Pharmacy and Poisons Board

The Lifesaver

The Kenya National Medicines Information and Pharmacovigilance Centre Newsletter

Ensuring Quality, Safety and Efficacy of Medicines for Better Healthcare

Multi-Drug Resistant Tuberculosis: Do Pharmacovigilantes Have a Role?

January 28th, 2009 is an unforgettable day for Job Osanwa's family. On this day Job was informed by his doctor that the cause of his persistent cough and ill health was a dangerous form of Tuberculosis (TB) called Multi-Drug Resistant Tuberculosis (MDR-TB) or 'TB Sugu' in Kiswahili. The doctors explained that the TB Sugu was not curable using normal anti-TB drugs...*

(actual name withheld for privacy purposes)*

Role of Pharmacovigilantes in the Management and Control of Multi-Drug Resistance TB

Monitoring and Managing Adverse Drug reactions to anti-TB medications

Ensuring appropriate use of anti-TB medicines through proper prescribing, adherence to treatment guidelines, proper dispensing and labeling of medicines; proper counseling of patients on the use of their medication, adverse effects and how to handle them, consequences of poor compliance

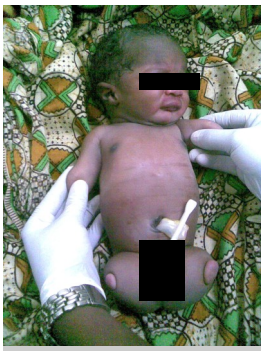
Enforcement of Regulations to control the sale, importation and supply of anti-TB medicines and reduce penetration of counterfeit products into the market

Improving pharmaceutical management practices to assure quality and regular supply of anti-TB medicines

Strengthening infection control practices *at health facility levels*

Good manufacturing practices *to assure quality of anti-TB medicines*

Incorporation of training on MDR-TB *at the pre-service and in-service levels*



Phocomelia case detected in Eastern Province. Read more on page 5.

"Medicine is a science of uncertainty and an art of probability."

William Osler

Pharmacy and Poisons Board
2nd Edition of the Kenya National Medicine Information and Pharmacovigilance Newsletter, March 2012

Special Points of Interest:

- *655 MDR– TB cases documented in Kenya since 2003*
- *PPB taking disciplinary action against suspected dealers of falsified Zidolam -N Tablets*
- *A focus on Tenofovir*
- *Medication error that led to a patient's death*
- *Post Market Surveillance Survey Reports released*

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Editorial Team: Jayesh Pandit, Edward Abwao, George Muthuri, Mary Njeri, Christabel Khaemba, Janet Kimeu, Ndinda Kusu
Special Contributors: Titus Kahiga, R Muthoka, C Olwande, S Kinyanjui, J Gachengo, Irene Mukui, Maureen Kimani

Facts About: Multi Drug Resistant TB (MDR-TB)

WHO estimated 2016 MDR-TB cases in Kenya in 2007. Of these, 1.7% were among the new TB cases and 7.9% were retreatment cases. In Kenya, 655 MDR –TB cases have been diagnosed and documented since 2003.

Drug Resistant TB has two forms:

- MDR-TB where TB bacilli are resistant to both rifampicin and isoniazid therapy which are part of the first line treatment for susceptible TB.
- Extensively Drug Resistant TB (XDR-TB) where the TB bacilli are resistant to a fluoroquinolone and an injectable used for second line TB treatment e.g. Kanamycin, Amikacin, Capreomycin or Viomycin

Factors contributing to MDR-TB:

- *patient related factors* e.g. poor compliance to treatment, use of anti-TBs with other medication and herbal products that interfere with efficacy
- *Healthcare provider factors* e.g. Inappropriate prescribing, dispensing, counseling, poor inventory management practices
- *Drug Related Factors* e.g. inadequate regulation and enforcement leading to counterfeits

Effects of MDR TB

* Increased morbidity and mortality
* Increased costs resulting from expensive 2nd and 3rd line medication, long durations of treatment, prolonged hospital stays and loss of man hours.

Drugs Used in the Management of MDR– TB

- Injectibles: Kanamycin (Km), Amikacin, Capreomycin [Cm] , Tabs Protionamide [Pto], Tabs Levofloxacin [Lfx] ,Tabs Cycloserine [Cs] (or Para amino salicylic acid (PAS) ,Tabs Pyrazinamide [Z] (or Ethambutol [E])

Drug Resistance TB (continued from Page 1)

Job was sent home to wait for the hospital to make arrangements to transport him to Nairobi for specialized treatment. Previously Job had been treated twice for TB with remarkable improvement only for the disease to return resulting in painful coughs, weakness and loss of weight. From the doctor's explanation of how MDR-TB develops, Job was quick to admit he did not complete his TB treatment courses as directed by the nurse.

