activities over the next three years (GLP, lab training, and quality systems);

- Determine the needs of the quality control (QC) laboratories in term of reference standards and high performance liquid chromatography (HPLC) columns to test second-line TB medicines;
- Update the PQM work plan (QA) for FY13 and discuss it with USAID and PQM colleagues;
- Conduct a field visit to one MQM sentinel site;
- Conduct a baseline GMP assessment of Sandoz Indonesia;
- Visit Phapros pharmaceutical company to discuss bio-batch and dossier submissions and set targets for production; inspect renovated facility in Semarang; address any issues related to pilot bioequivalence study with Equilab International.
- Meet local partners (NTP Manager, NA-DFC, PPOM, Directorate General of Disease Control and Environmental Health) to update the current status on PQM's work in Indonesia and discuss the way forward.
- Meet the NQCL-FD Director and senior staff to discuss strategy and plans to speed up the MQM of anti-TBs in the field and help address any technical and operational issues.
- Meet with serviced office providers in Jakarta to identify potential country office location.
- Introduce the WHO PQ program to ATB manufacturers in Indonesia and to engage them to actively participate in the process.

Overview of Activities

March 18-19, 2013

Meeting with BPOM-PPOMN in Palembang, Sumatera

PQM Consultants, Dr. Abdelkrim Smine and Mr. Christopher Raymond, traveled to Palembang, Sumatera, to meet with provincial QC laboratory managers (BBPOM) and the National Director of the Indonesian National Quality Control Laboratory of Food and Drugs, or Pusat Pengujian Obat dan Makanan Nasional (PPOMN) of BPOM, Drs. Syamsudin, and senior staff, Dra. Ati Setiawati and Dra. Mira Wati, to discuss the PQM plan for QA/QC activities under USAID support. In addition, the team discussed upcoming analytical trainings sponsored by the Global Fund for AIDS, Tuberculosis and Malaria (GFATM) to be held at the PPOMN lab in Jakarta during April (for first-line anti-TB medicines), June (antiretrovirals, tentatively), and August (antimalarials, tentatively). PQM also finalized details for the upcoming MQM field visit to Makassar for March 25-26 with PPOMN.

During the meeting, key topics discussed were:

- GFATM trainings are being offered at the PPOMN lab of 26 provinces over a two-week period in collaboration with a local (unnamed) university with assistance from a Belgian university (also unnamed). However, the PPOMN senior staff thought it was a priority to have on-site trainings conducted by external experts at the provincial level, which has never been done before.
- NTP must comply with the GFATM QA policy regarding anti-TB medicines procured through its grants; the PPOMN lab can conduct testing in-country since it already holds a recognized ISO/IEC 17025 accreditation from the Komite Akreditasi Nasional di Indonesia accrediting body, which is a signatory to the International Laboratory

Accreditation Cooperation (ILAC) Agreement. There is a need to quickly build capacity among the central and provincial labs for advanced testing of ATBs.

- PQM and PPOMN will develop a three-year implementation plan to identify priority trainings, both at the central PPOMN lab and in five provincial laboratories (BBPOM) — Surabaya, Makassar, Mataram, Medan, Pontianak — as a pilot project. This includes advanced analytical training on selected anti-TB products, developing an achievable action plan for expanding the current ISO/IEC 17025 with the aim to eventually achieve WHO PQ (esp. for the PPOMN lab), and provision of USP reference standards, U. S. Pharmacopeia-National Formulary (USP-NF) reference books, and other supplies. Each lab will develop its own three-year implementation plan in collaboration with PQM, according to agree-upon targets.
- During the meeting, PPOMN also asked that selected BPOM staff be included in the visiting scientist program at USP or another ISO-accredited laboratory in the region to receive hands-on training.
- PPOMN requested that PQM experts help lead the trainings set for August/September 2013 on advanced analysis of antimalarials according to compendial methods.

Next Steps

- PQM will help to identify a way to import USP reference standards (RS) into Indonesia to support the PPOMN central QC lab and five provincial BBPOM labs, as discussed with national director Drs. Syamsudin. These arrangements can be made through the USP Technical Assistance Program (TAP) allowing Indonesia to benefit from discounted prices based on the country's classification of the World Bank index. (*Ongoing*)
- PQM will review and adapt the FY13 workplan, and develop a three-year implementation plan for the QA/QC portion of Indonesian activities under USAID funding by end of March 2013. (*Ongoing*)
- PPOMN will make a request to participate in the USP Visiting Scientist program or another mechanism for further training in a regional reference lab in Southeast Asia by April 2013. (*Completed*)

March 20-21, 2013

Meeting with NTP, at Hotel Mulia in South Jakarta, Java

PQM staff (Dr. Souly Phanouvong, Dr. Smine, and Mr. Raymond) met with NTP National Manager Dr. Dyah Mustikawati and NTP Monitoring and Evaluation Manager Dr. Triya Dinihari to plan two meetings: An internal meeting with NTP, BPOM, and state-owned pharmaceutical manufacturers on March 28; and a Prequalification Partners Coordination Meeting with BPOM, NTP, Koninklijke Nederlandse Centrale Vereniging (KNCV)-TB Care, Management Sciences for Health (MSH), PQM, Phapros, Indofarma, and Kimia Farma planned for April 1. This meeting follows up discussions initiated by MOH Director General Dr. Tjandra Aditama at USP Headquarters in December 2012 to engage the Indonesian Ministry of state-owned companies.

Next Steps

- Minor revisions to workplan to reflect current status of activities to be discussed with USAID during debriefing meeting on April 1. (*Completed*)
- Prequalification Partners Coordination Meeting at NTP planned for April 1. (*Completed*)

Meeting with Working Groups, Association of Southeast Asian Nations (ASEAN) Secretariat, Jakarta, Java

The PQM team met with representatives from the ASEAN Working Group on Pharmaceutical Development (AWGPD), Ms. Shirley Ramesh and Mr. Galih Rizki; and with the ASEAN Consultative Committee on Standards and Quality Pharmaceutical Product Working Group (ACCSQ PPWG), Dr. Ferdinal Fernando and Ms. Jintana Sriwongsa, at the ASEAN Secretariat. Each group gave presentations on their regional activities, followed by discussions about potential areas of collaboration, with main focus on PQM's Building Regional Expertise in Medicines Regulation/Enforcement (BREMERE) initiative and USP's Network of Medicines Control Laboratories (NOMCOL)-Asia Pacific activities. Priority activities for the 2013 ASEAN AWGPD, including the ASEAN-USP Scientific Symposium to be held in Vietnam, can be found in [Annex 1](#).

