Using Regulation to Strengthen Drug Access and Quality- *Regulator's view from the Pharmacovigilance lens*

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Pharmacy and Poisons Board

Ministry of Medical Services

KENYA

Tuesday 4th October 2011

1st Global Forum on Bacterial Infections, New Delhi, INDIA

Role of Pharmacy and Poisons Board

The PPB is the Drug Regulatory Authority of the Ministry of Health, Kenya.

It was established in 1957 under the Pharmacy and Poisons Act- Cap 244 of the Laws of Kenya, with the mandate:

“to make better provision for the practice and profession of pharmacy and the trade in pharmaceutical products.”

Looking back yesteryears

- Drug Regulatory Authority established in 1957, 1st of May
- Concentration on medicine procurement and distribution: *access*
- Monitoring of safety, efficacy and quality of these medicines wanting- *no formal mechanism*
- Formal launch of the National Pharmacovigilance System on 9th June 2009

Pharmacovigilance

- Pharmacovigilance is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medicines, biological products, herbals and traditional medicines, with the view to:
  - **Identifying new information about hazards, and**
  - **Preventing harm to patients.**

From:

- Greek *pharmakon*- drug
- Latin *vigilare*- to keep awake or alert, to keep watch

- **Safety……Efficacy……Quality**

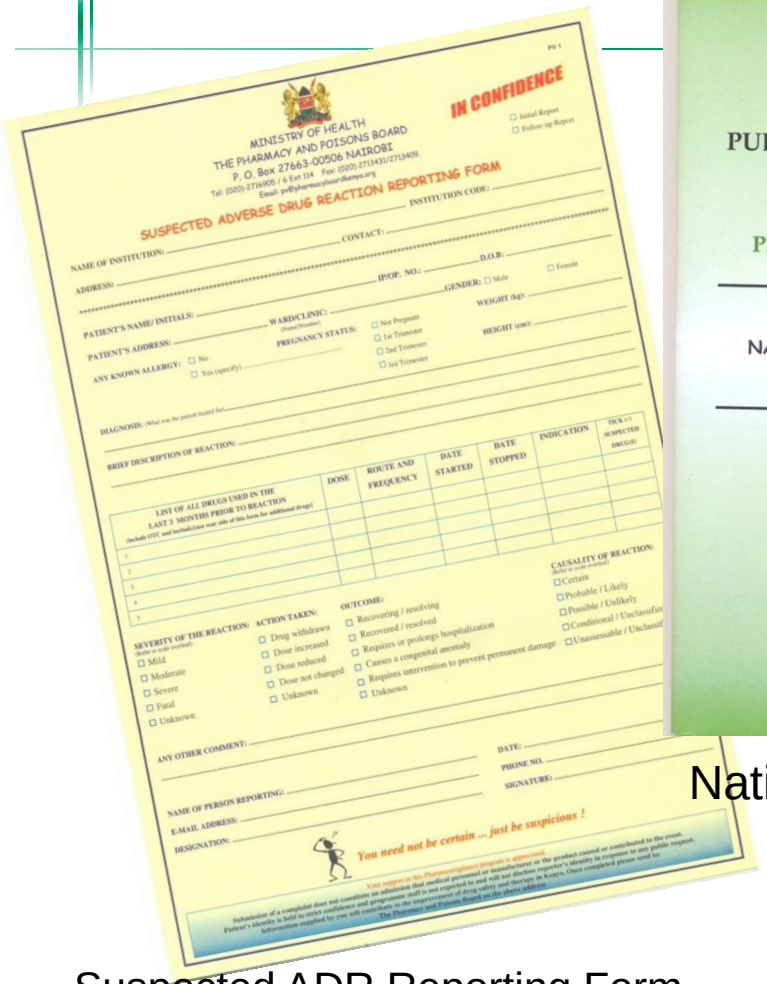
Widening scope of Pharmacovigilance

These include:

