



Strengthening Indonesia's Pharmaceutical Post-Marketing Surveillance Capacity

Technical Brief | September 2018

Background



As the world's fourth most populous country spread across more than 17,000 islands, Indonesia faces unique challenges in providing access to essential and lifesaving medicines for its population. Beyond ensuring that medicines are consistently available, it is also critical that the quality of these medicines is maintained throughout the supply chain and across both public and private sectors. Poor-quality medicines—those that are substandard, falsified, or unregistered—can cause treatment failure and adverse reactions, may contribute to the development of antimicrobial resistance, and can lead to death.

To ensure a robust system for monitoring the quality of medicines circulating in the Indonesian market, the Promoting the Quality of Medicines (PQM) program supported Indonesia's Ministry of Health (MOH) and the National Agency for Drug and Food Control (abbreviated locally as BPOM) to improve intra-government communication and develop regulations to ensure that a robust quality assurance system was not only in place but also being implemented across the public and private sectors. By catalyzing communication and implementation of new regulatory policies, PQM supported BPOM in establishing systems necessary to provide patients access to quality-assured medicines.

Beyond ensuring that medicines are consistently available, it is also critical that the quality of medicines is maintained throughout the supply chain and across both public and private sectors.



Key Term

post-marketing surveillance: surveillance activities following market approval of a medicine, including maintenance of product authorization and/or registration of variations or renewals; regular inspections of manufacturers, wholesalers, distributors, and retailers; quality control testing; pharmacovigilance; promotion control; public reporting of poor-quality products; handling of market complaints; and removal and disposal of noncompliant products.

Indonesian Context

Mandated by Presidential Decree in 2001, BPOM serves as Indonesia’s independent medicines regulatory authority responsible for medicines registration, post-marketing surveillance, and other vital regulatory functions.

Because it is unrealistic to test the quality of every product on the market, BPOM must carefully select where to focus its efforts. BPOM does so by using a risk-based approach to testing the quality of medicines for post-marketing surveillance. The products to be sampled and the locations from which they are to be sampled are determined through annual prioritization exercises. Each year, BPOM samples and performs quality testing on 13,000–18,000 pharmaceutical products from pharmacies, distributors/wholesalers, storage warehouses, hospitals, clinics, and other outlets.¹ The failure rate of medicines tested through quality control surveillance in previous years has hovered between 1 and 2 percent but primarily consists of samples taken from the private sector.²

Medicines for disease control programs in the public sector are managed as government inventory/property. The manner in which they are procured, distributed, stored, and dispensed is carefully regulated, although no formal policy or regulation existed that allowed BPOM to sample these medicines from government-run storage facilities, hospitals, or health centers. This left BPOM unable to test many of the medicines imported by MOH for disease control programs or under special provisions (e.g., the Special Access Scheme).

Furthermore, BPOM data were traditionally kept confidential, and dissemination of results or data sharing for decision-making with other government partners—including MOH—was minimal. Additionally, the results from BPOM’s quality surveillance in the private sector often did not apply to public sector government products, as government disease control programs relied on medicines and formulations (e.g., loose tablets instead of fixed-dose combinations for tuberculosis (TB) treatment) different from those available in the private markets. Barriers in sampling medicines from the private sector, product variation between the public and private sectors, and bureaucratic challenges between MOH and BPOM resulted in difficulties in getting the right information to the right stakeholders at the right time. In some cases, these challenges could mean that poor-quality products may continue to circulate, even after official recalls, due to confusion over jurisdiction, methods for removing/replacing failed products, general lack of transparency, and a lack of access to key data.

Further hampering BPOM’s capacity to monitor the quality of medicines were weaknesses at the national control laboratories where medicines are sent for testing. The quality control laboratory system, consisting of 36 institutions nationwide, was limited in terms of both the types of tests that could be performed and in technical competence on advanced analytical quality control testing according to internationally recognized standards.

A pharmacist in Medan, North Sumatra collects medicine samples as part of BPOM’s national risk-based post-marketing surveillance system. Photo credit: PQM.



Strategic Approach and Implementation

Recognizing the major gaps in quality surveillance, the lack of validated methods and standards for quality control testing, limited human and institutional technical capacity for analytical testing, and the regulatory challenges between BPOM and MOH, PQM helped to design a comprehensive plan of action to strengthen the overall capacity of Indonesia's quality assurance system through a multipronged approach involving communication, collaboration, and policy change.