Key topics discussed in the meeting were:

- ASEAN PPWG is developing a technical assistance program for GMP over the next two years and is looking for a partner to help implement it. PQM could potentially collaborate through its active programs: Asian Network of Excellence in Quality Assurance of Medicines (ANEQAM)/BREMERE and NOMCOL-Asia Pacific.
 - ASEAN could coordinate their program within ANEQAM/BREMERE to access GMP experts to support GMP activities, including training and inspections, and possibly help the medicines regulatory agencies of its member states move towards Pharmaceutical Inspection Co-operation Scheme (PIC/S) recognition.
- Meetings planned in eight countries on GMP under ASEAN support.
- Indonesia is developing a strategy to address the problem of counterfeit drugs; ASEAN is in the implementation phase on this work program.
- The ASEAN-US Government-funded Work Plan 2012-2014 under USAID support could be coordinated with PQM's workplan.
- PQM aims to encourage adoption of current donor-funded programs to be incorporated into country-level Ministry of Health (MOH) operational plans (funding to local level).
- The possible incorporation of BREMERE and NOMCOL-Asia Pacific into the ASEAN structure, for long-term sustainability, was under consideration. ASEAN could begin the advocacy process now to develop a health statement or declaration at the Ministerial level to incorporate and promote the PQM Initiatives. PQM's presence on ASEAN Working Groups is essential to this advocacy.

Next Steps

- PQM will present during the ASEAN PPWG meeting (May 13-17; Nusa Dua, Bali, Indonesia) to provide information on regional activities and identify specific areas of collaboration.

- ASEAN PPWG and PQM will exchange Indonesian and ASEAN focal points by April/May 2013. *(In progress)*
- ASEAN will link PQM with its counterfeit medicines activities in Indonesia by May 2013. *(In progress)*
- ASEAN will provide PQM with a schedule of Working Groups meetings by April 2013. *(Completed)*
- Set of ASEAN working documents on priority activities will be shared by April 2013. *(Ongoing)*
- PQM and ASEAN PPWG will discuss coordinating upcoming workshops. *(In progress)*
- PQM will provide ASEAN PPWG with contacts at the President's Malaria Initiative for malaria, drug resistance, and counterfeits by April 2013. *(Completed)*
- PQM will submit a summary of its current work in the region to share with Working Group partners during the ASEAN meeting in Brunei in mid-March. *(Completed)*

March 22, 2013

Convention on Pharmaceutical Ingredients (CPhI), Southeast Asia Jakarta Information Seminar on WHO Prequalification, Jakarta International Expo, Kemayoran, Jakarta, Java

With financial support from USAID, a half-day workshop was jointly organized by PQM, NADFC, Indonesia, GDF, and WHO to inform manufacturers and regulatory personnel about the WHO PQ program, technical assistance PQM can provide in the prequalification process, and the outlook on the global anti-TB medicines market.

Representatives from a total of 25 companies learned about the WHO PQ Programme, the process to achieve prequalification status, procedures, and requirements. Background was provided on the GDF and its efforts to increase access to anti-TB medicines, the technical assistance that PQM can provide in the process, and information on what to expect during a Good Manufacturing Practices (GMP) inspection.

Representatives of all three sponsoring programs —WHO, GDF, and PQM — presented, then held a panel discussion and Q&A session during which the participants could interact with the workshop facilitators and receive clarification on key technical issues surrounding the program, technical assistance, and the challenges and obstacles they face in achieving WHO PQ.



Three additional manufacturers expressed interest in WHO PQ and in receiving technical assistance from PQM for ATBs on the GDF/WHO PQ priority list. They completed the screening questionnaires and submitted them to PQM.

See [Annex 2](#) for more detailed information about the Workshop, and [Annex 3](#) for the complete conference agenda, a list of participating companies, and a list of companies interested in receiving technical assistance from PQM.

Next Steps

- PQM will follow up with the three new Indonesian companies (PT Sanbe Farma, PT Dexa Medica, and Sandoz Indonesia) and one company from the Philippines (Hizon Laboratories) that stayed for one-on-one discussions to pursue WHO PQ. (*Ongoing*)
- PQM will also reach out to additional companies that are interested in manufacturing second-line ATBs and set up site visits to encourage them to pursue WHO PQ. (*Ongoing*)

Planning meeting with NTP and BPOM, Jakarta International Expo, Kemayoran, Jakarta, Java
Staff from PQM, NTP, BPOM, and KNCV met briefly to discuss the agenda and priority areas for fast-tracking registration, coordinating between NTP and BPOM, and supporting local manufacturers to encourage more rapid implementation of the prequalification process under PQM technical assistance. The Prequalification Partners Coordination Meeting was scheduled to be held on April 1 at the NTP.

Next Steps

- PQM will convene a meeting for partners along with the public sector manufacturers on April 1 at the NTP. (*Completed*)
- NTP and BPOM will convene an internal meeting with manufacturers on March 28 to encourage more rapid follow-up and implementation of recommendations towards WHO PQ under the PQM technical assistance program. (*Completed*)

March 23, 2013

Meeting with Sagitto Ltd. on Near Infrared Hand-held Technology for Analyzing Drug Quality
The PQM team (Phanouvong and Mr. Edwin Toledo) met with George Hill, Managing Director of Sagitto Ltd. from New Zealand. Sagitto is applying for a grant to USAID to conduct field research on the application of a hand-held Near Infrared device that would detect counterfeit or substandard medicines. The technology has not been validated and the prototype needs to be redesigned before it could potentially be used in basic research in the field. The technology is at the beginning stages of development and, at this point, does not offer a valuable adjunct to the validated Minilab screening methods.

March 25-26, 2013

Field visit to the Makassar Sentinel Site for Medicines Quality Monitoring in Sulawesi

The PQM team (Phanouvong, Raymond) conducted a supervisory field visit to the medicines quality monitoring (MQM) sentinel site in Makassar, Sulawesi. Together with PPOMN national director Drs. Syamsudin, PPOMN senior staff, Dra. Ati Setiawati, and Mr. Tiar Salman of KNCV-TB Care, they evaluated the progress made on the first round of MQM in Indonesia. The PQM team met with the local BBPOM staff in Makassar to discuss implementation and to conduct visits to various sampling locations. See [Annex 4](#) for the field visit agenda and photographs.



