Special Edition

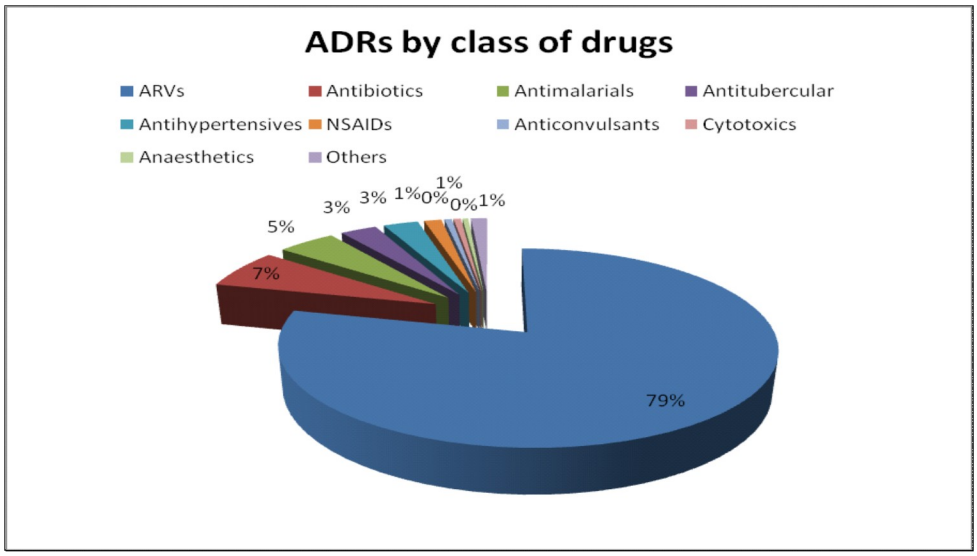
The Lifesaver

The Kenya National Medicines Information and Pharmacovigilance Centre Newsletter

Ensuring Quality, Safety and Efficacy of Medicines for Better Healthcare

First Fruits of Boosted ART ADR Sentinel Surveillance

An analysis of 1490 Suspected Adverse Drug Reaction (ADR) reports received at the National Pharmacovigilance Centre revealed that majority (79%) of suspected Adverse Drug Reactions are related to antiretroviral medicines. Approximately 46% of ART ADR reports that clearly indicate the name of the facility, are from boosted sentinel surveillance sites. This could be attributed to focused efforts to boost reporting at these sites. The approach has been effective and will be adapted in future following introduction of new medicines. The other classes of drugs that had notable suspected ADRs were Antibiotics (7%), Antimalarials (5%) and Anti TBs with 3% of all the reported suspected ADRs.



The most common suspected ADRs reported for the ARVs include;

- Lipodystrophy
- Lipoatrophy
- Nausea and vomiting
- Peripheral neuropathy
- Pruritis
- Rash
- Anemia
- Erythema multiforme
- Maculopapular rash

See Page 4 for feedback from a pharmacovigilante' at an ART ADR Sentinel Surveillance Site

Pharmacy and Poisons Board

1st Edition of the Kenya National Medicine Information and Pharmacovigilance Newsletter, September 2011

Special Points of Interest:

- ADRs related to ARVs account for bulk reports
- Quality of anti-malarials in Kenya well assured
- Pharmaceutical Company closed down due to its poor quality products
- PPB develops a registry for clinical trials
- World Health Day highlights

Inside this issue:

Editorial Team: Jayesh Pandit, Edward Abwao, George Muthuri, Mary Njeri, Christabel Khaemba, Janet Kimeu, Ndinda Kusu
Special Contributors: Danvers Omolo, Stephen Kimatu, Petronilla Nyaribakarani

Quality of Anti-malarials in Kenya Found Better Than in 5 Other Sampled Countries

Almost 30% of anti-malarial medicines (ACTs and sulfadoxine/pyrimethamine (SP) treatment) collected from Cameroon, Ethiopia, Ghana, Kenya, Nigeria and the United Republic of Tanzania failed to meet international quality standards according to the Quality of Anti-malarials in Sub-Saharan Africa (QAMSA) survey report. Samples from Kenya were however well assured. Extreme deviations, likely to be associated with direct, negative health effects, were found in 11.6% of the samples tested. The reasons for quality failure ranged from insufficient active pharmaceutical ingredient (API), an excess level of degradation substances and poor dissolution. Two samples were found to totally lack one of the API(s). Substantial differences were noted across 6 target countries.