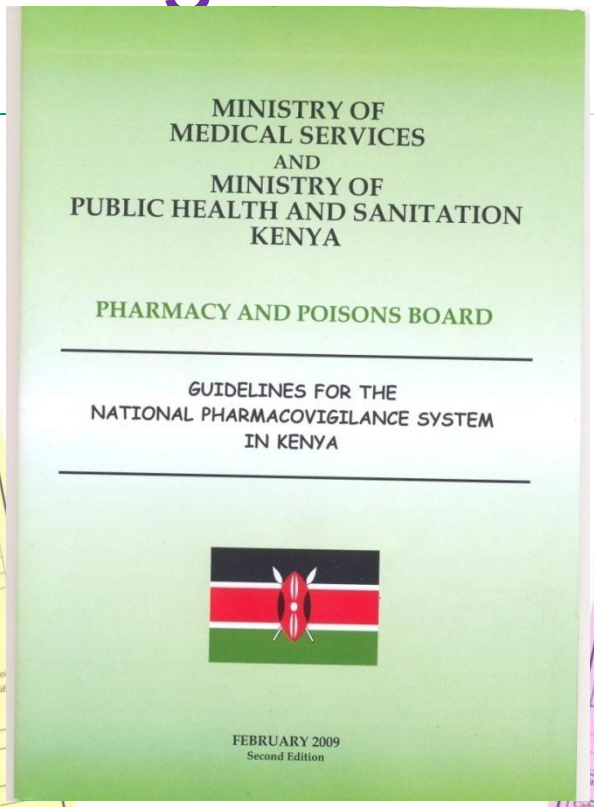
- Substandard and counterfeit medicines
- Product development
- Medication error reporting
- Adverse interactions of medicines with chemicals, other medicines, and food reports

- Assessment of drug-related mortality
- Abuse and misuse of medicines reports
- Efficacy monitoring
- Off-label use of medicines
- Case reports of acute and chronic poisoning