Closing the Communication Gap

In 2015, in collaboration with the World Health Organization (WHO), PQM brought BPOM and MOH together to analyze data related to the quality of TB and HIV medicines from each health program. With minimal information available on government medicines, the communication gap between the two agencies quickly became apparent and revealed the urgent need for a formal mechanism allowing sanctioned access to government facilities for ongoing quality control purposes.

PQM and WHO convened a national workshop for BPOM and MOH to discuss the challenges in accessing public medicines for quality control purposes. MOH and BPOM jointly recommended development of an innovative policy that would enable BPOM to sample and test medicines from MOH storage facilities to ensure a long-term, sustainable system for quality control of both locally procured and imported products.

Enacting Policy Change

The joint MOH–BPOM recommendations resulting from PQM's consultations led to the initiation of "Ministry of Health Regulation 75/2016 Regarding Implementation of Medicines Quality Testing in Government Pharmaceutical Installations" (PMK 75/2016). The regulation formally outlined the roles and responsibilities of BPOM and MOH in conducting effective post-marketing surveillance. PMK 75/2016 detailed the inclusion of government medicines in BPOM's annual sampling guidelines, requirements for timely data dissemination and regulatory enforcement, and collaboration between MOH and BPOM for enhanced policy and procurement decisions.

Following the initial draft of the regulation, PQM supported a number of national consultations between MOH and BPOM, which led to multiple revisions of the regulation until it was finally adopted in 2016. The revisions incorporated stronger medicines quality assurance components and timely reporting requirements that were lacking in the earlier iterations.

The stage was set with an unprecedented policy shift, but Indonesia's medicines quality testing laboratories were still lacking the necessary equipment and materials to handle samples coming in from both the private and public sectors.



PQM training on analytical techniques used in testing medicines collected during BPOM's post-marketing surveillance.

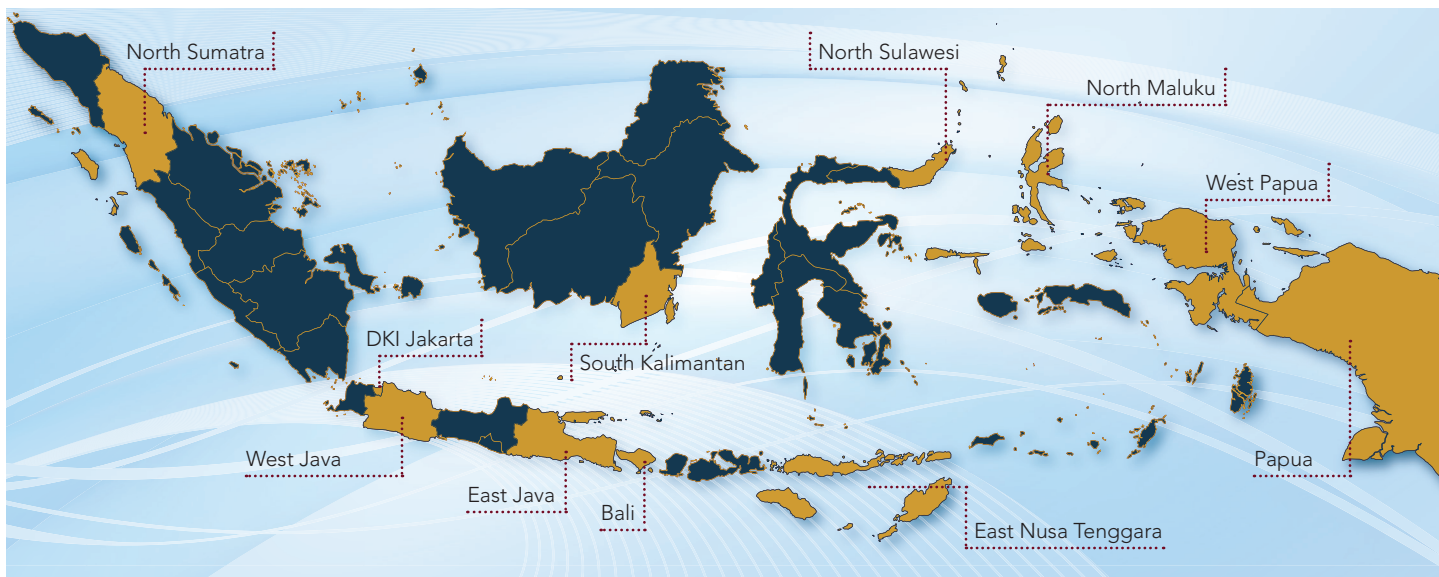
Photo credit: PQM.