- The Makassar BBPOM had collected a total of 132 anti-TB and antibiotic samples. They were currently in the process of testing and had already identified some samples that would need confirmatory testing at the central QC lab level.
- The samples were taken from 25 locations, including private sector pharmacies, public and private sector hospitals (including Labuang Baji, the public sector reference hospital for the Programmatic Management of Drug-resistant Tuberculosis (PMDT) program), one health center, and the Makassar City Pharmacy Warehouse.
- While the BBPOM Makassar lab is ISO 17025-accredited under the Komite Akreditasi Nasional di Indonesia (KAN), the post-marketing surveillance program in Makassar has limited capacity for testing anti-TB products due to a lack of reference standards and specialized training, especially in the area of impurities testing and compendial methods for second-line TB medicines. The PPOMN and BBPOM Makassar are currently participating in ASEAN reference standards development and using Indonesian Pharmacopeia reference standards.

PQM and NQCL-DF, accompanied by the local BBPOM authority, also visited Labuang Baji Hospital to observe the storage and dispensing practices of second-line ATBs. Key observations: The center received all necessary second-line ATBs from the NTP central level on a quarterly basis; no stock-out nor expired products were found; and, all second-line ATB products were stored in a refrigerated condition room located on the fourth floor. The first-line ATBs were received on a yearly basis from the provincial level distribution chain with a 10% buffer; they were stored at the hospital warehouse on the ground floor in non-air-conditioning rooms. The team was told that in the summer the temperature could reach 38-39°C with high humidity. Staff dispensing and handling the medicines had not been re-trained on good pharmacy/dispensing and storage practices for many years and had requested opportunities to attend trainings. It was also observed that the hospital had very limited storage space; shelves and ventilation would require a lot of renovation to make them suitable for storing medicines.

The group then visited the Makassar City central warehouse where first-line ATBs and other pharmaceutical products were stocked. The warehouse was not equipped with air-conditioning or humidity control. It had very limited physical space, poor lighting, and few shelves and cabinets for storing medicines. The temperature could reach over 39°C in the summer season which could potentially harm most medicines that were not kept in the container/boxes. Most of the warehouse staff had limited managerial knowledge or technical skills in good pharmacy/dispensing and storage practices. They all expressed strong interest in training in these subjects.

Next Steps

- PQM will follow up on providing the BBPOM lab in Makassar with current USP-NF, reference standards, and training requests. (*Ongoing*)
- BBPOM requested a budget to dispose of old medicines samples following the MQM and retention period. (*Will be included in FY13 budgets*)
- PQM will initiate procedures for Indonesia to apply to the USP Technical Assistance Program to benefit from discounted prices for reference standards.

- BBPOM Makassar will provide a full report on findings for Round 1 and Round 2 upon completing the second round of sampling and testing in June 2013.

GMP follow-up Assessment at Phapros in Semarang, Java

Senior GMP Specialist Edwin Toledo traveled to Semarang in North Central Java to the manufacturing site of Phapros Indonesia to follow up on recent CAPA implementations, renovations, and reformulation of fixed-dose combination (FDC) products. Phapros is one of the state-owned public-sector manufacturers in Indonesia currently receiving technical assistance from PQM towards their submission for WHO Prequalification. A progress update from this visit is included as [Annex 5](#); a detailed report was submitted separately to relevant parties.

March 27, 2013

Baseline GMP Assessment at Sandoz Indonesia in East Jakarta, Java

The PQM team (Phanouvong, Raymond, Toledo) conducted a baseline assessment of the Sandoz Indonesia manufacturing site. Sandoz Indonesia is a private-sector manufacturer that recently submitted an Expression of Interest and questionnaire to the PQM prequalification team. After PQM reviewed the questionnaire submitted for 2FDC, 3FDC, and 4FDC preparations, PQM reviewed the stability data for these products as, initially, some data had been missing. Now Sandoz is expected to begin compiling their dossiers into the required Common Technical Document (CTD) format. The Country Director and Regional QC Manager, along with other senior staff from Sandoz, expressed to the PQM staff their long-term commitment to achieving WHO Prequalification for their products. They will form a PQ team in order to begin the process, and PQM will conduct a full GMP assessment, tentatively scheduled for May 2013. A baseline report will be submitted separately from this trip report. A summary of activities is included as [Annex 5](#) and an audit plan for Sandoz as [Annex 6](#).

Next Steps

- Sandoz will begin compiling product dossiers in CTD format and form a prequalification focal team to interact with PQM by April 2013.
- PQM will re-visit the Sandoz manufacturing site in May 2013 to conduct a more extensive GMP assessment.

March 28-29, 2013

Initial Walk-through and Introduction to Sanbe Farma in Bandung, Java

The PQM Team (Toledo, Phanouvong and Raymond) was invited to conduct an initial baseline survey for a potential new recipient of PQM technical assistance: Private manufacturer Sanbe Farma, based in Bandung, Java. The company is submitting two second-line ATB products for prequalification: Kanamycin 1g powder for injection, and Levofloxacin 500mg tablets. President Commissioner Mr. Santoso and the Sanbe Farma senior management hosted the team and provided a tour of their facilities as well as those of its sister company, Caprifarma, which is located on the Sanbe Farma campus. Sanbe Farma has already submitted an Expression of Interest for kanamycin 1g powder for injection to WHO; the active pharmaceutical ingredient (API) is sourced from Meiji Pharmaceuticals. Caprifarma proposes to submit for consideration the levofloxacin 500mg tablets it produces. Sanbe Farma will submit its Oxytocin product for



prequalification; however, this product is not eligible to receive technical assistance from PQM under the current funding mechanism. For more information, see [Annex 5](#) below.

Next Steps

- Sanbe Farma will submit an Expression of Interest (EOI) to PQM to begin receiving technical assistance towards PQ for levofloxacin 500 mg tablets. (*timeline*)
- WHO will send a short-term consultant to Sanbe Farma at the end of April to assess review its GMP maturity of sterile production lines common for kanamycin and oxytocin. If there are GMP non-compliance issues in need of addressing, PQM can provide technical assistance under the normal process.
- PQM will conduct a follow-up visit to Sanbe Farma to perform a more detailed and extensive GMP assessment after receiving the company's EOI and questionnaire.



Follow-up Visit to San Clin EQ Contract Research Organization in Bandung, Java

The PQM Team (Toledo, Phanouvong, and Raymond) visited San Clin EQ to follow up on CAPA implementation following two consultant assessments on Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) guidelines. San Clin EQ is currently in the process of implementing recommendations, although some delays have occurred.

Next Steps

- San Clin EQ will continue to implement CAPA recommendations and renovations for GLP and GCP compliance, and will report in writing to PQM by no later than May 2013.