Kenya	United Republic of Tanzania	Ethiopia	Cameroon	Ghana	Nigeria
0.045% samples failed confirmatory tests. 100% passed mini-lab tests.Samples were well Assured attributable to the effectiveness of recent effort made by these countries an partners, such as WHO, to improve their medicines regulatory processes		No samples failed quality testing. 41% represented unregistered product suggesting likely penetration of products with unknown properties	37% of samples failed test-ing	39% of samples failed test-ing	64% of samples failed testing

Failure rates were:

* higher for countries where many products from many different manufacturers are sold.
* higher for domestically-manufactured products than for imported products.
* noticeably low for imported products manufactured by well-established global manufacturers, and for WHO-prequalified products. *Less than 4% of samples of WHO-prequalified medicines collected failed testing; in each case the deviation observed was minor.*

Although each of the countries assessed has a legally designated national medicines regulatory authority, and many of them are committed to regulating medicines effectively, complex legislative frameworks and unclear delineation of regulatory responsibilities are impeding regulatory efforts. Lack of sustainable funding is another problem, as is a shortage of qualified staff and regulatory enforcement systems.

To view the full WHO QAMSA report, log on *http://www.who.int/medicines/about/en/index.html*

UNITED STATES PHARMACOPEIA (USP) AND PHARMACY POISONS BOARD (PPB) JOIN HANDS

In December 2009, the USP, through funding from USAID started working with PPB and Division of Malaria Control (DOMC) on a programme to monitor the quality of anti-malarial medicines in the Kenyan market. USP has supported the training of 29 officers on sampling and testing using Minilabs and donated 3 Minilab kits, lab reference standards, reagents, and supplies. In addition, USP has since supported two rounds of the programme where, in each round, samples were collected and tested at 5 sentinel sites using the Minilabs in Kenya.

Thereafter, through sampling of the passed, doubtful and failed samples, confirmatory testing was carried out at Kenya's WHO-Prequalified laboratory, National Quality Control Laboratory (NQCL), using a Minilab and later compendia testing. Round 1 has been completed and the report is currently being finalized. Round 2 started in May 2011 and confirmatory testing is ongoing. The programme is being coordinated by Dr. Patrick Lukulay and Dr. Latifa El Hadri of USP, Dr. Stephen Kimatu of PPB and Dr. Andrew Nyandigisi of DOMC in conjunction with the Division of Medicines Information and Pharmacovigilance, PPB. Due to this collaboration, several regulatory actions have been taken against companies manufacturing and selling unregistered anti-malarial medicines, including GMP inspection of facilities, withdrawal of unregistered products, expired products and closure of a pharmaceutical company.

Minilab trainees at NQCL. With them is Dr. Nyandigisi of DOMC

Pharmaceutical Company Closed Down Due to Poor Quality of Products

Gesto Pharmaceuticals Ltd was closed down in July 2011 following repeated complaints on poor quality of its products from the field and subsequent confirmatory quality assurance testing reports. PPB has since recalled two products manufactured and distributed by the company as detailed below. All healthcare providers are urged to be on the lookout for these products as they are a risk to patients. For more details of other poor quality products that have been withdrawn and recalled from the Kenyan market, please refer to the Pharmacovigilance Newsletter Volume 1 Issue 2.