PQM reached out to the Global Fund for AIDS, Tuberculosis and Malaria (Global Fund) and secured a procurement contract for laboratory equipment and reference standards to support the medicines regulatory authority, representing a new model for leveraging multiple donor support for quality control via the disease control program fund.

Engaging in Joint Sampling

Global Fund financing included joint sampling activities to pilot the formal implementation of PMK 75/2016. Following extensive planning and training workshops on sampling and analytical testing, PQM coordinated a joint pilot sampling exercise between BPOM and MOH. Representatives from both government agencies traveled to health department storage facilities in 11 provinces across the country to collect medicine samples side by side. The primary focus was on collecting samples from public facilities and medicines from the TB control program. Initial outcomes from this joint sampling exercise, as well as other ad hoc sampling and testing activities, have already revealed several areas in need of improvement. Both MOH and BPOM are already planning for early data sharing to improve response rates and regulatory actions.

A total of 102 samples of TB and HIV medicines were collected during the first round of the joint sampling and testing pilot activity that was designed to jumpstart the



Locations of joint sampling pilot activity: North Sumatra, DKI Jakarta, West Java, East Java, Bali, East Nusa Tenggara, North Maluku, North Sulawesi, South Kalimantan, Papua, and West Papua.



Sampling medicines from government facilities following PMK 75/2016 implementation pilot activity.
Photo credit: PQM

implementation of the PMK regulation and to test drive some of the technical guidelines on sampling from government facilities. This was the first time that BPOM inspectors joined forces with provincial and district health offices in collaborative sampling and testing efforts specifically to assess the quality of government-held medicines. This exercise will be replicated and expanded annually with the aim of incorporating these activities into the long-term routine post-marketing surveillance as part of the government’s official sampling strategy. PQM will assess the activity and outcomes to identify future training and technical assistance needs. During the joint sampling exercises, MOH–BPOM field teams made note of improvements needed for the proper physical storage of medicines.

The joint recommendations led BPOM to introduce the “Ministry of Health Regulation 75/2016 Regarding Implementation of Medicines Quality Testing in Government Pharmaceutical Installations” (PMK 75/2016) which formally outlined the roles and responsibilities of BPOM and MOH in conducting post-marketing surveillance.

International Impact

Availability of data on medicines quality is a major priority for MOH's national disease control programs as well as procurement agencies, donors, and health professional communities. Data from post-marketing surveillance influence procurement policies for imported and locally produced medicines and determine the severity of regulatory actions (e.g., recalls, investigations, manufacturer sanctions, quarantines).

A highly functioning quality assurance system supports the identification of problems in the supply chain and amelioration of any issues related to the distribution or use of substandard or falsified medicines that could harm patients. This is especially crucial in an era in which many antibiotics and other antimicrobials are developing resistance to many common medicines. In Indonesia, with the second highest prevalence rate of TB in the world, concern for drug resistance is not merely theoretical. Efforts are underway to address the numerous challenges in medicines production, supply chain, and use to ensure that medicines available in the government and private markets are quality assured and retain their quality at all stages in the distribution chain. As Indonesia continues to develop its risk-based post-marketing surveillance system—fortifying analysts with better skills, equipping the provincial



Government BPOM inspectors sampling TB medicines for testing at the provincial quality control laboratory. Photo credit: PQM.

and district laboratories, and enhancing inter-agency communications and data sharing with stakeholders—the country is poised to emerge as a regional and global leader in the medicines quality assurance arena.

Lessons Learned

Introducing policy change across Indonesia's decentralized government and provincial-level authorities is complex and multifaceted, requiring coordination with various technical counterparts, funding agencies, and partners. Poor inter-agency communication had occurred both horizontally (at the central level between MOH, donors, and BPOM) and vertically (to the provinces and districts). Achieving effective communication required patience, persistence, and discarding pre-existing assumptions about inter- and intra-agency interactions.

Gaps in the technical capacity to perform quality control activities must be addressed in tandem with policy development. As priorities shifted regarding selected medicines, testing capabilities of laboratories had to be concurrently built to be able to handle the new influx of samples. This required communication and coordination with international donors to meet government expectations.

