FACT SHEET: Promoting the Quality of Medicines Program in the Philippines

January 2015

Technical Assistance toward WHO Pre-Qualification of Anti-Tuberculosis Medicines held last March 2014 at Sofitel Philippine Plaza, Manila

Photo: Maria Kathrina Olivarez

PQM established a sustainable mini-laboratory with the assistance of the City Mayor in Zamboanga Peninsula and the City Health Office

Photo: Maria Kathrina Olivarez

Conducting Minilab® Basic Testing at the Sentinel Site in Calabarzon

The Promoting the Quality of Medicines (PQM) Program, funded by United States Agency for International Development (USAID) and implemented by the United States Pharmacopeial (USP) Convention, has partnered with the Philippines Food and Drug Administration (FDA) and the National Tuberculosis Control Program – Department of Health (DOH) since 2008 to strengthen the country's capacity in assuring the quality of tuberculosis (TB) medicines.

BACKGROUND

The 2014 World Health Organization (WHO) Global Tuberculosis Report noted that TB remains the world's deadliest communicable disease and the Philippines is listed as one of the 22 highest TB burden countries in the world. In addition, there is a high burden of multidrug-resistant tuberculosis (MDR-TB), primarily due to large numbers of TB patients who are inadequately treated. There is a great need to improve and monitor the quality assurance (QA) and quality control (QC) of TB medicines that are procured and distributed throughout the National TB Control Program in the regional offices and Local Government Units (LGUs). It is also important to develop and implement strict regulations and put measures in place regarding the procurement and sale of TB medicines in the private sector, which challenges NTP efforts to control the development of MDR-TB.

APPROACH TO IMPROVING TB MEDICINE QUALITY AND FDA CAPACITY BUILDING

PQM activities have focused on (1) Establishing a medicine quality monitoring (MQM) program for detection of poor quality TB medicines through post-marketing surveillance (PMS); (2) Disseminating objective and up-to-date information about medicine quality and raising awareness among the general public about medicine quality issues to mobilize policy makers, regulators, and health professionals; (3) Strengthening the capacity of the FDA by providing a variety of trainings that range from analytical testing in the laboratory to evaluation and registration of pharmaceutical products, which support the Association of South-East Asian Nations (ASEAN) regional harmonization strategy; (4) Supporting local manufacturers to achieve WHO Prequalification (WHO PQ) for high demand of 1st and 2nd line TB medicines. WHO prequalified products is quality assured for both domestic and international markets. This is particularly important as international organizations such as the United Nations, Global Drug Facility, Global Fund, etc. can procure these medicines.

HIGHLIGHTS OF PROGRESS

PQM activities have gradually expanded in scope and budget due to the great need to improve the QA/QC system for TB medicines nationwide.

Photo: Maria Kathrina Olivarez

TB DOTS facility inspection at Bagong Barrio Zone 1 Health Center Caloocan City

Photo: Maria Kathrina Olivarez

TB DOTS facility inspection in Tibagan Health Center, CHO II, City of San Juan

Demonstration of sample extraction at CEDRES Bioanalytical Laboratory

Photo: Maria Kathrina Olivarez

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Establishing MQM

- The FDA, DOH, National TB Control Program, and PQM established an MQM program for TB medicines in order to obtain evidence-based data on their quality in the public and private sectors. PQM and the FDA work in close collaboration with selected regional offices and LGUs to monitor the quality of TB medicines, with the end goal being reduction of poor quality TB medicines circulating in the country.
- The MQM program currently operates at 8 sites in the Philippines which includes 5 regional offices (Bicol, Calabarzon, Cebu, Davao and La Union) and 3 LGUs (Iloilo, Malolos and Zamboanga). In 2014, MQM activities and scope (drugs for testing) have been expanded to antibiotics (Amoxicillin, Cephalexin, and Ciprofloxacin).
- Conducted an inspection of selected TB DOTS facilities for quality monitoring of ATBs drugs using the GPHF-Minilab® Kit.

Disseminating information and mobilizing policy makers, regulators, and health professionals

- Acted as the technical advisor in the previous meeting on "Quality – Assured Drugs for Better Public Health: Strengthening and Harmonizing the Regulation of TB Medicines in the Western Pacific Region".
- Facilitated a round table discussion with USAID/ Philippines, WHO/WPRO, Inter-CAs, DOH, FDA and partners on Strengthening the QA and control systems of TB medicines in the Philippines.
- PQM took a pledge of commitment at FDA's 4th National Consciousness Week against Counterfeit Medicines. All pledges were enclosed in a time capsule which will be opened in 2019.

Strengthening FDA QA/QC systems

- PQM conducted "USP PQM – ASEAN – Philippines FDA Joint Training Workshop on BA/ BE Studies" with participants from Philippines FDA, ASEAN Member States (AMS), Center for Drug Research, Evaluation and Studies, Inc. (CEDRES).
- The USP Technical Assistance Program (TAP) was renewed between Philippine FDA and USP. In line with this, FDA shall receive a 75% discount on USP reference standards, books and publications.
- One senior officer at FDA was sent to attend the Strategic Management of Regulatory and Enforcement Agencies (SMREA) Training at Harvard University.

Supporting local manufacturers

- Facilitated a workshop on "PQM Technical Assistance toward WHO Prequalification Anti – Tuberculosis (TB) Medicines and Medicines for other Diseases". This aim to inform the senior management and regulatory affair representative about WHO PQ, TA opportunities, global market outlook for TB Manufacturers in the Philippines.
- The PQM GMP team has visited three manufacturers in the Philippines and performed assessments in reaching the WHO PQ.

PARTNERS

Philippine Food and Drug Administration
National Tuberculosis Control Program
National Center for Pharmaceutical Access and Management
Regional Office
Local Government Unit