Republic of Kenya

Pharmacy and Poisons Board

PHARMACOVIGILANCE IN KENYA ONE YEAR ON….

Kenya Becomes 98th Full Member of the WHO Programme for International Drug Monitoring

Volume 1, Issue 1

August 2010

Kenya is now the 98th Full Member Country of the WHO Programme for International Drug Monitoring within a year of the formal launch of its National Pharmacovigilance system.

On 4th May 2010, Dr. Lembit Rägo, Coordinator, Quality Assurance and Safety: Medicines, Essential Medicines and Pharmaceutical Policies of the World Health Organization (WHO), confirmed that Kenya was the 98th full member with immediate effect. In his letter to the Pharmacy and Poisons Board, he pointed out that WHO considers the International Drug Monitoring Programme a vital network in promoting Pharmacovigilance throughout the world.

The WHO programme was set up in 1968 as a result of the "Thalidomide tragedy". It consists of a network of the National Centers for pharmacovigilance, WHO Headquarters (Geneva), WHO Collaborating Centre for International Drug Monitoring and the Uppsala Monitoring Centre in Sweden.

It provides a forum for WHO member states to collaborate in the monitoring of drug safety. Within the Programme, individual case reports of suspected adverse drug reactions are collected and stored in a common database, presently containing over 5 million case reports.

As of May 2010, 98 countries had joined the WHO Drug Monitoring Programme, and in addition, 32 'associate members' were awaiting compatibility between the national and international reporting formats.

Kenya was granted full membership following submission of the required number of Good ADR Reports to the Uppsala Monitoring Centre in Sweden.

The Department of Pharmacovigilance at the Pharmacy and Poisons Board Kenya appreciates all individuals and organizations that have supported the initiative by sending Suspected Adverse Drug Reaction Reports, Poor Quality Medicines Complaints and establishing strong and efficient systems.

Read about the functions of the WHO Programme on International Drug Monitoring on pg 3…..

Senior officials from the Ministries of Medical Services and Public Health and Sanitation during the National launch of Pharmacovigilance in Kenya in June 2009.

Special points of interest:

- *Kenya becomes 98th full member of the WHO Programme for International Drug Monitoring*
- *PPB sets up an Expert Safety Review Panel (ESRP) to review all ADR and Poor Quality Medicine reports .*
- *DMS emphasizes the need for ADR sentinel Surveillance during launch of National STGs and AMU guidelines.*

Inside this issue:

PPB Partners with MSH to Build the Capacity of Over 5000 Health Care Workers on Pharmacovigilance

During the launch of the National Pharmacovigilance system on 9th June 2009, key government officials underscored its importance in ensuring patient safety.

Key tools that were launched during the ceremony included the National Curriculum and Implementation Guide, Trainer's Manual, Participants Manual, Reporting tools for Suspected Adverse Drug Reactions (ADRs) and Poor Quality Medicinal Products and reporting flows. Since then, PPB partnered with MSH/SPS through support provided by USAID to train 56 regional focal champions who were instrumental in implementing the National training roll–out plan. Further, over 5000 healthcare workers from both the private and public sectors have been sensitized and trained on pharmacovigilance.
Adult learning teaching methods and a multi-disciplinary approach were applied during the trainings where medical doctors, pharmacists, pharmaceutical technologists, nurses and laboratory technologists were targeted.

The response has been fabulous and health providers have confessed that "the Pharmacovigilance trainings provided were very different from the routine ones that have been offered, especially because they provided us with a chance to make a direct difference to the health care provision in Kenya."

ESTABLISHING THE NATIONAL PHARMACOVIGILANCE SYSTEM…. KEY MILESTONES

Since 2004, several milestones have been realized in the establishment of Kenya's National Pharmacovigilance System.
These include:

- Development and countrywide dissemination of National Guidelines on Pharmacovigilance
- Establishment of efficient reporting systems which include the tools, courier system and information flow design
- Development and implementation of National Pharmacovigilance Curriculum and Implementation Guide
- Development of job aids and IEC materials on Pharmacovigilance
- Creation of e-shot—an email based communication mechanism between 'Pharmacovigilantes' and PPB. e-shot currently boasts of over 100 users. See pg 3 for more...
- Development of a National Post Market Surveillance Strategy
- Setting up of a webpage dedicated to Pharmacovigilance on the PPB website through which visitors can access updates, tools and other available resources. See www.pharamacyboardkenya.org
- PPB has also set up an Expert Safety Review Panel in line with the national guidelines. The panel reviews all the pharmacovigilance related reports that have been received with a view of taking appropriate follow up actions. So far, more than 7 products have been recalled and a couple have been rescheduled.
- Post market surveillance activities for anti– TB, anti-malarials, cough and cold preparations and anti-retroviral medicines.
- Enhancing capacity of PPB to use Vigiflow and conduct clinical trials.