April 1, 2013

Meeting at MOH with NTP, BPOM, PQM, KNCV, MSH, Phapros, Indofarma, and Kimia Farma, East Jakarta, Java

The PQM team (Phanouvong, Raymond) met with BPOM, NTP, KNCV, MSH, Phapros, Indofarma, and Kimia Farma to update them on progress made in the prequalification process, identify gaps and needs, and support development of a Technical Working Group on Prequalification that would meet on a quarterly basis. Meeting minutes, next steps, and a list of meeting participants are included as [Annex 7](#); status updates can be found in [Annex 5](#) and [Annex 7](#). Key outcomes from the meeting include the need to have a “letter of designation” for the formation of the Technical Working Group drafted at the Ministerial level; BPOM and the NTP agreed to take the lead on this. In addition, Kimia Farma re-initiated its commitment to the WHO Prequalification process after having opted-out the previous year. They have re-submitted their CAPA implementation report to PQM, which is under review.

Next Steps

- An MOH-designated team will form a Working Group to coordinate PQ efforts, such as:
 - Roles and responsibilities in PQ process;
 - Face-to-face meetings quarterly and as technical issues arise; and,
 - Budget for meetings—under GFATM
- First, the NTP and BPOM will review and approve the meeting minutes and proposal for the Technical Working Group, then Ibu Dyah of NTP will report the meeting minutes/summary to MOH and minutes of state-owned companies within 10 days
 - Attach draft “Letter of Designation” to formalize coordination and appointment of Working Group members.
- Follow-up contacts: Ibu Dyah and Ibu Dini (NTP) can compile contacts, together with draft letter of designation, etc.
- Manufacturers will provide contact information for those staff and management involved in the PQ process
- For details on follow-up with each manufacturer, see [Annex 5](#).

Meeting with U.S. State Department at the new U.S. Embassy Annex in Central Jakarta, Java

The PQM team (Phanouvong, Raymond) met with Amy Rule, Economic Officer of the U.S. Embassy in Indonesia, to discuss the development of a public awareness campaign on counterfeit medicines in Indonesia, funded by the US Department of State. PQM proposed a number of potential activities, including making use of the PQM-developed public service announcements (PSAs), documentary films, and other media. One potential activity will involve screening the films after they have been dubbed and subtitled in Bahasa Indonesia, using in-house capacity at the State Department in Jakarta.

Next Steps

- PQM will provide Amy Rule and the State Department in Jakarta with copies of the films, PSAs, and other works as part of a campaign in Indonesia, in close collaboration with and approval of the Indonesian authorities and PQM partners. (*Ongoing*)

Debriefing USAID/Indonesia Mission at U.S. Embassy Annex in Central Jakarta, Java

The PQM team (Phanouvong, Raymond) debriefed Kendra Chittenden, Mary Linehan, and Candyana Yohan at the new USAID offices in Jakarta about this trip, and discussed the current workplan implementation. A summary of the debriefing is contained in [Annex 5](#).

Next Steps

- PQM will submit an initial draft of the FY14 Workplan to the USAID/Indonesia Mission for comments by the end of April 2013.
- PQM will draft a five-year strategic paper for Indonesia to be submitted to the USAID/Indonesia Mission by May 2013.
- PQM will schedule a supervisory MQM visit to Medan, Sumatera, by PQM, USAID, NTP, BPOM, and PPOMN for the last week of May 2013.

April 2-5, 2013

Locating a PQM Office in Indonesia, Central Jakarta, Java

The PQM team (Phanouvong, Raymond) scouted numerous locations to establish a PQM office in Indonesia. Working with the contracted local agent, Bali Expat Services, PQM selected a potential office from more than a dozen candidates visited in Greater Jakarta.

Next Steps

- PQM will sign a lease and set up an office in the Jakarta space prior to April 30, 2013.

Annex 1

Priorities Activities for 2013 of ASEAN Working Group on Pharmaceutical Development (AWGPD)

The 28th AWGPD Meeting agreed that the following activities will be prioritised and implemented in 2013 include:

- a. The 3rd Workshop on Rational Use of Antimicrobial Agents in ASEAN, led by Malaysia to be implemented in June 2013. Resources will be cost sharing basis, technical support from WHO, and the Government of Malaysia for Meeting cost;
- b. Situational analysis of the RUM in ASEAN, led by Philippine with technical support from WHO;
- c. ASEAN Forum on Pharmaceutical Care and its Effective in ASEAN, led by Indonesia to be convened in September 2013. Resources will be cost sharing basis for participating countries, technical support from WHO Indonesia, and the Government of Indonesia for Meeting cost;
- d. Drug Resistance in Malaria, proposed to collaborate with AEGCD and participate in the following activities:
 - Activity 1.1 : AWGPD to be part of the Regional Malaria Steering Committee to oversee and guide, and develop TOR;
 - Activity 1.2 : AWGPD to participate in the workshop on development of the regional framework on Malaria Elimination & Prevention/Containment of Artemisinin Resistant;
 - Activity 1.3: AWGPD to participate in the assessment of country's Malaria and Artemisinin resistant situation; and
 - Activity 3.1 AWGPD to involved in the replacement of Artemisinin base monotherapy by Artemisinin Combination Therapy (ACT) by the year 2014.
- e. Proficiency Testing activity
- f. Production of ASEAN Reference Substances (ARS) and ASEAN Certified Reference Material (ASEAN CRM)
 - *E- compilation of the list of ARS to be uploaded in the ASEAN Website*
 - *Submit an article on ARS activity for the 3rd issue of ASEAN E- Health Bulletin by April/ May 2013*
 - *3rd ASEAN-USP Scientific Symposium will be convened in 2013 in Viet Nam, the date to be confirmed.*
- g. Follow up activities on Building Up and Strengthening ASEAN's Capacity in GCP and Clinical Trial, led by Thailand:
 - Complete and summary findings from collected questionnaires
 - Conduct a Training on GCP Inspection in July 2013 in Bangkok
 - Develop an article for the next issue of E-Health Bulletin

- h. Follow up activities on ASEAN Collaboration in Combating Counterfeit Drug, led by Indonesia:
- Participate in the Global Reporting System, subject to confirmation from WHO;
 - Participate in APEC LSIF-RHSC on Supply Chain, Jakarta, February 2013, subject to confirmation from the organizer through coordination of Indonesia and Thailand;
 - Develop a concept note for training on current GDP, Risk based on sampling, cyber - crime, investigation and intelligent; and
 - Compile the findings and develop an article for ASEAN E-Health Bulletin.



**CPhI Jakarta Workshop on WHO Prequalification
March 22, 2013 ♦ Jakarta International Expo
Jakarta, Indonesia**

Highlights of Workshop Deliberations and Presentations

With financial support from USAID, a half-day workshop was jointly organized PQM, NA-DFC, Indonesia, GDF, and WHO to inform manufacturers and regulatory personnel about the WHO PQ program, technical assistance PQM can provide in the prequalification process, and the outlook on the global TB medicines market.