Job said that the medicines were causing him to have skin rashes, bloody urine and loss of libido. After six long months of waiting for treatment, Job's son developed similar symptoms to those of his father. Job was so troubled, he believed he had infected his son with the disease. He decided to commit suicide to avoid spreading the 'curse' to the rest of his family. His suicide attempt failed when passersby saw his dangling body, rescued him and rushed him to hospital.

The Ministry of Health intervened and quickly transferred father and son to one of the MDR– TB treatment Centres in Nairobi. Sadly, three months later, Job died. His son however was cured after 27months of treatment which included 200 injections

Treatment Regimen for MDR– TB

8 Km-Pto-Lfx-Cs-Z/12Pto-Lfx-Cs-Z

The regimen consists of an **intensive** phase of 8 months **continuation** phase of 12 months .

Documented ADRs to anti - MDR-TB Medicines:

* Hepatitis, Gastro-instestinal Tract Disturbance, Peripheral Neuropathy, Seizures , Hearing Loss ,Psychotic Symptoms, Renal toxicity, Optic Neuritis, Arthralgias

" The role of pharmaceutical personnel in provision of comprehensive pharmaceutical care to all MDR TB patients is an important element that needs strengthening in all the treatment centres."

Dr. Richard Muthoka, DLTLD

Update on Falsified Zidolam –N Tablets

Following a patient's complaint on the moulding, and crumbling of Zidolam-N tablets, Pharmacy and Poisons Board (PPB) and NASCOP, in collaboration with WHO, MSF and MSH/HCSM, took several actions. The team quarantined the product, issued a public alert requesting patients taking the product to report to their healthcare providers immediately, heightened alertness and provided guidance on how to handle related complaints. Samples of the poor quality tablets were collected and taken to the National Quality Control Laboratory (NQCL) for analysis. Follow up investigations indicated that though the product passed analysis, it was established that this batch (E100766) of Zidolam-N was falsified and was not intended for the Kenyan market. The investigations further revealed that these were donated medicines which were being offered for sale to unsuspecting clients without the authority of the manufacturer. The batch size found in the market was also notably bigger than that produced by the manufacturer.

The suspected dealers in this product are currently facing disciplinary action by PPB and legal processes are underway.

Updates Provided Through E-shots

Based on reports submitted to PPB, the following E-shots were sent out to all pharmacovigilantes since the last issue of this newsletter:

- Voluntary recall of Scheriproct Ointment (Prednisolone caproate + Cinchocaine HCl)
- Recall and withdrawal of Locaine A dental cartridges and Lotem suspension manufactured by Adcock Ingram
- Suspected lack of efficacy of Oxitin (oxytocin) Injection manufactured by Apoorv International (India)
- Poor quality Flagimed (Metronidazole Suspension 200mg/5ml manufactured by Medivet Products Ltd, Kenya
- Withdrawal of Xigris (Drotrecogin Alfa (activated)) from the market due to lack of efficacy
- Safety information on Strattera (Atomoxetine Hydrochloride)- risk of increased blood pressure and heart rate
- Poor quality Nevirapine 200mg Tablets manufactured by Strides Arcolab Ltd
- Safety information on Glustin (Pioglitazone Hydrochloride) - increased risk of urinary bladder cancer
- Falsified Zidolam -N Tablets manufactured by Hetero Drugs India

Get the medicine safety 411… Stay Informed! 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

* *The subject line is not necessary and can be left blank*
* *The first line of the body of the email is the most important. The rest of the email can be blank.*

E– shot is a free service provided by the Department of Pharmacovigilance to keep you informed on medicine safety alerts.

ART ADR Surveillance: Knowledge and Experiences from Sentinel Sites

Provincial Pharmacists and Core teams from 12 ART ADR Sentinel Surveillance Sites converged in Nakuru to share experiences and challenges faced since their establishment in 2010.
Core teams highlighted the facility ADR Monitoring and Reporting Systems, achievements since implementation, lessons learnt among others.

It was encouraging to note that each facility had an established facility based system of monitoring and reporting ADRs. Having a focal member of the core team to collect and collate the reports had positive returns.