Brand Name	Active Ingredient	Manufacturer	Batch No.	Reason for Recall
Benzyl Penicillin 1 MU	Benzyl penicillin 5ml 1 MU	Nestor Pharmaceuticals Ltd	All batches	Corrosion on caps
Gestamol Tablets	Paracetamol BP 500mg	Gesto Pharmaceuticals Ltd	All batches	Change of colour, growing mould

Updates Provided Through E-shots

The following E-shots have been sent out to all pharma-covigilantes since the last issue of this newsletter

* Latest version of the National Guidelines for Diagnosis, Prevention and Treatment of Malaria in Kenya
* Moulding of Gestamol Tablets by Gesto Pharmaceuticals Ltd
* Corroded vial caps for Benzyl Penicillin injections by Nestor Pharmaceuticals Ltd
* Clinical Guidelines for Management and Referral of Common Conditions: Level 1,Levels 2 and 3 and Levels 4-6
* Poor quality Flagimed suspension by Medivet Products Ltd
* Poor quality dextrose 5% intravenous infusion by Parenteral Drugs India Ltd
* Unregistered Fuzole suspension and granules by Cosmos Ltd

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

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

Unregistered Products in the Kenyan Market

	Brand Name	Manufacturer	Reason for Mopping from the Market and Destruction
1	Laefin Tablets	Laboratory & Allied Ltd	Unregistered
2	Arsun-AQ	Dawa ltd	Unregistered
3	Pharmasidar Tablets	Sishui Xierkang Pharmaceuticals	Unregistered
4	Co-fantrine forte	Comet Healthcare	Unregistered
5	Cach-Art Tablets	Cachet Pharmaceuticals Ltd	Unregistered

Kenya National ART ADR Sentinel Site Surveillance

What value did the training on ART ADR Sentinel Surveillance add to your work?

I have understood more about drug reactions to the extent that when taking care of my patients more emphasis is put on diagnosing, treating and prevention of adverse drug reactions. Before the training, I was aware that drugs had side effects but considering that a patient can be admitted because of a drug reaction was even the last thing to come to my mind.

It is now very necessary for me to know all the medication my patient is on, has been using in the past and before making my prescription I do an evaluation of the drugs to prescribe to ensure the patient benefits and also to avoid exposing the patient to an adverse drug reaction.
This is facilitated by making a clear diagnosis, clinical assessment, laboratory investigations and even making contacts with the other health facilities where the patient was seen before coming to the facility through phone or sending caretaker with a letter to get more information.

It is important noting that continuous capacity building of health care workers (nurses, pharmacists, clinicians) on pharmacovigilance and empowering the community including the patients through IEC materials is paramount to achieving medicines safety and improved patient care.

I also wish to request for a forum where those trained can share their experiences and challenges in their day to day practice, which will indeed help me together with others be aggressive pharmacovigilantes'.

Thanks,
Dr.Petronille Nyirabakarani,
St. Carmillus
Karungu

New Partnerships

Together We Can Save Lives!

The Pharmacy and Poisons Board is happy to have initiated collaboration with the World Custom Organization's Regional Intelligence Liaison Office for Eastern and Southern Africa (WCO-RILOESA) on issues pertaining to Pharmacovigilance. A very fruitful meeting was held on 14th July 2011 where key staff of WCO-RILOESA shared their mandates with staff from the Division of Medicines Information and Pharmacovigilance of the PPB. In turn, PPB updated RILO on its Pharmacovigilance activities and how it has been working to ensure patient safety. We anticipate a long and fruitful collaboration with WCO-RILOESA.

WCO– RILOESA Representatives (L-R: F.Lunani, J. Mwadime, K. Ochola, W. Kanyora) pose for a photo with PPB staff

ACA Awareness Division staff: Ms. Agnes Karingu and Ms. Katherine Namachi with PPB staff

The Pharmacy and Poisons Board was happy to host the Kenya Anti-Counterfeit Agency's (ACA) Awareness Division on 3rd August 2011. Though recently appointed, ACA has taken quick steps in the fight against counterfeit medicines and seeking opportunities to liaise with partners and stakeholders to create awareness on the activities being carried out. This visit was mainly to be able to understand how Pharmacovigilance is assisting the fight against counterfeit medicines, how reports come to PPB, how ACA receives formal complaints and how best to cooperate to create awareness to the public by joining activities. We look forward to working with ACA.