The target audience included representatives from senior management and/or regulatory affairs and representatives from Medicines Regulatory Authorities who are involved in the dossier evaluation of TB medicines for registration. It was strongly recommended that each company invited send a member from one of those teams in order to gain the most from this experience and make any appropriate decisions on behalf of the company.

The following products were included in the priority list for the workshop:

- Amikacin, solution injection 500mg/2 ml vial, amp; powder for injection 1g vial, amp
- Capreomycin, powder for injection 1g, vial
- Cycloserine, capsule 250mg
- Ethionamide, tablet /capsule 250mg
- Kanamycin, powder for injection 1g, vial
- Kanamycin, powder for injection 500mg, vial
- Levofloxacin, tablet/capsule 250mg, tablet 500mg, tablet 750mg
- Moxifloxacin, tablet /capsule 400mg
- Ofloxacin, tablet /capsule 200mg; 400mg
- Prothionamide, tablet /capsule 250mg
- Para-Aminosalicylic Acid (PAS) sachets, 4g granules
- PAS Sodium 100g jar granules, 4g / 9.2g sachets granules; powder for oral solution sachets
- Terizidone, tablet/capsule, 300mg



Opening Ceremony

Dra. Retno Tyas Utami, Deputy 1, Therapeutic Products, Narcotics, Psychotropic and Additive Substance Control, Agency of Drug and Food Control, Indonesia and Dr. Allan Hong, GMP Manager, PQM, welcomed the participants during the opening ceremony. Following the opening remarks Dr. Kaspars Lunte, Team Leader at GDF and the Stop TB Partnership Secretariat, gave an overview of the global TB situation, the need for quality-assured ATBs, and the anticipated demand for ATBs in the next few years. She also presented GDF's role and current activities.

Dr. Milan Smid, Technical Officer, WHO PQ, presented an overview of the WHO PQ Programme and provided participants with detailed information on the format of the dossiers. Dr. Allan Hong presented on the PQM program and its mandates, explaining the types of technical assistance that PQM provides to manufacturers. Dr. Souly Phanouvong spoke about PQM program in Indonesia in conjunction with WHO PQ.

Conference Deliberations

Representatives from a total of 25 companies participated. Three additional manufacturers expressed interest pursuing WHO PQ and in receiving technical assistance from PQM for ATBs on the GDF/WHO PQ priority list; each completed a screening questionnaire and submitted it to PQM. A list of the companies newly-interested in receiving PQM technical assistance is attached. Some manufacturers also inquired about other priority medicines, such as those for HIV/AIDS and malaria.



Key challenges and obstacles the companies expressed that they face in achieving WHO PQ:

- Limited and/or incomplete availability of Master Files from the API producers/suppliers. Many API producers/suppliers are reluctant to provide this information to finished pharmaceutical products (FPP) manufacturers, which creates obstacles to compiling and submitting complete dossiers to PQM or WHO PQ.
- Limited understanding of the process, eligibility, procedures, and requirements of WHO PQ and GDF as well as the process of obtaining technical assistance from PQM.
- Concerns about the capital investment they may have to make in order to improve their facility and quality systems to comply with WHO GMP requirements.
- Need for high-level management commitment and support to participate in WHO PQ. Market size and demand for second- and third-line ATBs is not as well-defined as for first-line products.



**CPHI Jakarta Workshop on WHO Prequalification
March 22, 2013 ♦ Jakarta International Expo
Jakarta, Indonesia**

AGENDA

Time	Topic	Presenter/Speaker
08:30-08:45	Opening Remarks; Introduction of seminar	Mr. Allan Hong, PQM
08:45-09:30	GDF Quality Assurance Policy and Processes and Demand for 2 nd Line TB medicines	Mr. Kaspars Lunte, GDF
09:30-10:00	WHO PQ: Principles, Functions, and Procedures	Mr. Milan Smid, WHO PQP
10:00-10:15	Break	ALL
10:15-10:45	WHO PQ: Essential Requirements	Mr. Milan Smid, WHO PQP
10:45-11:30	USP PQM Technical Assistance to Manufacturers	Mr. Allan Hong, PQM
11:30-12:00	Question and Answer Session	ALL



**CPHI Jakarta Workshop on WHO Prequalification
March 22, 2013 ♦ Jakarta International Expo
Jakarta, Indonesia**

Workshop Participants

Companies Attending the Workshop

Asia Pacific Pharmaceutical Co., Ltd
Blessindo Mulia Abadi, PT
Catur Dakwah Crane Farmasi
Combiphar
Dexa Medica
Equilab International
Essindojaya Perdana, PT
Ferron Par Pharmaceuticals, PT
Genero Pharmaceuticals, PT
Guardian Pharmatama, PT
Hizon Laboratories, Inc.
Indocare, PT
Indofarma, PT
Kalbe Farma, PT
LPK GMP
Medifarma, PT
Megasetia Agung Kimia, PT
National Agency of Drug and Food Control, Indonesia
Pertiwi Agung, PT
Phapros, PT
Pharma Metric Labs, PT
Pharos Indonesia, PT
Sanbe Farma, PT
San-Clin-Eq Laboratory
Sandoz Indonesia, PT
Sydna Farma, PT
TDP

**Companies Interested in Receiving
PQM Technical Assistance**

PT Dexa Medica
Hizon Labs (existing PQM company)
PT Sandoz Indonesia
Sanbe Farma



**Makassar Sentinel Site Visit
BBPOM & Minilab ♦ March 25, 2013
Partners: BBPOM Makassar, Jakarta PPOMN, KNCV, USP PQM**

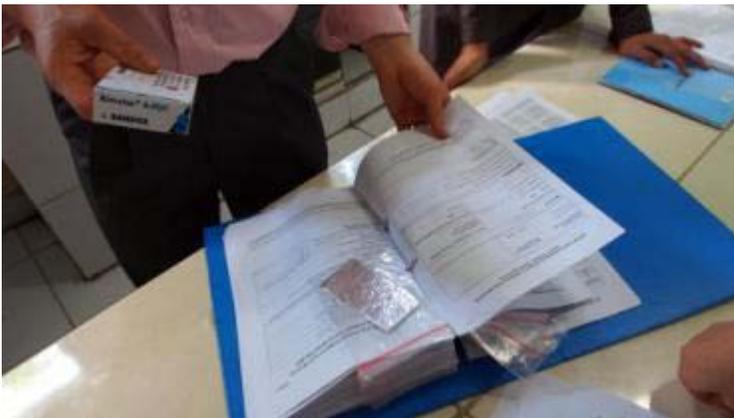
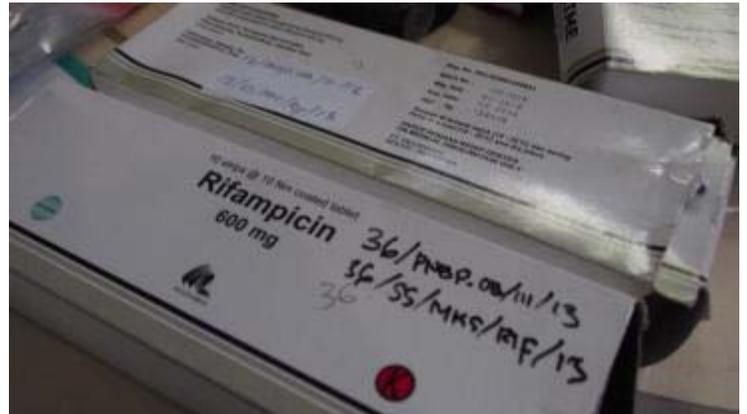
PROGRAM AGENDA