All the facilities had made considerable progress in the detection, monitoring and reporting of ADRs. 25% of the facilities were actively analyzing the ADRs they had reported to PPB themselves to see the common suspected medicines and ADRs.

that pharmacovigilance had immediate benefits. ADRs were detected early before they became severe and fatal. This meant decreased ADR related admissions and financial expenditure being wasted.

Key challenges experienced included lack of ownership of PV by other cadres, limited awareness at lower levels of care, workload and limited time to
report and similarity in ADRs reported leading to monotony.

Core teams identified the following as recommendations:

- Development of e-reporting system
- Sensitization and training of staff at lower levels of care
- Capacity building on use of pharmacovigilance information for decision making

Some of the lessons learnt and shared by the sentinel site core teams included the following:

" Pharmacovigilance is a responsibility that we as care givers need to prioritize if we desire safer and more efficient medication"

" ART programs will need to implement Pharmacovigilance systems so that patient safety is assured in the face of rapidly changing ART treatment

" Some ADRs are preventable if the drug use cycle is followed properly i.e. proper assessment/ diagnosis, prescription, dispensing and adherence to the treatment."

" Medicines and Therapeutics Committee has a major role in the implementation and co-ordination of Pharmacovigilance activities in the facility."

" PV Should be incorporated into the hospital AOP as one of the indicators, the syllabus of medical students and staff performance appraisal.

" It is important to know a patient's history. Emphasis on diagnosis, treatment and prevention of ADRs is important."

" Involving patients by educating them on drug safety and possible ADRs is key in minimizing incidences of ADRs. "

A focus on Tenofovir (TDF)
Have you evaluated your patient on ARVs for toxicity?

July 2010 was marked by changes in the Guidelines for Antiretroviral Therapy in Kenya. This was necessitated by revisions in the WHO Guidelines on ART in light of growing concern on the increased toxicity to stavudine (d4T) and the need to use ARVs with better toxicity profiles. The guidelines recommended the gradual phase out of d4T as the key first line ARV and recommended use Tenofovir (TDF) for ART initiation and substitution for those with d4T related toxicities.25 months on, over 28% adults on ART are using TDF based regimens. TDF may cause renal injury with the characteristic features of the fanconi syndrome, hypophosphatemia, hypouricemia, proteinuria, normoglycaemic glycosuria, elevation in creatinine, and , in some cases, acute renal failure. Renal toxicity is often asymptomatic, but patients may complain of muscle pain. Risk factors for renal toxicity include pre-existing renal disease (elevated creatinine at baseline), low CD4 count,advanced age (> 35 years at initiation of therapy); low body weight and concurrent use of nephrotoxic agents such as amphotericin B and IV acyclovir.

For patients at risk of TDF induced renal toxicity, baseline and follow up laboratory evaluation of creatinine is recommended.

The cumulative frequency of renal impairment following initiation of TDF-containing regimens has been found to be 1% to 4%.

It is advisable to consult a specialist physician in case of renal impairment at baseline and following initiation of TDF. Renal function should be monitored using the Cockroft-Gault Equation:

In Men	***In Women***
CrCl (mL/min) = 1.23 x (140 – age) x weight PCr (µmol/l) (Age in years, weight in kg)	CrCl (mL/min) = 1.04 x (140 – age) x weight PCr (µmol/l) (Age in years, weight in kg)

In case of renal impairment, tenofovir doses should be adjusted appropriately using the guide below:

Tenofovir Dose Adjustment in renal impairment

Creatinine Clearance mL/min	**Dose of TDF**	**Dose of TDF 300/FTC 200/EFV 600 FDC**
= 50	300 mg once daily	One tablet once daily
30 – 49	300 mg every 48 hours	1 tablet every 48 hours
10 - 29	300 mg every 72 hours	Not recommended
< 10	300 mg weekly	Not recommended

Counseling Endpoints on the Use of Tenofovir

Before prescribing Tenofovir,

- *Take a thorough past medical history and lab investigation (including urinalysis) to rule out liver and kidney disease*
- *Check for renal function and serum phosphate before treatment . Patients with Creatinine Clearance < 30ml/min should not receive TDF.*

After prescribing Tenofovir

- *Monitor renal function closely*
- *Stop treatment if severe adverse reactions occur*

Patients taking TDF should:

- *Take it with food especially high fat meal to increase bioavailability*
- *take a lot of water*
- *avoid taking alcohol*
- *See the doctor immediately if the following changes occur : upset stomach, loss of appetite, excessive tiredness, weakness, dark yellow or brown urine, unusual bleeding or bruising, flu-like symptoms, yellowing of the skin or eyes, and pain in the upper right part of the stomach.*

Pharmacovigilance Training Updates

University of Nairobi : Training of B. Pharmacy Final Year Students

One of the most fulfilling pre-service Pharmacovigilance trainings was conducted at the University of Nairobi in October 2011. 67 Bachelor of Pharmacy final year students participated in a one-day training conducted by UoN, PPB and MSH/HCSM. It was exciting to pass the knowledge and skills to the students before they graduated.

"*Training in PV just before graduation will ensure these students make best use of their medicines to enhance patient safety*," says Dr. Jayesh Pandit. Professor Thoithi, the then Dean of the School of Pharmacy appreciated the support provided by PPB, USAID and MSH/ HCSM in making their degree course a cutting edge program.

"Anyone who stops learning is old, whether at twenty or eighty. Anyone who keeps learning stays young. The greatest thing in life is to keep your mind young."

Henry Ford

Pharmacovigilance at the Tea Zone

34 health care workers drawn from Walter Reed Program supported health facilities in Kericho and surrounding districts were trained on Pharmacovigilance in October 2011. The training was conducted in cognizant of the importance of detecting and reporting ADRs and poor quality pharmaceutical products by WRP.

Ms. Mary Njeri of PPB facilitating a discussion during the KDF training on Pharmacovigilance

Kenya Defence Forces Training on Pharmacovigilance Training

17 Health Units of the Kenya Defence Forces were engaged in a week long training on pharmacovigilance in February 2012. The participants agreed unanimously that the training was beneficial to them and their patients.

"Knowing is not enough; we must apply.
Willing is not enough, we must do."

Goethe

Kenya Defence Forces health care providers engaged in intense group work discussions during the Pharmacovigilance Training in Febraury 2012

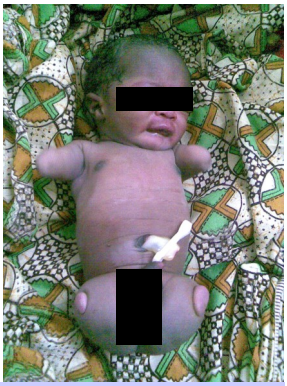
Pharmacovigilance Training Updates

Third National Pharmacovigilance Training

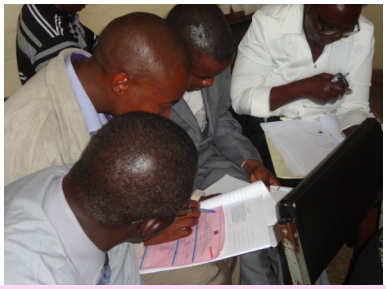
The third National Pharmacovigilance Training was successfully conducted by PPB and MSH/ HCSM in November 2012.
51 enthusiastic participants attended the training. These were drawn from health facilities in Rift Valley, Central, Western, Nyanza, North Eastern, Eastern Provinces, Division of Leprosy Tuberculosis and Lung Diseases (DLTLD) and Anti-counterfeit Agency (ACA).
The training culminated with the participants preparing action plans. Most of the participants have implemented part of their action plans.
Mr Cyrus Kisinga, District Pharmaceutical Facilitator for Ijara District has provided feedback to the DHMT and HMT, sensitizedMasalani Hospital staff and rural health facility in-charges on Pharmacovigilance and availed reporting tools have been to all the relevant departments and wards. Mr. Kisinga says future plans are to integrate pharmacovigilance into any health related trainings conducted in the district and support supervision to enhance detection, monitoring and management of ADRs.

Regional Sensitizations

Staff from four health facilities in Central and Eastern Provinces benefitted from PPB, MSH/HCSM supported sensitizations on pharmacovigilance. The sensitizations were conducted in the institutions by previously trained Pharmacovigilantes taking on a leading role in the organization and facilitation. During one of the sensitizations, facility staff and the training team learnt that a case of phocomelia had been detected at the hospital in 2009 but was not reported to the National PV Center. Details pertaining to the case are being investigated.



Phocomelia case detected in Eastern Province in 2009



Embu PGH staff practice how to fill the form for reporting Suspected Poor Quality Medicinal Products

The revised edition January 2012 of the National Pharmacovigilance Curriculum and Implementation Guide, Participant and Trainers Manuals.