Kenya Hosts Two Unique PV Training Courses

"*What more can I do to get more ADR reports?*"
"*How can I get our doctors to report more ADRs?*
"*How can I enhance spontaneous reports?*"

These are some of the questions most ***pharmacovigilantes*** have pondered about. Then the stark reality hits … *"we are resource-limited countries so we cannot do more than this!"*
In resource limited settings, scaling up PV activities remains a challenge due to financial and technical staff constraints. In view of these challenges, a common school of thought is: "*Spontaneous Reporting of ADRs is our only way forward in spite of its limitations*".

It was keeping these comments and facts in mind that the World Health Organization (WHO) and *the* Uppsala Monitoring Centre (UMC) embarked on exploring methods that would complement spontaneous reporting mechanisms. A platform to explore for methods that would complement spontaneous reporting was provided through the WHO Monitoring Medicines' 7th framework project (MM FP 7) that is coordinated by the Uppsala Monitoring Centre (UMC), Uppsala, Sweden and funded by the European Commission.
47 "**pharmacovigilantes**" from about 13 Countries met at the Travellers Beach Hotel, Mombasa, Kenya, from 13th to 19th June 2011 to conceptualize "Targeted Spontaneous Reporting" (TSR) and discuss Cohort Event Monitoring (CEM).

Facilitator's included experts in patient safety from New Zealand, Denmark, Tanzania, Nigeria, UMC-A and WHO Collaborating Centre-Ghana, WHO-Geneva, UMC-Sweden and Kenya.
Six countries were chosen based on need for training. These were Ethiopia, Burkina Faso and Kenya for CEM of Antimalarials and Botswana, Uganda and Zimbabwe for TSR of Antiretrovirals.

Participants at the Targeted Spontaneous Reporting and Cohort Event Monitoring Training held in Mombasa

The trainings were intense and the participants remained enthusiastic the entire week. At the end of the six-day training, participants became familiar with CEM and TSR methodologies and their implementation.

Participants have been provided the opportunity of developing and submitting a country plan to WHO in order to access European Commission's funding set aside for the implementation of CEM and TSR (for anti-malarial and anti-retroviral respectively).

Two successful country plans, one for each method, will be funded for one year. The selected countries will pilot the adaptation and implementation for meeting disease-specific pharmacovigilance objectives using one of the methods. They will collect reports of adverse events or suspected reactions in patients treated with medicines for malaria or HIV/AIDS, using CEM and TSR methods.

The Pharmacy and Poisons Board is proud to be a project partner in the MM FP-7 project and happy to have hosted this training to enhance patient safety in Africa.

Regional Highlights

Rift Valley Province

35 healthcare providers working in ART sites supported by Walter Reed Project were beneficiaries of the National Pharmacovigilance training. Regional focal champions trained the participants on the principles of pharmacovigilance.

Eastern Province

17 district representatives were sensitized on the National Pharmacovigilance guidelines and tools through support provided by NASCOP, CDC and HCSM. Following the sensitization, they were provided with copies of the same for use at their facilities.

Should Medication Errors be Reported?

Jane walked into a chemist to buy some medicine for her cousin who had been complaining of tingling sensations on her feet. One week later, Jane had to take her cousin back to the hospital for review. The problem had worsened. When the pharmacist at the hospital inquired whether the medicine had been bought, Jane's cousin insisted it had and she had taken the medicine faithfully. When the pharmacist asked to see the tablets, she was surprised to see 'pregnidoxine tablets' inscribed on the medicine envelope. The clinician had prescribed pyridoxine tablets.
This is just one among the many medication errors that occur on a daily basis.

Koki Tula 20/08/2011
23yrs IP NO: 345678

Tabs P.doxine 1 tds x 1/52

Dr. Saidia
saidia

What was the intended medicine Pyridoxine or Pregnidoxine????