Tentative Schedule for Monday

Time	Place	Activity
8:30-10:30	BBPOM lab or Minilab site or other location as the local partner see appropriate	Introduction to BBPOM staff, discussion of TB medicines supply/distribution in Makassar, storage of samples and reference standards, etc.
10:30-12:00	Site visits	Public sector Rumah Sakit Labuang Baji, examining dispensaries for MDR-TB program (PMDT) and 1 st -line TB clinic
12:00-13:15	Lunch	TBD
13: 15-3:00	Site visits	Site visit to the Makassar City Pharmacy Warehouse
3:00-5:00	BBPOM Minilab site	Review data, recommendations, troubleshooting, wrap-up
Schedule for Tuesday Morning		
8:30–10:00	BBPOM	Discuss next steps and address any technical and/or programmatic issues

Dispensary for second-line TB medicines at PMDT site





PQM Indonesia Progress Update, March 2013

WHO-Prequalification Program

The PQM GMP team conducted a symposium on WHO Prequalification at the Convention on Pharmaceutical Ingredients SE Asia on March 22, 2013. Many local and international manufacturers attended, as well as BPOM and NTP. The symposium was convened by PQM in collaboration with CPHI, WHO PQP, and GDF. The symposium was supported by the USAID Core TB funding with contribution from WHO and GDF.

The GMP team conducted site visits and baseline and follow-up assessments at Phapros, Sanbe Farma, and Sandoz Indonesia manufacturing plants. The team met with senior management and prequalification teams involved in the PQ process. Sanbe Farma is a new addition under consideration for providing TA towards WHO PQ for two second-line anti-TB medications: Kanamycin 1g powder for injection and Levofloxacin 500mg tablets. Full audit and assessment reports will be provided to the manufacturers. Status reports are as follows:

Activity	Status	Timeline
<i>Manufacturer</i>		
Phapros (2FDC and 4FDC)	• Facility renovation and reformulation completed	end March/early
	• Preparing production of 4FDC pilot bio batch	mid-April
	• Some parts of 4FDC dossier to be recompiled and submitted to PQM for review	end of April
	• 6 months of stability data following bio batch	end of May
	• Conducting pilot bioequivalence (BE) study of 4FDC with 12 subjects following production of bio batch (at Equilab)	May-July
	• Full BE study with 36 subjects	June
	• To begin 2FDC project following completion of the 4FDC production and BE studies	Completed March
Indofarma (2FDC/4FDC)	• In discussions with NA-DFC for new manufacturing plant construction; awaiting approval	n/a
	• PQM is reviewing and providing feedback on blueprint designs of FDC production facilities	In progress
	• Following approval for new plant construction, need: reformulation, including dossier compilation, process validation, equipment qualification, bio batch production, stability study, and BE studies must be conducted at the new block following completion of construction	
Sandoz (2FDC/3FDC/4FDC)	• Reviewed questionnaire submitted to PQM by Sandoz for WHO-PQP	Completed
	• PQM evaluated stability data of 2FDC/3FDC and 4FDC formulations. Some data missing	Completed
	• PQM to conduct on-site baseline assessment	Completed
	• PQM to send CTD dossier template	March
	• PQM met Sandoz high level management (country and regional directors) who committed to participate in PQ with TA from PQM	March 27
	• Sandoz management to create focal team for WHO PQP	April 2013

PQM Activities in Indonesia, March-April 2013

Sanbe Farma (kanamycin & levofloxacin)	<ul style="list-style-type: none"> PQM team conducted on-site walk through and met with President and senior management to begin process of providing TA for two second-line TB products: kanamycin 1g powder for injection, and levofloxacin 500mg tablet 	Completed March
<i>Contract Research Organizations</i>		
Equilab	<ul style="list-style-type: none"> CAPA plan implementation almost 100% complete BE study protocol for Phapros 2FDC (R/H) study reviewed by PQM and WHO PQP PQM incorporated WHO PQP inputs and submitted to Equilab Ready to conduct BE studies for Phapros 4FDC in relation to WHO PQP 	<p>In-process</p> <p>Completed</p> <p>Completed</p> <p>April 2013</p>
San Clin	<ul style="list-style-type: none"> Working on CAPA implementation to comply with GLP/GCP guidelines as recommended during previous PQM audit 	In-process

Medicines Quality Monitoring and QA/QC Activities

The PQM team conducted a site visit for monitoring to the Makassar BBPOM provincial QC lab, along with the director of the PPOMN national QC lab, Drs. Syamsudin, and his staff. The team visited the QC lab at the BBPOM in Makassar, as well as the city medicines warehouse and the Labuang Baji public sector referral hospital (a PMDT referral hospital).

The team also met with national and provincial QC lab managers at a national workshop in Palembang, Sumatera to discuss upcoming training on compendial methods and planning for PQM-supported activities to build capacity for advanced analytical testing of TB medicines. Also discussed was the recently-submitted sub-recipient grant proposal by BPOM (PPOMN) for Phase Two of the SSF grant to the NTP.