National Pharmacovigilance Training Package Revised

The National Pharmacovigilance Training Curriculum has now been revised and updated in line with changes in policies and various guidelines. The revision and printing was made possible through support from USAID. Copies of the curriculum are now available at the Division of Medicines Information and Pharmacovigilance.

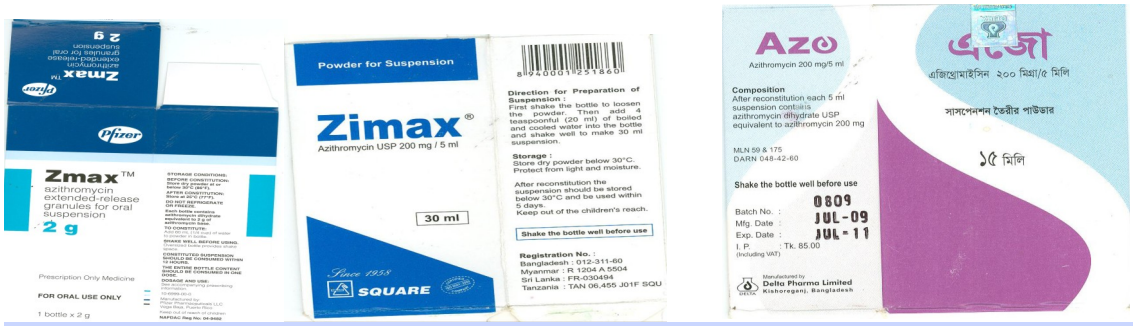
Medication Errors: What we heard .....

According to the USA National Coordinating Council for Medication Error Reporting and Prevention, medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. In our last issue, we asked you to share any medication errors you have come across. Here are a few examples that you shared.

Note: Examples have been published for purposes of learning and prevention of re-occurrence.

UNFORTUNATE DEATH .... COULD IT HAVE BEEN AVOIDED?????

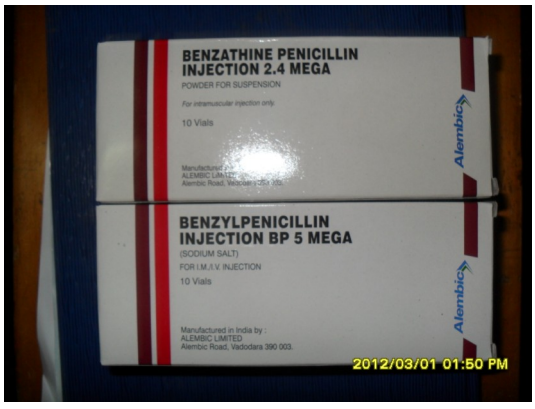
Benson* walked into a hospital feeling ill. He went though the routine examination and was diagnosed with an upper respiratory infection. Benson was directed to the injection room where the nurse administed Benzyl penicillin injection as per prescription. (The clinician had prescribed the injection to continue with Amoxycillin 500mg tid for 5 days). Benson was aware that he was allergic to penicillin but did not inform the clinician or the nurse. Unfortunately, both healthcare providers did not inquire about Benson's known drug allergies. As the nurse turned to dispose the syringe and needle after administering the injection, Benson started sweating and vomiting. Benson collapsed thereafter. The nurse tried to manage the anaphylactic reaction without success. The cause of death



This product does not have adequate instructions for reconstitution. This could lead to potential errors by the dispenser.

*An example of sound alike medicines. **Zmax** (above) is an adult oral suspension of azithromycin 2g while **Zimax** (below) is a paediatric oral suspension of Azithromycin 200mg/5ml. The manufacturers for these two products are different. As both products have similar names and molecules, it is possible for the prescribers and dispensers to confuse the two.*

Medication Error	Effect on the Patient
Diclofenac injection given iv instead of im	Patient got palpitations
Adrenaline given iv instead of im	Patient got palpitations
Benzathine penicillin injection reconstituted with lignocaine	Patient collapsed
Pethidine given instead of plasil iv	Patient developed hypotension
Largactil given instead of lasix	Patient went into deep sleep
Adrenalin injection administered instead of lignocaine	Patient got palpitations and lost consciousness
Insulin overdose	Patient went into hypoglycaemic shock



Look alike benzathine penicillin 2.4 MU and benzylpenicillin 5MU found in a facility recently