There are several instances where the safety of patients is compromised by medical procedure and/ or **medication errors**. Since these errors are rarely documented or deliberately not reported it becomes difficult to establish the magnitude of the problem and to develop institutional and national guidelines on prevention and management of medical and medication errors.

Medication errors occur for several reasons. It could be that the wrong medicine is dispensed, wrong dose is prescribed or the route through which the medicine is administered is wrong.
Dispensers are known to make mistakes especially when handling medicines with similar sounding names (sound alike) and look-alike packs.

According to Robin (2006), a medication error is a failure in the treatment process that leads to, or has the potential to lead to harm to the patient.

The safe use of medications is an important component of any healthcare delivery system and many patients' safety initiatives. It is reflected in the credo 'first do no harm' shared by all medical and allied health professionals. Whereas detection and minimization of medication errors is discussed in most forums, reporting of errors when they occur is rare due to various factors.

The Pharmacy and Poisons Board, through its Division of Medicines Information and Pharmacovigilance has initiated the establishment of a Medication Error Reporting and Monitoring System in Kenya.

We request you to share with us your experiences in having prescribed / dispensed / administered a medicine and noted a Medical or medication error and briefly explain what happened. Also consumers can write back to us giving their experience for medicines that they took which was given as an error. All information received will be handled in confidence.

Remember, no names of persons… ***we want to build systems to understand and address medication errors and not be punitive!***.

Ciloxoral: Sodium Picosulphate oral drops
Ciloxan: An ophthalmic antibacterial solution containing ciprofloxacin

Examples of look–alike or sound alike packs

Arimidex: Anastrozole (oestrogen antagonist) containing tablets
Ardinex: An opioid analgesic

Clinical Trials Registry Developed at PPB

The Clinical Trials Registry (CTR) recently developed at the Pharmacy and Poisons Board is a novel concept designed to capture all data pertaining to all clinical trials being undertaken in the country for ease of management and follow up. Thus, it is a first of its kind, a central data repository in East and Central Africa on Clinical Trials undertaken and approved by the Medicines Regulatory Authority, PPB in Kenya.

Clinical trials include any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s) and/or to identify any adverse reactions to an Investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the objective of ascertaining its safety and/or efficacy. The term clinical trial is synonymous to the term clinical study.

The Clinical Trials Section is coordinated by the Division of Medicines Information and Pharmacovigilance at the PPB. The Board has developed an Expert Committee on Clinical Trials (ECCT) that guides the Registrar on matters pertaining to Clinical Trials in Kenya.

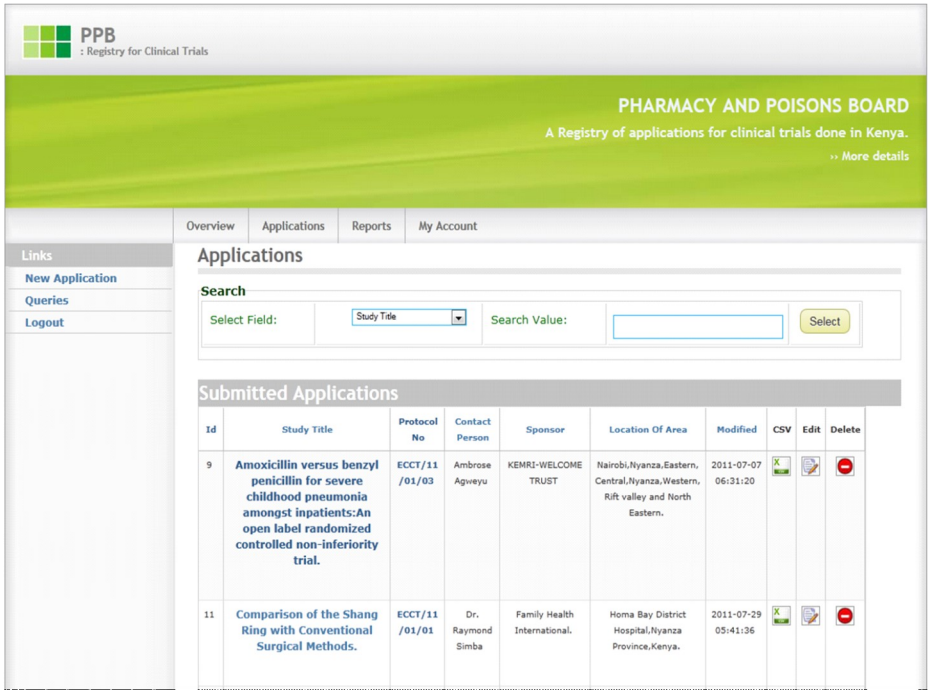
Some of the analyses that can be obtained from the CTR include summary statistics on:

* design and specific phase of trials on-going in Kenya
* average/ median duration for these trials
* disease areas in which these trials are targeted
* drugs under investigation
* list of accredited Ethics Review Committees (ERCs)/ Institutional Review Boards (IRBs)
* what population (e.g. age, gender, area) are being investigated
* trials completed
* summary of findings of each trial amongst much more.

This registry will permit analyses and monitoring of clinical trials being undertaken in the country while also promoting transparency in its review and approval processes. The ethical conduct of clinical trials will be shared and will also provide for showing key protocol-relevant information about each trial in the public domain. Apart from the aforesaid, this registry is expected to help sponsors and applicants to submit their protocols online and be able to track the review process online too. The above analyses will among other things provide an operational picture of the application, review and approval process and will provide useful information for operational efficiency, and work load burden indication in a highly transparent manner.

The CTR will also act as a knowledge sharing platform for researchers and the general public who need information on clinical trials being carried out in the county.

Once all data from protocols registered and approved by PPB is completed, it is proposed that the CTR will be expanded to include protocols reviewed by all ERCs in Kenya and foster better Communication and monitoring between the ERCs and PPB.



Left: One of the Clinical Trials Registry Screens showing sub-mitted applications

World Health Day… What is this? Why is it celebrated?

The World Health Day is a global event celebrated each year on 7th April to mark the founding of the World Health Organization (WHO). Each year, the WHO selects a key health issue of global health importance and this then becomes the theme for that year. This encourages all people, relevant institutions and Governments to hold events that highlight the significance of the theme and provides a platform for longer-term advocacy programmes that continue well beyond 7th April. The World Health Day has been celebrated since 1950. The last 5 themes for the World Health Day, including this year's, have been:

* 2011: Antimicrobial resistance: no action today, no cure tomorrow.
* 2010: Urbanization and Health: make cities healthier
* 2009: Save lives, make hospitals safe in emergencies
* 2008: protecting health from adverse effects of climate change
* 2007: International Health Security

This year's theme as stated above, "**Antimicrobial resistance: no action today, no cure tomorrow**" was launched on 7th April 2011. True enough, there is a lot more we need to do in Kenya together to ensure that we safe guard the health of all today and tomorrow against infections. "Antibiotics" strictly speaking, are substances that are produced by a micro-organism that kills, or prevents the growth, of another microbe. "Antimicrobials" are antibiotics that have been developed from natural living organisms and from synthetically formed compounds.

As part of the WHO and other global initiatives, professionals from various sectors with an interest in the preservation of effectiveness of antimicrobials in Kenya have in the last 3 years worked under the Global Antibiotic Resistance Partnership (GARP)- Kenya chapter. Various policies relevant to the major objective of the initiative have been discussed and these have been presented in a common Policy Document for relevant Government and non-governmental organizations, individuals and relevant stakeholders to consider for implementation.

I would urge that proposals from the GARP- Kenya chapter that have been developed need to be adopted and urgent action should be taken to prevent a disaster in the use of antibiotics in Kenya.

In the past where, our forefathers used to succumb to death after contracting some infections such as tuberculosis, or after surgeries such as open heart or open abdominal surgeries. Very few antimicrobials were available then. Today, we have progressed with science to develop better and safer procedures for carrying out heart, kidney and knee surgeries. We also have many more antimicrobials to choose from to ensure that the cuts and wounds heal well after the surgery.