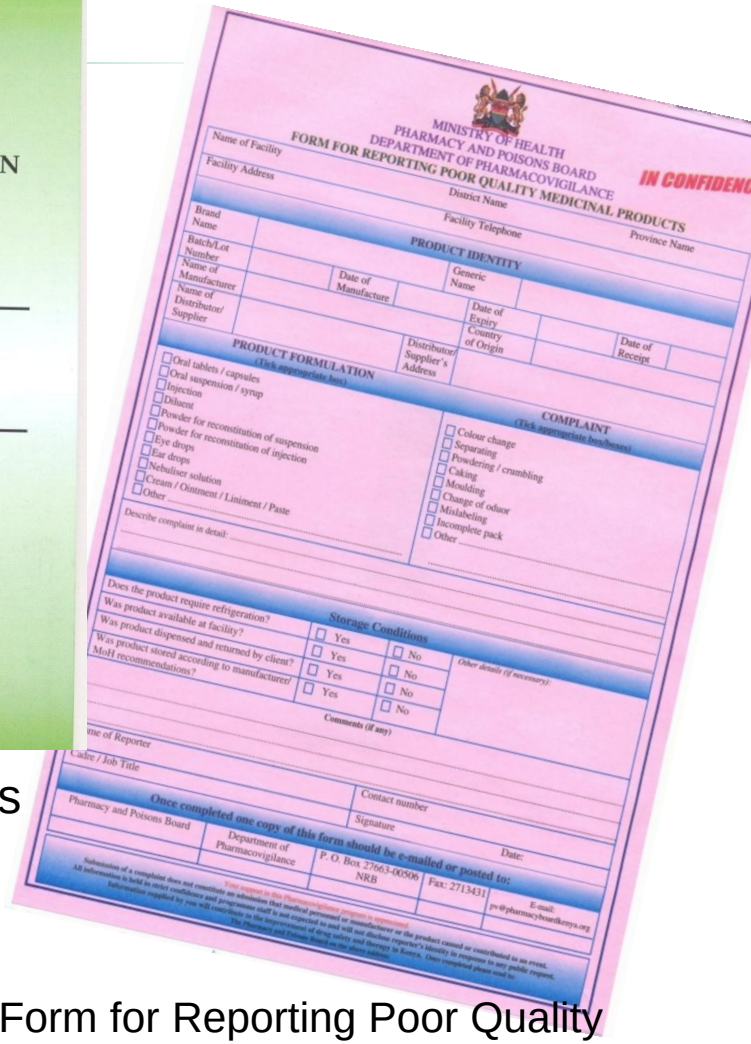
Pharmacovigilance tools



Suspected ADR Reporting Form

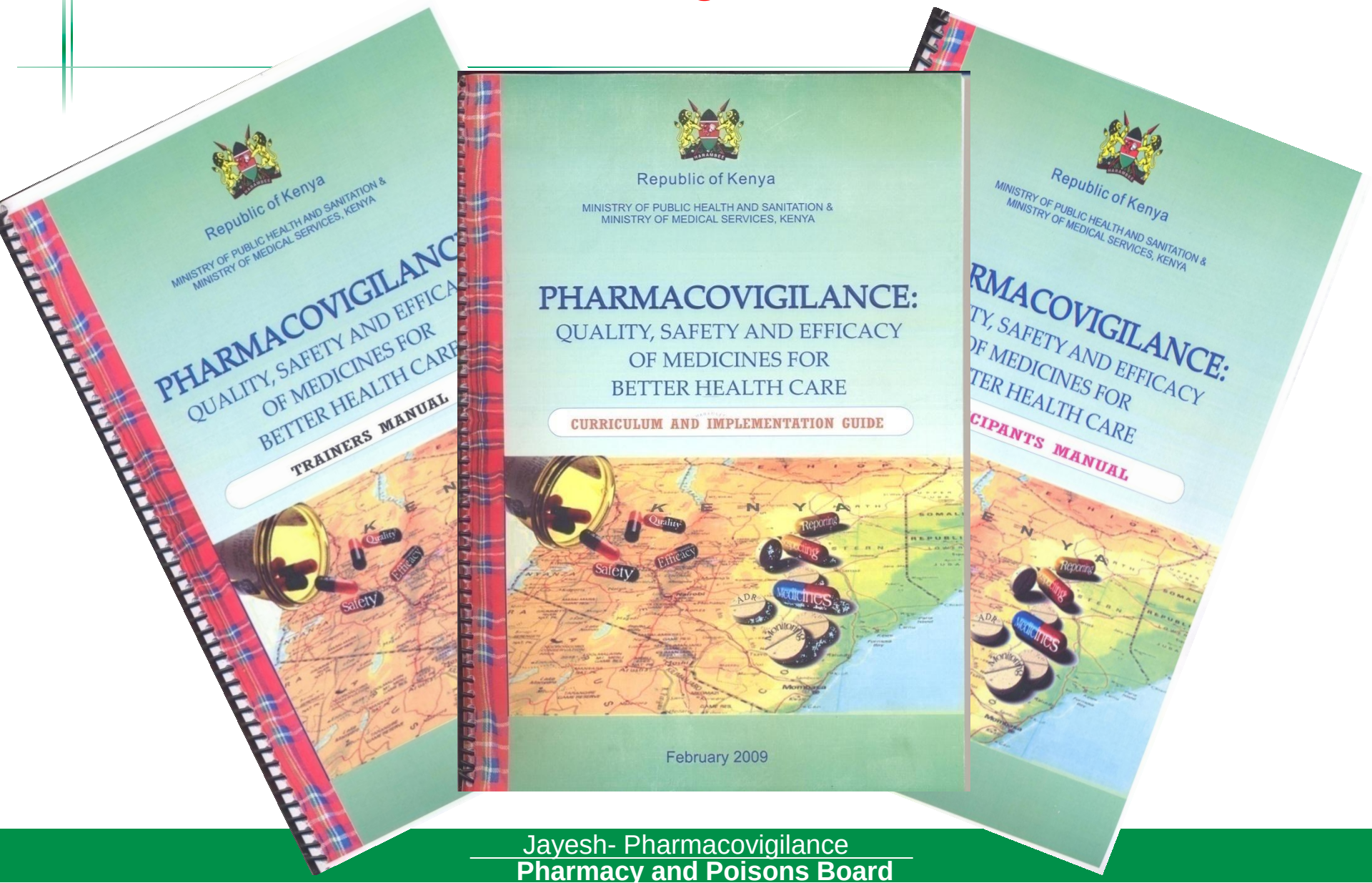


National PV Guidelines



Form for Reporting Poor Quality Medicines

PV Training Manuals



We have…

- Training materials
  - Curriculum and Implementation Guide
  - Participant's Manual
  - Trainer's Manual