Chief Pharmacist and Registrar , Dr. Koskei (seated right), following proceedings during the National Pharmacovigilance training of focal regional champions.

Sentinel Surveillance for Malaria and HIV programs

In June 2010, the Director of Medical Services officially launched the National Standard Clinical Guidelines. In his keynote address, he emphasized the need for ADR sentinel surveillance as an avenue of obtaining the required data that will inform future revision of policies and guidelines.

So far, the Pharmacy and Poisons Board has assisted the Division of Malaria Control to set up five Sentinel sites to boost reporting of ADRs and monitoring of poor quality medicines. This involved development of protocol for monitoring quality of medicines (in collaboration with United States Pharmacopoeia), design of the sentinel surveillance system, identification and training of focal persons, provision of necessary tools, guidelines and other reference materials.

"Pharmacovigilance is not a luxury… it is a need."

Dr. Jayesh Pandit, Head of Department of Pharmacovigilance, PPB.

Over 500 samples of anti-malarials have been sampled and tested at the Sentinel Sites. Confirmatory testing is currently underway at the National Quality Control Laboratory (NQCL).

These sentinel sites, along with other interventions, has boosted reporting of suspected ADRs and poor quality medicinal products to 451 and 86 reports respectively. Several recalls have taken place.

Following the release of recommendations by WHO to change the ART treatment guidelines, the National AIDS and STI coordinating Program (NASCOP) was challenged by the Director of Medical Services to collect data on ADRs so that future policy changes are strongly backed by local evidence.

NASCOP is currently in the process of setting up Antiretroviral Therapy (ART) ADR Sentinel Surveillance Sites while borrowing lessons learnt during the set up of the Malaria Sentinel sites.
It is hoped that these sites would boost reporting of ADRs related to ART.

Feedback from health professionals..

"The National Pharmacovigilance System has certainly increased awareness of ADRs and Poor Quality Medicinal Products amongst health professionals. Health professionals now realize that poor treatment outcomes may be linked to these issues. In addition, it has resulted in enhanced teamwork among members of the healthcare team."

Dr. Fathiya Hamumy
Pharmacist in– Charge
Coast Province General Hospital

"Substandard drugs and adverse drug reactions in Kenya was taken as a 'norm' rather than an **issue** or **event** requiring redress. This was because there was no authoritative body engaged and no one seemed to care. Reports, if ever done were for internal institutional consumption, mainly in private settings which had active pharmacy personnel and functioning medicine and therapeutic committees.

Today, this has become part of a performance measure in most private institutions where both the healthcare worker and patient take responsibility, with the biggest impact and improvement seen in the field of ART and Malaria. The pharmacist's role in healthcare, being the focal person in coordination of this process, is now being recognized and valued to the extent it deserves. Kudos to pharmacovigilance"

Dr. John Jao Majimbo

Pharmacist in –charge, Kenya Ports Authority & Chairman, PSK Coast Branch

QUICK READ: PHARMACOVIGILANCE NEWS

Enhanced Collaboration Resulting from Pharmacovigilance

The National Pharmacovigilance System has enhanced collaboration within and outside the Pharmacy and Poisons Board.

PPB currently works closely and collaboratively with the parent ministries—Ministry of Medical Services and Ministry of Public Health and Sanitation, the public, partners and other stakeholders.

Moreover, greater collaboration has been realized in terms of technical and financial support provided by WHO and USAID (through MSH).

The Department has also been collaboration with International Police (INTERPOL) to curb the menace of counterfeit medicines.

Launch of Consumer Reporting System in Kenya

Since the formal launch of the National Pharmacovigilance System in June 2009, over 5000 healthcare workers have been trained/ sensitized on the reporting and monitoring of ADRs and poor quality medicines.

The Department of Pharmacovigilance officially launched the Consumer Reporting System for ADRs and Poor Quality Medicines on 12th August 2010 in a well attended media breakfast conference. Over 40 medical journalists from all the major media houses were present during this launch and the Department of Pharmacovigilance educated them and the public through their broadcasts on medicine safety issues.

A panel of experts namely, Professor W. Jaoko, Dr. M. Wasunna, Dr. F. Siyoi, Dr. J. Pandit, Dr. J. Mecha presided over the launch.

Two patients gave their testimonies reflecting on their personal experiences on medicine related adverse effects and encouraged all consumers to seek medical advice and report any side effects to the Pharmacy and Poisons Board promptly.

Medical journalists responded to the launch positively and the same was reported widely in all the main media channels.

It is hoped that this step will improve consumer reporting on medicine related issues.