Common problems with the use of antimicrobials that can cause Anti-Microbial Resistance(AMR):

* Inappropriate choice of antibiotics
* Wrong condition for treatment with the right antibiotic
* Overuse of antibiotics
* Self prescribing
* Use of antibiotics as growth promoters in animals
* Wrong dose (not based on weight)
* Excessive use as prophylaxis, e.g. with travelers
* Poor adherence (3 days vs 5/7 days complete course)
* Wrong route of use
* Failure to take enough rest by the patient when unwell.

If we do not use these anti-microbials rationally today, we may face a day when we have the most developed surgical procedures but simple infections after these procedures will claim our life! *Why?* The micro-organisms will be resistant to these antimicrobials.

Dr. Jayesh Pandit was nominated by Afya House to speak at "Good Morning Kenya", a live, call-in, television talk show on Kenya Broadcasting Corporation (KBC) on World Health Day 2011.

Picturespeak.....

The Pharmacy and Poisons Board was happy to welcome Hon. Samwel Kazungu Kambi, Assistant Minister, Ministry of Medical Services on 22nd July 2011. Hon. Kazungu Kambi was visiting the Pharmacy and Poisons Board to deliver key messages and understand the challenges that the PPB is facing in carrying out its daily activities.
Also present at the Board was the Representative of the Permanent Secretary, The Director of Medical Services, Dr. Francis Kimani and members of the Board of Directors, PPB. ***Bwana Minister, thank you for all your support...Karibu tena!***

Hon. Samwel Kazungu addresses members and staff of the Pharmacy and Poisons Board during the visit

Members and staff of the Pharmacy and Poisons Board pose for a picture with Hon, Samuel Kazungu

Hon. Anyang Nyongo receives copies of the National Pharmacovigilance Newsletters from Dr. Mary Wangai during the official launch of the Health commodities and Services Program.

Looking on is Dr. Kimani, DMS MOMS and Maria Franscisco, Health Systems Technical Lead at USAID

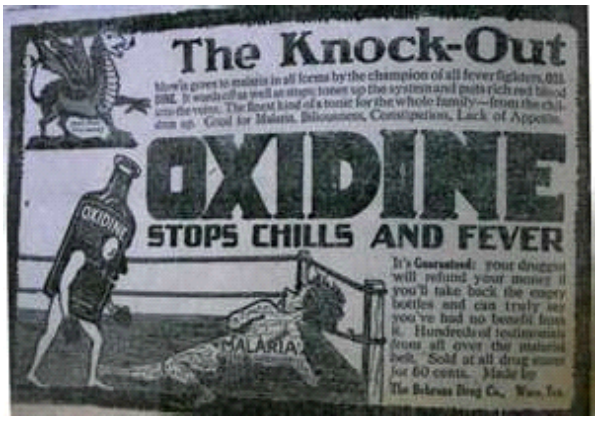
Growth in the National Pharmacovigilance Team

In August, the Ministry of Medical Services brought good news to the National Pharmacovigilance Centre by the addition of two new members to its team. These are Ms. Mary Njeri and Dr. Christabel Khaemba.

Ms. Mary Njeri, a Senior Pharmaceutical Technologist, gives a needed boost to this young and vibrant centre. She brings with her vast experience having previously worked at the Office of the Provincial Director of Health- Eastern Province and at NASCOP ART Care and Treatment Department. Mary has been a focal trainer in Pharmacovigilance and has also been involved in a post-market survey of ARVs that was carried in September 2009. Welcome Mary!

Dr. Christabel N.Khaemba, Assistant Chief Pharmacist, brings her vast experience having previously worked as a District Pharmaceutical Facilitator in Nyamira and Nyando Districts, as the Medical Superintendent at Ahero Sub District Hospital and as the Provincial Pharmacist - Nyanza Province. Christabel has been a focal trainer in ART and Malaria programmes and a strong crusader of Pharmacovigilance. Welcome Christabel!