- Job Aids and Information, Education & Communication (IEC) Materials

- Expert Safety Review Panel

- VigiFlow as our National Database and International Reporting Tool

Specific Activities

- We train HCWs on pharmacovigilance via:
  - 5-day PV training course
  - 3-day focused course
  - 1-day sensitization
  - 1-day, 1/2-day, 1-hour CME/CPD and
  - Presentations at professional conferences
- Create public awareness on PV / Patient safety
- Receive and review reports on ADRs, PQMP and lack of efficacy / suspected counterfeits
- Take regulatory actions: *recall products, revoke regn, revoke application for registration*
- Provide feedback to reporters

Specific Activities (2)

- Introduction of mini-lab screening for antimalarials
  - Scale up to other medicines planned
- Development of a Post Market Surveillance Strategy (PMS) for Kenya
- Collaboration with WHO and other partners
- Collaboration with INTERPOL on anti- counterfeiting

Returns from our activities (1)

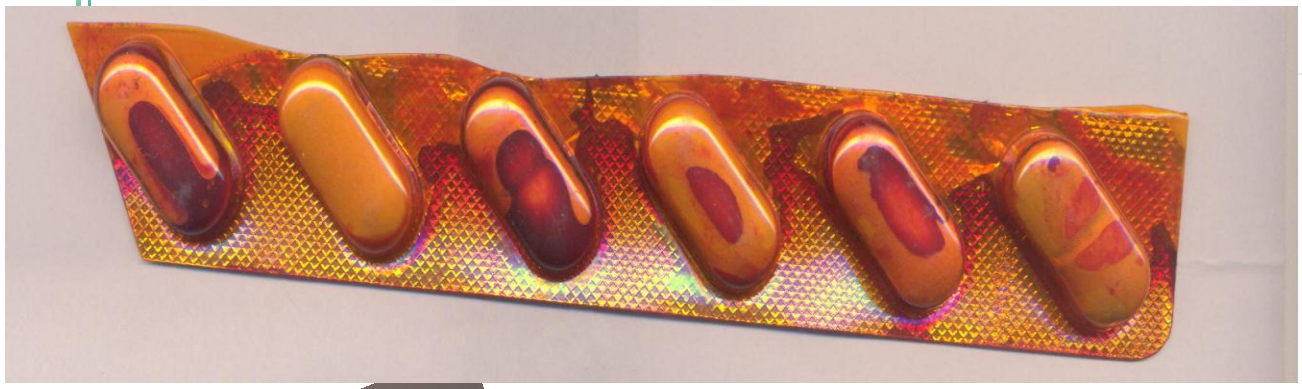
- **Suspected ADR reports received: 2484**
- **193 poor quality medicinal products complaint forms received**
- **Post Market Surveillance activities:**
  - **Anti-malarials, anti-TB, ARVs, herbals…**
  - Anti-TB: 10/120 failed: assay… all over 110% upper mark!
  - ARV: 1/274 failed - uniformity of weight
  - Antimalarials: under analysis
    - Magnitude of problem: AM > Anti-TB > ARV
  - Herbals: 11/11 failed: growing mould!

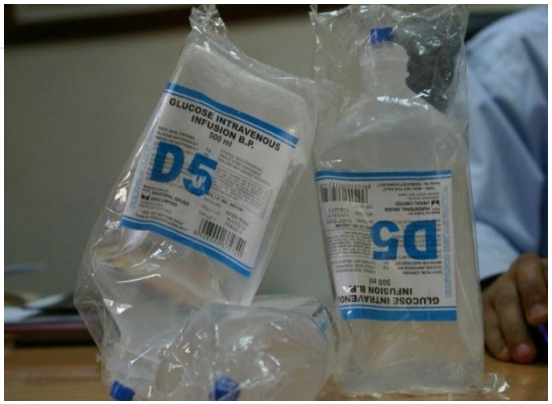
Returns from our activities

Poor quality medicinal products complaints received:

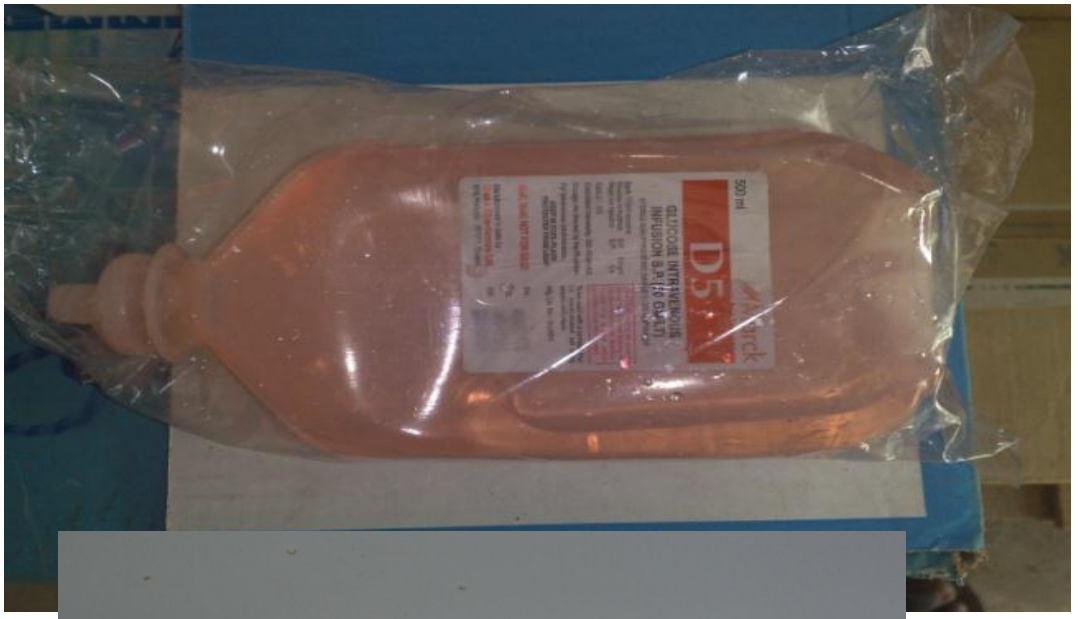
- "Caking
- Not-flowing
- Moulding
- Laminating
- Floating particles
- Crystalization
- Corrosion of Al covers
- Change of colour
- Poor coating
- Chipping
- Poor packaging
- Expired medicines
- Lack of efficacy
- Suspected counterfeits
- Un-registered products..."

Some poor quality Medicines found in Kenya





Some poor quality Medicines found in Kenya (2)



Returns from our activities (2)

- Kenya now (proud) 98th Full Member of the International Drug Monitoring Program: 4th May 2010
- Demands for PV cascade trainings!
- Review of pre-service training curricula and eyes on training PV in University
- Enhanced working relationship with Public Health Programs making patient safety a core agenda in their work and work of Medicines and Therapeutic Committees (MTCs) within hospitals across Kenya

Area of Antibiotics?

- Very little work done
- Very few reports of poor quality ABs received

- Need to have a formal action for ensuring antibiotic stewardship…

Upcoming Activity: *Antibiotic Q, S and E*

- Urgent need to carry out a baseline PMS on ABs in Kenya
- Look at:
  - *Range and Availability of ABs in Kenya*
  - *Verify Registration Status*
  - *Analysis of Quality of these medicines*
  - *Regulatory action*

Antibiotic Q, S and E … (2)

- GARP- Kenya report is our benchmark tool
- Partnerships being explored for the PMS
- Choice of class of ABs to be surveyed / analysed to be decided, vet and human ABs?
- "Start small and then grow bigger?" *(Or other way round?)*
- Take necessary regulatory action
- *Future: Policy, Legislation and Regulation ensuring AB stewardship*
- *Sustainability*

Financial Sustainability

PPB generated income through fees charged

- Product registration
- Premises licences- Retail and Wholesale
- Manufacturers licences
- Medical representatives licences
- Annual practice licences for pharmaceutical technologists and pharmacists
- GMP Inspection fees
- Professional registration examination fees.
- Pharmacy training institution accreditation fees
- Advertisement fees
- Clinical trials' fees

Support from partners

- WHO
- USP/ USAID
- MSH-SPS
- HAI-Africa

In Summary

We still focus on ***Access*** to Medicines…

but we now have ***Responsible Access*** to these Medicines

Vibrant Media

Pharmacist tells how to identify fake drugs shop

BY NATION REPORTER

"Medicines should only be bought from pharmacists licensed by the board" — Dr Jayesh Pandit, head of the pharmacovigilance department

Antiretroviral Medicines

September 2009 AFYA DIGEST — You & AIDS

By Drs. Dorine Kagai and Shobha Vakil

Cough and Cold Syrups for Children safe, Pharmacy and Poisons Board Assures

Ignorance and misinformation fuelled alarm and anxiety

AFYA DIGEST

Your child: Parents guide to childhood immunization

Health and Beauty: Treating skin pigmentation

Continued on page 16

THURSDAY, MARCH 4, 2010 / THE STANDARD

NATIONAL / Page 25

Questions arise over flu vaccine

By ELIZABETH MWAI

Pharmacists have raised an alarm that the Swine Flu vaccine destined for Kenya next month is yet to be clinically tested in Africa.