How can pharmacovigilantes prevent such occurrences? Write to us: pv@pharmacyboardkenya.org

News Round Up

Nairobi International Trade Fair and Mombasa ASK Show

More than 300 members of the public paid visits to the Pharmacy and Poisons Board and Anti-Counterfeit Agency stands at the recently concluded annual agricultural shows held in Mombasa and later Nairobi. The Division of Medicines Information and Pharmacovigilance displayed and disseminated the tools used in reporting suspected ADRs and poor quality medicinal products. Pharmacovigilance IEC materials were used to explain to the public pointers in the detection and reporting of ADRs. One of the visitors to the stands was issued with an alert card as they had just experienced an ADR to Cotrimoxazole tablets.

This is what some of the visitors to the stands wrote in the visitors Book:

- *Congratulations for the efforts you are putting in place to ensure patient safety*
- *More stringent measures to assure quality of medicines in the Kenyan market required*
- *Engage media more in sensitizing the public*

Advertisement Guidelines

A stakeholder meeting was held at the Pharmacy and Poisons to finalize the Advertisement Guideline. The guideline is pending approval by the Director of Medical Services and Director of Public Health and Sanitation.

It is anticipated that this guideline will address issues such as advertisement of unregistered medicines, medicines with otherwise little safety, quality and efficacy-related data and advertisements and promotions that have not been approved by the Medicines Regulatory Authority- the Pharmacy and Poisons Board

In Honor of a great Pharmacovigilante

We celebrate the life of the Late DR DORIS IKONGE MOENGA, a promising doctor and pharmacovigilante' who left us too soon. At the time of her death, she was the Medical Officer in charge of Obstetrics Department at Vihiga District Hospital. She was an exemplary mentor to the medical and clinical officer interns. Dr. Moenga was at the forefront of promoting the best medical practices through Continuous Medical Education, on job trainings, seminars, audits and evaluations. She participated in the Pharmacovigilance training in November 2011 and indeed she was a true pharmacovigilante. Her focus was on improving patient care and safety, encouraging safe and rational use of medicines. She was enthusiastic about pharmacovigilance, reporting any ADRs she came across and together with other pharmacovigilantes in the hospital had plans to train and sensitize colleagues on the same not only in the hospital but also across Vihiga County.

May God rest her soul in eternal peace.

PPB and MEDS Meeting

The Pharmacy and Poisons Board met the Quality Assurance Team at the Mission for Essential Drugs and Supplies (MEDS) on 6th January 2012 to foster a stronger working relationship regarding Pharmacovigilance and Post-Market Surveillance. MEDS is a major supplier of medicines across Kenya and their commitment to provide PPB any information pertaining to quality, safety and efficacy of medicines in a timely fashion will further enhance patient safety in Kenya.

Picturespeak.....

Left: Angola MOH team, PPB and MSH staff following an educative tour of the National Pharmacovigilance System in Kenya
Right: Dr. Jane Masiga, Dr. Donald Muathe and Dr. Wycliffe Nandama meet Mr. George Muthuri and Dr. Jayesh Pandit at MEDS Centre.

Stakeholder Meeting to Approve and adopt draft Advertisement Guidelines

Third National Pharmacovigilance Training

Left: *Paul Ndungu of Nyumbani Childrens Home highlights roles of health care providers in pharmacovigilance*
Right: *Participants watching the video clip on counterfeiting medicines*

Laughter... The Best Medicine

Lady says to Pharmacist: "Why does my prescription medication have 40 side effects?"
Pharmacist replies : "Cause that's all we've documented so far."

Pharmacy Bridal Registry

Jacob, age 92, and Rebecca, age 89, living in Florida, are all excited about their decision to get married.They go for a stroll to discuss the wedding, and on the way they pass a pharmacy. Jacob suggests that they go in and have a look around.

Jacob addresses the man behind the counter: "Are you the owner?"
The pharmacist answers, "Yes."
Jacob: "We're about to get married. Do you sell heart medication?"
Pharmacist: "Of course we do."
Jacob: "How about medicine for circulation?"
Pharmacist: "All kinds."
Jacob: "Medicine for rheumatism and scoliosis?"
Pharmacist: "Definitely."
Jacob: "How about Viagra?"
Pharmacist: "Of course."
Jacob: "Medicine for memory problems, arthritis, jaundice?"
Pharmacist: "Yes, a large variety. The works."
Jacob: "What about vitamins, sleeping pills, Geritol, antidotes for Parkinson's disease?"
Pharmacist: "Absolutely."
Jacob: "You sell wheelchairs and walkers?"
Pharmacist: "All speeds and sizes."
Jacob: "Perfect! We'd like to use this store as our Bridal Registry."