Advertisements… Are there guidelines for medicine related advertisements?



Advertisements and promotions of medicines and medical devices is a means of giving information to both clients and medical professionals with a view to making them use, purchase or prescribe the products. The promotion may also be used to give the audience new information about an existing product or to introduce a totally new product. The target audience is given information to make them prefer or consider a certain product over others.

The Division of Medicines Information and Pharmacovigilance (DMIP) appreciates the importance of advertisements and promotions to both the health professionals and the public at large. DMIP also acknowledges that the advertisements need to be current, factual and unbiased. To this end, DMIP is coming up with guidelines to assist all those who want to carry out promotions of medicines and medical devises.

The guideline seeks to streamline the way advertisements and promotions of medicines and medical devices are carried out in the country and ensuring that only factual information is provided to the targeted clients and the general public who do not know much about medicines. The guideline seeks to protect the general public from being exploited by unethical marketers who only care about their sales and turnover.

In order to have ownership of the guideline, the Pharmacy and Poisons Board has engaged stakeholders in order to get their view on the proposals. Currently, the initial comments received from the stakeholders are being incorporated into the proposed guidelines before the second and final call for review of the proposed document by stakeholders. Following the review the proposed guidelines will become effective.

This guideline will be a living document that will be reviewed from time to time to keep it abreast with the changes taking place both locally and internationally on issues of medicine advertisements and promotions.

Going forward, PPB wants proper and structured regulation of all advertisements and promotions of medicines and medical devises in the country. The division is coming up with a document that will be able to assist all those who want to promote their products to know all the requirements for approval, the process involved and expected timelines of approval following submission of complete application.

In case of any comments or suggestions that you consider should be included in the guidelines, please feel free to contact us.

Remember: advertisements and promotions of medicines, if not done correctly, can cost lives!

Pharmacovigilance Job Aid 1: Cut Out this Job Aid and Display it at Your Facility

Republic of Kenya

MINISTRY OF PUBLIC HEALTH AND SANITATION & MINISTRY OF MEDICAL SERVICES

PHARMACY AND POISONS BOARD

When Should I Suspect an Adverse Drug Reaction?

An Adverse Drug Reaction is an unpleasant unintended reaction to medicines that occurs at the normal recommended doses.

Suspect an Adverse Drug Reaction if:

- **One develops symptoms soon after beginning medications**
- **One develops a new problem while on medications**
- **A Child is born with birth defects**

YOU NEED NOT BE CERTAIN...JUST BE SUSPICIOUS

USAID FROM THE AMERICAN PEOPLE

msh SPS Strengthening Pharmaceutical Systems

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Upcoming Events

- Stakeholders forum for dissemination of ARV and Anti– TB medicines Post Market Survey Results
- Training of University of Nairobi B. Pharmacy Final Year Students on Pharmacovigilance
- Visit us at various Exhibitions and Trade Fairs

For more information, please contact:

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Providing Medicine Information to Kenya!

Provision of up-to-date, unbiased and factual medicines information remains a need in Kenya today. Healthcare providers routinely receive individual product updates mainly from pharmaceutical companies and at Continuous Medical Education (CME) programs which again, more often, are sponsored by pharmaceutical companies.

Healthcare providers have expressed a need to have an independent source of medicine information provision to support their daily practice.

The Pharmacy and Poisons Board (PPB) has taken up this challenge and embarked to set up, initially, 5 centres- a medicine information centre at its Headquarters and to further establish four (4) Regional Medicines Information Centres across the country in 2011-2012. These are high-volume facilities in order to support the healthcare fraternity and the public expeditiously.

In support of the same, we appreciate the contribution of updated reference materials received, under no prejudice, from Famy Care Ltd and Indoco Remedies Ltd towards the same. A complete list of required reference materials is available at the Division of Medicines Information and Pharmacovigilance for any other person willing to support this activity.

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.

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About HCSM
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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msh Management Sciences for Health