Enhancing the interface between the Department of Pharmacovigilance and its beneficiaries through e-shot

E-shot is an innovative email based means of communication through which the Department of Pharmacovigilance can provide updates to the users and users can in turn share feedback on issues. Since the set up of e-shot, the following messages have been posted:

- Alert on herbal contraceptives
- Ceftriaxone-Ca2+ interaction
- Quarantine of paracetamol tabs
- Recall of paracetamol tabs
- Kenya Becomes 98th Full Member of the WHO Programme for International Drug Monitoring and appreciation of all contributors
- Didanosine: Risk of non-cirrhotic portal hypertension
- Saquinavir: Possible association with abnormal heart rhythms

To subscribe to e-shot send an e-mail to: **mdaemon@pharmacyboardkenya.org** with the first line of the body of the mail (not subject line) of the email being: SUBSCRIBE ESHOT@PHARMACYBOARDKENYA.ORG

Note:

- The subject line is not necessary and can be left blank
- The first of the body of the email is the most important and must be **subscribe eshot@pharmacyboardkenya.org** and the rest of the email can be blank.
- The email must be sent to: **mdaemon@pharmacyboardkenya.org** not to **eshot@pharmacyboardkenya.org**

Functions of the WHO Programme for International Drug Monitoring

- Information exchange between WHO and National Centers, mainly through 'Vigimed', an e-mail information exchange system
- Publication of periodical newsletters, (WHO Pharmaceuticals Newsletter and Uppsala Reports), guidelines and books in the pharmacovigilance and risk management area
- Supply of tools for management of clinical information case reports.
- Provision of training and consultancy support
- Provision of training and consultancy support establishing pharmacovigilance systems
- Computer software for case report management centers (Vigiflow)
- Annual meetings for representatives of National Centers organizational matters are discussed
- Methodical research

Pharmacy and Poisons Board Staff undergo training on Vigiflow in Accra, Ghana.

For more information on the WHO Programme for International Drug Monitoring, visit www.who-umc.org

Upcoming Events

National Pharmacovigilance Systems: Ensuring the Safe Use of Medicines Conference, Nairobi August 2010

Dissemination of Pharmacovigilance job aids and IEC Materials September 2010

Quotable Quote

" To undergo treatment you have to be very healthy, because, apart from your sickness, you have to withstand the medicine."
Molière

Pharmacovigilance Core Team

Meet the faces behind the Pharmacovigilance team at the Pharmacy and Poisons Board…..

Left -Right :
Dr. E Abwao, Dr. F Siyoi, Dr. K Koskei, Dr. J Pandit and Mr. G Muthuri

Pharmacovigilance in Kenya: A glimpse of the future..

The Department of Pharmacovigilance at the Pharmacy and Poisons Board has taken on newer responsibilities– the department of pharmacovigilance has been merged with the Division of Medicines Information. These changes were communicated by the Registrar, Dr. K. C. Koskei, in July 2010.

In addition the department is already working with established Medicine and Therapeutic Committees in various public and private health facilities to institutionalize Pharmacovigilance, post-market surveillance and now also envisages to expand to capture information on medication errors. These new roles provide the department of pharmacovigilance with an opportunity to apply a holistic approach to Pharmacovigilance.

With support from USAID and MSH, the department has also developed simple job aids for health providers to improve the reporting culture. These job aids will be availed to health facilities in the near future and uploaded on the PPB website for ease of access.

In addition, PPB is working to finalize a the Post Marketing Surveillance Strategy and disseminate it to key stakeholders.

The Department of Pharmacovigilance was set up in late 2004 at the Pharmacy and Poisons Board with a vision to develop, implement and continuously upgrade an appropriate system for detecting, reporting and monitoring adverse drug reactions (ADRs) and other relevant medicine related problems in Kenya. The department strives to ensure the safety and efficacy of pharmaceutical products in Kenya. The department also carries out routine post market surveillance on all medicines in Kenya which helps ensuring that the quality of these medicines also remains as required.

" All great journeys begin with a single step." The Pharmacy and Poisons Board is grateful to all stakeholders, partners and especially our 'pharmacovigilantes' for their active reporting and support to the National Pharmacovigilance System in Kenya.

Production of this newsletter was made possible through support provided to Management Sciences for Health by the U.S. Agency for International Development, under the terms of cooperative agreement number GHN-A-00-07-00002-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

About SPS
The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services.

SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

For more information, please contact:

Upcoming Events
Department of Pharmacovigilance
Pharmacy and Poisons Board
Ministry of Medical Services
Lenana Road
P.O. Box: 27663-00506
Nairobi, KENYA

Email: pv@pharmacyboardkenya.org

Website: www.pharmacyboardkenya.org

Telephone:
(+254-20-) 3562107
(+254-0-) 733884411 / 720608811
(+254-20-) 2713431 / 2713409

"You need not be certain… just be suspicious"… Report all suspected ADRs and Poor Quality Medicines.

USAID FROM THE AMERICAN PEOPLE

Pharmacy and Poisons Board

msh Management Sciences for Health SPS Strengthening Pharmaceutical Systems