MOH Partner

PPOMN and provincial sentinel sites	<ul style="list-style-type: none"> Minilabs deployed to PPOM provincial labs in Medan, Serang, Makassar, Surabaya and Mataram Sentinel sites to test samples collected during 1st round of collection PQM and PPOMN conducted monitoring visit to Makassar BBPOM QC lab 	<p>Completed</p> <p>In progress</p> <p>March</p>
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Other Activities

- | | |
|--|--------------------|
| <ul style="list-style-type: none"> Entered into new contract via Bali Expat Services with Consulting Chief of Party to represent PQM in Indonesia | March, 2013 |
| <ul style="list-style-type: none"> PQM in the process of identifying location to open country office in Jakarta using Bali Expat Services | End of March/April |
| <ul style="list-style-type: none"> PQM was approached by a New Zealand Sagitto Ltd to discuss potential collaboration to deploy a preliminary prototype miniature near-infra-red spectrophotometer for detection of counterfeit medicines | March |
| <ul style="list-style-type: none"> PQM provided inputs to Project Hope on application for a US Embassy grant on raising awareness of counterfeit and poor quality medicines. | February |



AUDIT PLAN

Item	Description
Institution Evaluated	PT. Sandoz Indonesia
Date	March 27-28, 2013
Specific Objectives	Assess overall compliance with WHO (Technical Report Series No. 908, 2003 Annex 4) GMP standards in the manufacturing activities of 2FDC, 3FDC and 4 FDC anti TB medicines.
Scope	The audit will focus on the activities relating to processes involved in Manufacturing, Process Control, Testing, Packaging, Storage and Distribution of the manufactured materials.
Documentation	<p>Documentation requested during the audit:</p> <ul style="list-style-type: none"> • Copy of GMP certificate • Copy of ISO certificate, if applicable • Copy of site plans • Copy of Organization Chart • Copy of SOPs list • Site Master File • Validation Master Plan • Process and Cleaning Validation • Qualification and maintenance plan • List of changes, rejections, deviations and complaints • Manufacturing batch record • Product Quality Review <p>Additional documentation can be requested during the audit.</p>

Proposed Agenda

Time	Activity
Day 1	Oral Dosage Form Facility
Morning 09:30	<p><u>Opening meeting with key personnel</u></p> <ul style="list-style-type: none"> • Introductions of all personnel • Confirmation of proposed inspection plan/schedule • Company presentation: company overview, site description and activity
10:30	Facility Tour :

Time	Activity
	<ul style="list-style-type: none"> ● Receiving Raw Material and Packaging Materials. ● Raw Material and Packaging Material Warehouse. ● Manufacturing Areas ● Finished Products Warehouse ● Shipment ● Quality Control ● Chemistry Analysis (SOP, Specifications, Records) ● Microbiological Analysis (SOP, Specifications, Records) ● Stability Studies (SOP, Specifications, Records)
13:00-14:00	Lunch break
14:00-16:00	Document Review
	<p><u>Quality Management System review:</u></p> <ul style="list-style-type: none"> ● Personnel Policies: Organization charts, Job descriptions, Training, Health and Hygiene ● List of products/Production planning/Batch numbering system and batch register ● SOP and document preparation, review and control ● List of SOPs/SOP Index ● Deviations/Change control/OOS + related SOP ● Reprocessing/Reworking policy + SOPs ● Finished product release procedure ● Self inspection (SOP, Plans, reports) ● Complaints handling system ● Product recall system ● Product Master Files, production flow diagrams and specifications key raw materials and FPP for the product in focus ● Validation Master Plan ● Equipments Qualification ● Pest Control ● Batch Records ● Maintenance Program ● Calibration Program ● Supplier Qualification ● Internal Audits ● Change Control ● Recalls from the Market ● Complaints Managements ● Deviation Managements

Meeting Minutes
Promoting the Quality of Medicine (PQM)/WHO Meeting
Jakarta, April 1, 2013

Place: Gedung B lantai 2 Ditjen. PP&PL, MOH
Agenda: Progress PQM WHO at 3 Local Manufactures for TB medicines
Chairman: Deputi 1 Bidang Pengawasan Produk Terapetik & Napza-BPOM

Opening remarks by Deputy 1 BPOM:

- The purpose of WHO PQ for TB drug manufacturers in Indonesia is not only to increase the availability in the market for TB drugs, but also for the needs of the whole of Indonesia building capacity beyond TB.
- Following from the previous USP workshop in Jakarta, Ibu Deputy expected that progress could be fully followed because many private manufacturers are interested in receiving technical assistance from PQM and the Prequalification.
- At this meeting, she expected that all of the public sector pharmaceutical manufacturers present (Kimia Farma, Indofarma, and Phapros) can focus through the PQM program until submission to WHO to achieve prequalification.

Presentation by P. Souly:

1. Progress on Phapros

Up to now progress PQM in Phapros:

- For 4 FDC : dossier review stage 1 phase
- For 2 FDC : dossier compilation phase
- Renovations and inspections are completed and is already final report
- To study stability and BE, it is required commitment letter from the Phapros
- For other activities are expected to be implemented in April and May 2013
- By October 2013 is expected that Phapros has sent a proposal to PQM WHO for approval

2. Progress Indofarma

- PQM WHO started all over again because Indofarma has plans to build a new facility
- For 4 FDC and 2 FDC : baseline GMP assessment phase
- Indofarma established and had new team for the implementation of the PQM WHO
- The Blueprint from Indofarma is still awaiting approval from BPOM and (information from Deputy 1) BPOM promising that the approval will be released next week (additional information from Mr. Agus Prabowo: Director Monitoring Prod PT & PKRT) when got an approval from BPOM, it will be continued with bidding process.
Ibu Deputy 1 requested: Quarterly report has to be updated (e.g. it has data for how many pharmaceutical industry that applied for WHO PQ).
- Indofarma also proposed for second-line TB drugs (Levofloxacin 500mg, Ofloxacin 200mg and 400mg and Zink). But until now is still in discussed about who will be the co-funding and how the dossier?

3. Progress Sandoz

- For 2FDC, 3FDC and 4FDC : baseline assessment GMP phase
- Sandoz has a high commitment in following the PQM WHO since November 2012

4. Progress Sanbe Farma

- Submit to PQM WHO for second-line drugs: Kanamycin (For powder injection) and Levofloxacin.
- Now is still in: questionnaire phase.
- It is expected in mid-April 2013 will be had a confirmation receiving Technical Assistance (TA) through WHO PQ.

5. Progress Kimia Farma

- The progress for antiretroviral (ARV) medicines is good and still running.
- In 2012 there is proposed for merger of state-owned/Local Manufacture, so the focus of Kimia Farma only for the HRD (Human Resource Development)
- According to the USP : there is no progress report for a year and a lack of commitment from Kimia Farma to the implementation of PQM WHO
- In 2013 Kimia Farma begin to build of a new facility (new site) on the 2nd floor with 730M fund, which is expected to be completed 3-4 years. So at this time, KF started to renovate facilities and machines which constitute the findings of the PQM WHO (USP).
- In 2013 KF has budget amount 40M for the PQM WHO for TB drugs.
- In 2013, KF also to reform, such as: air handling unit system.
- KF has already sent The Progress of CAPA to the PQM WHO (USP), but it will be checked again to whom it was sent, due to USP was not receiving the report yet.

