

**Field visit to Medicine Quality Monitoring Site with USAID, PQM, Indonesian Academy of Sciences, and former US Special Envoy for Science to Indonesia**

**Medan, Sumatera, Indonesia**

**July 4-5, 2013**

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***In-country Trip Debriefing***

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**Promoting the Quality of Medicines**

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**PROMOTING THE QUALITY OF MEDICINES**

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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. Sangkot Marzuki, President of the Indonesian Academy of Sciences and Director of the Eijkman Institute for Molecular Biology
- Dr. Bruce Alberts, former U.S. Science Envoy to Indonesia, President of the U.S. National Academy of Science , and Editor of Science Magazine

## Acronyms

ATB	Anti-tuberculosis Medicine
BA/BE	Bioavailability and Bioequivalence
BBPOM	Balai Besar Pengawas Obat dan Makanan (provincial quality control lab)
BPOM	Badan Pengawas Obat dan Makanan (the Indonesian NA-DFC)
CRO	Contract Research Organization
DQI	Drug Quality and Information Program
GCP	Good Clinical Practices
GDF	Global Drug Facility
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
MQM	Medicines Quality Monitoring
NA-DFC	Indonesian National Agency of Drug and Food Control
PPOMN	Pusat Pengujian Obat dan Makanan Nasional (national quality control lab)
PQM	Promoting the Quality of Medicines Program
PQP	Prequalification Program
QC	Quality Control
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

## Background

With financial support from USAID/ Indonesia, PQM has been providing technical assistance to Indonesia in the following areas:

- Strengthening the post-marketing surveillance capacity of the National Agency of Drug and Food Control (NA-DFC or BPOM) by establishing a medicines quality monitoring (MQM) program for anti-tuberculosis (ATB) medicines, in close collaboration with the National Quality Control Laboratory of Drug and Food (PPOMN)
- Conducting workshops with World Health Organization (WHO) and the Global Drug Facility (GDF) to inform manufacturers and NA-DFC about the WHO Prequalification (PQ) Programme and the related technical assistance that PQM provides
- Providing technical assistance directly to selected local manufacturers to improve their good manufacturing practices (GMP) and product dossier compliance, working toward WHO PQ. PQM is also providing support to capacitate two contract research organizations (CROs) 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 PQ
- Conducting research and surveys to determine medicines quality in the marketplace

## Purpose of Trip

USAID/Indonesia organized a tour of the Medan, North Sumatera Balai Besar Pengawas Obat dan Makanan (BBPOM Medan, the provincial quality control lab) to highlight PQM efforts in Indonesia. Mr. Raymond accompanied the tour, along with the former U.S. Science Envoy to Indonesia, President of the U.S. National Academy of Science, and Editor-in-Chief of Science Magazine, Dr. Bruce Alberts; the President of the Indonesian National Academy of Science and Director of the Eijkman Institute for Molecular Biology, Dr. Sangkot Marzuki; and the BBPOM Medan authorities.

## Overview of Activities

USAID/Indonesia, represented by Dr. Kendra Chittenden, organized a special site visit to Medan, North Sumatera to highlight the efforts of the PQM program in strengthening quality assurance systems for monitoring tuberculosis medicines in Indonesia. The visit to the provincial quality control lab (BBPOM Medan) coincided with an invited guest lecture given by Dr. Bruce Alberts at the Faculty of Medicine of the University of North Sumatera. The lecture was organized Dr. Sangkot Marzuki and attended by faculty members, medical students, researchers, and Mr. Raymond of PQM.

Following the lecture, the group visited BBPOM Medan, hosted by the center's Director, Drs. I. Gde Nyoman Suandi, and his staff. Drs. Suandi gave opening remarks, followed by Dr. Alberts and Dr. Marzuki, who provided introductions on their work and interest in science education, along with a brief introduction to the Indonesian National Academy of Science. Mr. Raymond then gave an introduction to the PQM program in Southeast Asia, with a focus on the work being done in Indonesia.



Mr. Raymond and Dr. Chittenden presented Drs. Suandi with the current United States Pharmacopeia and The National Formulary (USP–NF) for use by the Medan BBPOM as part of the MQM project implemented by PQM. The group adjourned to the lab, where Dr. Alberts, Dr. Marzuki, and Dr. Chittenden could observe the staff conducting basic tests on ATB medicines using the PQM-supplied Global Pharma Health Fund Minilabs<sup>®</sup>. They also conducted a site inspection of the analytical lab where routine post-market surveillance of medicines, food, and cosmetics is carried out for North Sumatera province.



## Conclusion

The visit was an important opportunity for outreach to the Indonesian National Academy of Science and to increase the visibility and highlight some of the achievements of the PQM program in Indonesia regarding medicines quality issues. The visit was highlighted on the Medan BBPOM website:

[http://www.pom.go.id/index.php/home/berita\\_aktual/3902/\\_Kunjungan\\_Team\\_USAID\\_.html](http://www.pom.go.id/index.php/home/berita_aktual/3902/_Kunjungan_Team_USAID_.html)

## Next Steps

- PQM will share a copy of the newly-completed *Pharmacide: the Mekong* documentary film with Dr. Alberts and continue discussions about material for a potential article for Science Magazine on counterfeit medicines
- PQM will provide USP36-NF31 and other reference materials to all provincial BBPOM sites involved in the MQM project (a total of 10 provincial sites plus the national PPOMN QC lab).