During the development of the PMK 75/2016 regulation, PQM worked with BPOM to outline detailed instructions and guidance for implementation of the regulation. PQM initiated, drafted, and facilitated finalization of the technical guidelines to ensure that sampling and testing algorithms, roles and



Routine medicines surveillance activities are carried out in Jakarta, Java. Photo credit: PQM.

responsibilities, timelines, documentation, and reporting requirements were clearly delineated within MOH and BPOM. PQM continues to work with both BPOM and MOH to distribute and implement these guidelines.

Future Directions



Moving forward, PQM plans to support post-marketing surveillance in Indonesia from three key perspectives: (1) advocating and developing policies to increase the overall percentage of TB and HIV medicines sampled from the government sector; (2) working with disease control programs to ensure that adequate data are available and accessible to programs, as well as to MOH, to support informed procurement decisions; and (3) supporting national and provincial medicines quality control laboratories in conducting testing according to international standards. By supporting these efforts, PQM is helping to ensure that MOH and BPOM will be able to maintain a routine and more robust mechanism for joint sampling and testing efforts.

As BPOM incorporates government medicines into its national post-marketing surveillance system, a concurrent scale-up in resources is necessary. Data obtained through the joint pilot testing of government sector medicines will help establish priorities for subsequent years, and MOH disease control programs will be able to use the newly generated baseline data to support a more responsive regulatory environment regarding products in circulation.

In order to expand post-marketing surveillance efforts, PQM is exploring other ways in which program medicines can be sampled and tested. PQM worked with MOH's National AIDS Program to experiment with a model of third-party contracting between MOH as client and the BPOM National Medicines Quality Control Laboratory as service provider. This model uses government funds paid directly to the quality control

laboratory to test antiretroviral medicines, with the results immediately available to be utilized for decision-making by the National AIDS Program. This activity is currently underway, and PQM will conduct a comparative analysis of the model so that MOH can develop and implement a long-term strategy for enhanced and expanded post-marketing surveillance.

Additionally, PQM has been working closely with BPOM to advocate for the use of simple, cost-effective field screening testing to support its post-marketing surveillance activities. The current practice of performing direct compendial testing on sampled medicines is costly, in terms of both financial and human resources. Incorporation of field-based screening tools, such as GPHF-Minilab™,³ will increase throughput of samples, reduce the burden of compendial tests to be performed by provincial and national laboratories, and increase the types of products tested. Such a screening tool will also support ongoing cooperation with MOH through collaboration between inspectors and health staff at government facilities to conduct onsite screening. Under mandate of the head of BPOM, PQM has piloted the use of screening technologies in Jakarta by equipping mobile testing vans for medicine testing. The pilot triggered the development of an official policy, and screening technologies are presently being rolled out in a stepwise manner to all 34 provincial laboratories, with plans to procure an additional 37 new Minilabs™ for district-level BPOM testing facilities.

Endnotes

- 1 BPOM's official Annual and Quarterly Reports from fiscal years 2012–2017.
- 2 Ibid
- 3 GPHF Minilabs™: <https://www.gphf.org/en/minilab/>

As its post-marketing surveillance system continues to develop, Indonesia is poised to emerge as a leader in medicines quality assurance.

This document is made possible by the generous support of the American people through the U.S. Agency for International Development (USAID). The contents are the responsibility of USP's Promoting the Quality of Medicines program and do not necessarily represent the views of USAID or the U.S. Government.

About PQM

The Promoting the Quality of Medicines (PQM) program is a cooperative agreement between the U.S. Agency for International Development (USAID) and the U.S. Pharmacopeial Convention (USP). PQM helps to strengthen medicines regulatory authorities and quality assurance systems and supports manufacturing of quality-assured priority essential medicines for malaria, HIV/AIDS, tuberculosis, neglected tropical diseases, and maternal and child health.

Contact Information

Promoting the Quality of Medicines
United States Pharmacopeia

USP–U.S.
12601 Twinbrook Parkway
Rockville, MD 20852-1790, USA
Phone: +1-301-881-0666
Fax: +1-301-816-8374
Email: pqm@usp.org

USP–Indonesia
Lt.23, Tower 1, Menara Prima
Jl. Dr.Ide Anak Agung Gde Agung, RT.5/RW.2
Mega Kuningan, Jakarta 12950
Indonesia
Phone: +62 21 2598 2748