Proposed Local Manufacturers to BPOM

- To purchase of raw materials for TB drugs in large numbers (pooled procurement) and BPOM to have a role to track supply chain from raw material to finished product.
- The pharmaceutical industry should provide information about Raw materials and BPOM assists for the mechanism, e.g. bidding into one (pooled), and how to accomplish this in a timely and effective manner.

About BE study

- BE Study is conducted in humans, and there should be a pilot study first, to know whether bio batch is successful or not. When it full BE studies are implemented, it may not be successful, and will have a huge cost disadvantages.
- According to BPOM for raw materials should preferably be using prequalified API
- The question: do production facilities for each TB product need to be in a separate facility?
Soully answered: no need, because TB drug is not like Beta Lactams which can contaminate other drugs.
- The advantages for Indonesia if participated in NOMCOL (Network of Medicine Control Laboratory) and the Technical Assistance Program (TAP) of USP since Indonesia is a middle-income country:
 - Get the discount price of 50% on USP reference standards up to a total of \$200,000 USD.
 - Get the training programs and participation in regional networking initiatives for national medicines QC laboratories
 - Proficiency Testing Provider (PTP)—ongoing proficiency testing for accreditation.
- Ibu Deputy 1 BPOM appointed Pak Agus Prabowo (Director of Production Control PT & PKRT) to be a coordinator to follow the PQM WHO for 3 Local Manufacturers for TB Medicines.

Comments from:

1. USAID (Ibu Kendra)

- She's pleased with the progress of PQM WHO in Indonesia, also that Kimia Farma has followed back for the process PQM WHO in 2013
- Private manufacturers also followed PQM WHO processes such as Sandoz and Sanbe Farma.

2. TBCare (Pak Jan Voskens)

- Recommended that the coordination among BPOM, Binfar, USP, MSH, KNCV and NTP (Subdit TB) further enhanced in assisting the process PQM WHO, in order to achieve a good quality of medicines in Indonesia

**NEXT STEPS—Quality Coordination Working Group
(WHO PQ process, QA/AC, Dist. Supply, Storage, etc.)
Jakarta 1, April 2013**

1. Working group team—designated by MOH—to coordinate on PQ
 - a. Roles and responsibilities in PQ process
 - b. Face-to-face meetings Quarterly and as issues arise (technical issues)
 - c. Budget for meetings—under GFATM
2. First, internal group review with partners, then Ibu Dyah to report on meeting minutes/summary to MOH & Min of State-owned Companies within 10 days
 - a. Attach draft 'letter of designation' to formalize coordination and appointment of working group members
3. Follow-up contacts: Ibu Dyah and Ibu Dini (NTP) can compile contacts, together with draft letter of designation, etc.
4. Manufacturers: contact information of those involved in PQ process

**Daftar Peserta
Pertemuan Promoting the Quality of Medicine (PQM) WHO
Jakarta, 1 April 2013**

No	Nama	Jabatan & Instansi	No HP	Email
1.	A.Retno Tyas Utami	Deputi 1 Bidang Pengawasan Produk Terapeutik & Napza-BPOM		retnoty@yahoo.com
2.	Dr. Slamet, MHP	Direktur Pengendalian Penyakit Menular Langsung, Ditjen. PP&PL, Kemenkes RI		slametbasir@yahoo.com
3.	Agus Prabowo	Direktur Pengawasan Produksi Produk Terapeutik (PT) dan Perbekalan Kesehatan Rumah Tangga (PKRT) - BPOM	0817187215.	prabowo1956@yahoo.co.id
4.	Drg. Dyah Erti Mustikawati, MPH	Kepala Subdit. Tuberkulosis, Ditjen. PP&PL, Kemenkes RI	08166892815.	dmustika@yahoo.co.id
5.	Dewi Ariyani	Kabid. Industri Strategis & Manufaktur, Kementerian BUMN	08129939312.	dewi-ariyani@bumn.go.id
6.	Nurraadah	Dit.Was. Prod. PT & PKRT-BPOM	087886200282.	inspeksiterapeutik@yahoo.com
7.	Sri Pujiati	Dit. Standardisasi PT & PKRT-BPOM	081386249642.	pujiati_mahoni@yahoo.co.id
8.	Nova Emelda	Dit. Penilaian Obat & Produk Biologi-BPOM	081213389342.	n_emelda@yahoo.com
9.	Neviyenti	Fungsional Farmasi Makanan, Dit. Penilaian Obat & Produk Biologi-BPOM	08129471321.	nevi_yenti@yahoo.com
10.	Djakfarudin Junus	Direktur Utama Indofarma	0816853439.	
11.	Kosasih	Direktur Prod. Indofarma	081510368941.	kos_qs@yahoo.co.id
12.	Sya Indradewi	Indofarma	08161406929.	sya.indradewi@indofarma.co.id
13.	Eko Dodi S.	Indofarma	08129351056.	eko.dodi@indofarma.co.id
14.	Wahyuli	Direktur Utama Kimia Farma	081220222899.	wahyuli@gmail.com
15.	Kus Aryani	GM SBU Manufaktur Kimia Farma	081513251475.	kus_aryani@yahoo.com
16.	Eko Sri W.	PT Kimia Farma	0815838267.	ekokf@yahoo.com
17.	Iswanto	Direktur Produksi Phapros	081808610632.	iswanto@ptphapros.co.id
18.	Rokhmi Fitria E.	Phapros	08151629641.	rochmi@ptphapros.co.id
19.	Dr. Triya Novita Dinihari	Kasi Bimbingan & Evaluasi	08129265650.	tndinihari@yahoo.com
20.	Rudy E. Hutagalung	Subdit. TB	081283246298.	r_huga@yahoo.com
21.	Yudhi Permana, ST	Subdit. TB	081511341137.	youdie_p@yahoo.com

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No	Nama	Jabatan & Instansi	No HP	Email
22.	Souly Phanouvong	Manager Asia Program	+1-301-816-8582	xsp@usp.org
23.	Chris Raymond	USP PQM Indonesia	081353959340	chrispqm@gmail.com
24.	Dr. Jan Voskens	TBCare/USAID	081218521130.	voskensj@kncvtbc.nl
25.	Tiar Salam, ST,MM	KNCV	08156055955.	tiarsalman@yahoo.com
26.	Ariesita, SSi, Apt.	KNCV	08123033045.	itakncv@yahoo.com
27.	Erwin S.	KNCV	08161924847.	erwin@kncv.or.id
28.	Dr. Setiawan Jatilaksono	WHO INO		laksonos@searo.who.int
29.	Kendra Chittenden	USAID-INDO	081288282733.	kchittenden@usaid.gov
30.	Andi Marsden	MSH Indonesia		amarsden@msh.org