USAID FUNDED PROGRAMS PARTNER WITH PHARMACY AND POISONS BOARD (PPB) TO ENHANCE SAFETY AND QUALITY OF MEDICINES IN KENYA

"You need not be certain, just be suspicious". Report all suspected ADRs and Poor quality medicines.

REPUBLIC OF KENYA
MINISTRY OF PUBLIC HEALTH AND SANITATION
MINISTRY OF MEDICAL SERVICES
Pharmacy and Poisons Board

NEXT STEPS

Today, Kenya’s PV system is truly making a difference and saving patients’ lives. Dr. Wahome of Kenyatta National Hospital’s Comprehensive Care Centre welcomes the implementation of PV system and stresses the role of health care workers in educating patients on medicine safety through medication use counseling. He notes, “Pharmacists should have a one-on-one session with patients to create awareness of possible [medicine] side effects, what to expect, what to do and how to report adverse drug reactions.”

PPB’s efforts to enhance the system continue, with support from the USAID funded HCSM program. Such efforts include incorporating PV into pre-service training, collaborating with private and faith-based hospitals so that patients seeking care in these facilities can also benefit, encouraging consumer reporting and raising public awareness on medicine safety.

“Indeed, we acknowledge the investment WHO, UMC, and USAID’s SPS and HCSM programs have made to ensure Kenyans have access to good quality, safe and efficacious medicines through the eyes of pharmacovigilance advocates across the country” says Dr. F.M. Siyoi Deputy Registrar at the PPB.

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Global public health initiatives in developing countries have increased access to medicines including those for HIV/AIDS, Malaria, and Tuberculosis (TB). This access creates the need to systematically monitor and promote the safety and effectiveness of these medicines via national pharmacovigilance programs.

Patient safety remains the core business of any medicines regulatory authority (MRA) across the world. Keeping up with the pace of this mandate in a modern fast-growing world is a challenge for most MRAs in Africa because many developing countries lack the appropriate structures, systems, and resources to systematically support the detection and prevention of adverse drug reactions (ADRs) and other medicine-related problems. This challenge is further complicated by emerging diseases, increasing number of medicines, co-morbidities and health technologies.

Setting the Pharmacovigilance System In Kenya

Beginning pharmacovigilance (PV) work in 2004 and launching a formal pharmacovigilance (PV) system in June 2009, Kenya today boasts of a robust PV system that is proving services to support Hippocrates’ admonition, “at least do no harm.” With the support and guidance from the World Health Organization (WHO), the Uppsala Monitoring Centre (UMC) and the US Agency for International Development (USAID)-funded Strengthening Pharmaceutical Systems (SPS) and Health Commodities and Services Management (HCSM) program, the Pharmacy and Poisons Board (PPB) and the Ministries of Health in Kenya established a national PV system with the aim of having “one National country-led system” as opposed to vertical disease-based programs. Kenya has implemented a patient safety program that enables all health care providers to suspect, identify, and report medicine-related concerns to the national PV center which then provides recommendations on the policy changes, medicine recalls and withdrawals, and other regulatory actions.

Spontaneous ADR Reporting System in Kenya Incorporates Product Quality

A systematic approach to cascade trainings and sensitization across the country provided all health care workers with an opportunity to become self-vigilant and report cases of suspected adverse drug reactions (ADRs) and poor quality medicines. In Kenya, the aspect of identifying poor quality medicines and suspected counterfeits is an integral part of PV program and an important mandate to closely link poor quality medicines with the orthodox adverse effects of medicines.

With support from USAID funded SPS and the HCSM programs, the PPB have been able to systematically roll-out a national PV system for monitoring and reporting adverse drug reactions and poor quality medicines. Implementing the systems approach has enabled us to involve all stakeholders and collaborate with the national public health programs, especially the Division of Malaria Control (DOMC) program, National AIDS and STI Control Program (NASCOP) and the Division of Leprosy, Tuberculosis and Lung Disease (DLTLD) program. Additionally, both USAID funded programs have leveraged support from parallel funding streams (e.g., President’s Malaria Initiative and the US President’s Emergency Plan for AIDS Relief) for comprehensive PV system strengthening.

The national PV system has been equipped with guidelines, reporting tools, and training materials. These guidelines define the roles and responsibilities of stakeholders and clearly elaborate the reporting system and communication mechanism for timely and regular information sharing. USAID through the SPS and HCSM programs has supported the courier system for transmitting reports from health facilities to the PPB that are subsequently entered into the WHO database through VigiFlow®. In addition, USAID has supported the development of an electronic reporting system that enables all consumers, health workers, pharmaceutical companies to electronically submit pharmacovigilance reports to PPB via a web portal using a computer or mobile devices.

Managing PV Data For Decision Making

- Obtained the 98th official membership of the WHO Programme for International Drug Monitoring in 2010.
- Received over 6000 suspected ADR reports and 270 poor quality medicine complaints by the end of 2012.
- Recorded that over 70 percent of ADR reports have been related to ARVs; this information was used for the review of the fourth edition of the national Kenyan ART guidelines, the Guidelines for antiretroviral therapy in Kenya, 2011.

Moving Forward with Active Surveillance, Risk Assessment and Evaluation

Over 900 pharmacovigilance advocates and over 10,000 healthcare workers have been trained or sensitized on the issues of pharmacovigilance and post-market surveillance. In collaboration with United States Pharmacopoeia (USP) and DOMC, PPB has established 5 sentinel sites to screen for poor quality antimalarial medicines. PPB has also established 12 sentinel sites to provide routine information on ADRs for antiretrovirals in collaboration with NASCOP. Many countries have sent senior government officials to Kenya to learn about our PV system, including Afghanistan, USA and Angola. PPB has progressed into targeted cohort event monitoring (CEM) of antimalarials and antiretrovirals to complement spontaneous reporting of adverse events. New advances include the introduction of electronic PV reporting tools and medication error monitoring and reporting. With these and more innovations, patient safety is expected to be further enhanced.