Growth in the National Pharmacovigilance Team

Following reorganization at the Pharmacy and Poisons Board, former head of the Division of Training and Assessment, Dr. Lawrence Nzumbu, is now the head of the Division of Medicines Information and Pharmacovigilance. He brings with him a wealth of experience as a Good Clinical Practice and Good Manufacturing Practice inspector with expertise in drug registration, product evaluation and WHO Prequalification of Medicines Programme.
This division is divided into three sections, namely; Medicines Information headed by Dr. Christabel Khaemba, Pharmacovigilance and Post Market Surveillance headed by Dr. Jayesh Pandit and Clinical Trials headed by Dr. Edward Abwao. The division continues to be supported by Ms. Mary Njeri and Mr. George Muthuri.

Pharmacovigilance Job Aid 2

Republic of Kenya

MINISTRY OF PUBLIC HEALTH AND SANITATION & MINISTRY OF MEDICAL SERVICES
PHARMACY AND POISONS BOARD

How to Report a Suspected Adverse Drug Reaction

- Document the facility's details
- Document the patient's information (for females, indicate the pregnancy status)
- Write the diagnosis
- Describe the adverse drug reaction
- List all medicines used within the last 3 months
- Grade the severity of the reaction
- Indicate the action taken
- Indicate the outcome of any intervention
- Document the probable cause of the reaction
- Write your name, contact and date of reporting

Key elements of a suspected ADR Report:

- Patient information
- ADR description
- Medication history
- Name contact of reporter
- Date of reporting

Remember.....

- Report all cases of Adverse Drug Reaction as soon as they occur regardless of:
  - Uncertainity of the drug that caused the reaction
  - Unavailability of all details

Where to report

- Forward the completed form to your pharmacy department for onward submission, mail or E-mail directly to the Department of Pharmacovigilance,Pharmacy & Poisons Board

Reporting is the responsibility of all healthcare workers

DEPARTMENT OF PHARMACOVIGILANCE,
PHARMACY AND POISONS BOARD
LENANA ROAD, NAIROBI P.O. BOX 27663 - 00506
TEL: (020) 2716905/6 , 020 3562107, (Ext 114.) 0720 608811, 0733 884411 Fax: (020)-2713538
E-mail:pv@pharmacyboardkenya.org Website:www.pharmacyboardkenya.org

USAID FROM THE AMERICAN PEOPLE

Upcoming Events

- World Health Day April 2012
- Africa Pharmacovigilance Meeting April 2012
- Msc. Pharmacoepidemiology and Pharmacovigilance at University of Nairobi October 2012

For more information, please contact:

Division of Medicines Information and 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

The Division of Medicines Information and 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 division 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.

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

Post Market Surveillance Survey (PMS) Reports Disseminated

Front Right: Dr Willis Akhwale follows the proceedings keenly.

Findings of three PMS surveys on anti-malarial, anti-tuberculosis and antiretroviral medicines were disseminated to key stakeholders in April 2012. The findings included unregistered and poor quality products in the market and weak infrastructure for storage of medicines
Key recommendations resulting from these surveys are:

- Greater collaboration between public health programs, Department of Pharmacy and PPB in the regulation of medicines
- Enforcement of penalties for unregistered products in the market
- Standardization of technical specifications for ARV procurement for use by all entities
- Installation of better equipment at NQCL to decrease the turnaround time for analysis of samples
- Increased budgetary and technical support for PMS related activities
- Manufacturer, importer and distributor compliance to legal requirements

The Government of Kenya, USAID and WHO pledged their support to post market surveillance activities for the furtherance of patient safety.

Your Views About *The* Lifesaver

Good work !!! Please make it regular, not a one-off.

I loved this newletter. Kudo's for an excellent job. This newletter has been very informative and knowledgeable and goes along way to reinforce the good work the pharmacovigilance department of PPB is doing. Really proud of you. Keep up the good work. All this gives hope for the pharmacy profession in Kenya.

Dr. Hassanali Mohamedali
Thunder Bay, Ontario

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The MSH/HCSM Program strives to build capacity within Kenya to effectively manage all aspects of health commodity management systems, pharmaceutical and laboratory services.

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