According to a document obtained by *The Standard*, the Pharmacy and Poisons Board (PPB) Committee has cautioned that the Swine Flu vaccine has not undergone any clinical trials in Africa.

The Standard also learnt that the H1N1 vaccine will have expired by the time it is distributed as it has a six-month shelf life with half already gone. The Ministry of Public Health has been pushing for the speedy registration of the H1N1 vaccine scientifically known as Fluvirin to safeguard against the Swine Flu pandemic.

"Suppose the Fluvirin vaccine is allowed in Kenya under the current situation (waiver) without enough data, who will shoulder the responsibility in case of a tragedy since its not registered in Kenya and the Novartis Company has not requested for registration?" posed the PPB committee.

DAILY NATION Friday September 3, 2010

PUBLIC HEALTH | Jayesh Pandit

Why patients are advised to check the safety of the medicine they take

The author follows proceedings during the medical conference

REPUBLIC OF KENYA
MINISTRY OF MEDICAL SERVICES
PHARMACY AND POISONS BOARD

PUBLIC ALERT ON "HERBAL CONTRACEPTIVES"

The Pharmacy and Poisons Board's attention is drawn to cases where unscrupulous people purporting to sell herbal medicinal products are indeed dispensing unauthorized and unregistered conventional medicines through "herbal/Chinese clinics". This is contravention of the Law, Cap 244, Laws of Kenya.

WARNING

DAILY NATION

HEALTH

Aids drug to be withdrawn

Though cheaper than others, Stavudine causes HIV patients to lose their body fat

Case for sector to be regulated

Drugs cause more diseases than cures

Herbal products from China have also been found to be adulterated

Our PV Newsletters

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

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 WI Programme on International Drug Monitoring on pg 3.....

Senior officials from the Ministries of Medical Services and Sanitation during the National launch of Pharmacovigil in June 2009.

PPB Partners with MSH to Build the Capacity of Ove 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, pharmacy nurses and lab were targeted.

The response health provid "the Pharma vided were routine one especially i with a cha ence to th Kenya."

Pharmacy and Poisons Board

KENYA PHARMACOVIGILANCE NEWSLETTER

Ensuring Quality, Safety and Efficacy of Medicines for Better Healthcare

..... MORE GAINS IN PHARMACOVIGILAN

Kenya Hosts First Global Conference on Pharmacovigilance

The first ever global conference in Kenya on Pharmacovigilance took place in August 2010. Over 100 delegates drawn from 30 countries participated in the conference which aimed at focusing attention to patient safety in the wake of increased access to treatment for AIDS, Malaria and Tuberculosis through various global initiatives. In addition, the conference provided participants with a framework for building, strengthening and optimizing pharmacovigilance systems at country level.

The conference was graced by top Kenya Government officials among them Minister for Public Service- Hon. Dalmas Otieno, Assistant Minister, Ministry of Medical Services—Hon. Samwel Kazungu, PS MoPHS —Mr. Mark Bor, DMS MOPHS- Dr. Shariff and Chief Pharmacist- Dr. Kipkerich Koskei.

Mr. Bor officially opened the conference and in his speech emphasized the significance of post market surveillance of medicines to chronicle long term effects unlikely to be observed during clinical trials.

He also noted that pharmacovigilance systems are beneficial for preventing drug-related morbidity and mortality, making savings on resources spent in healthcare costs and supporting better patient care.

"Many countries, he said, continue to be constrained in their medicine safety owing to weak legal frameworks, lack of regulatory structures and inadequate resources.

Permanent Secretary in the Ministry of Public Health and Sanitation Mr. Mark Bor officially opens the conference as Dr. Fred Siyoi, Pharmacy and Poisons Board and Dr. Mary Wangai, Chief of Party MSH/SPS Kenya look on.

On counterfeits, Mr. Bor expressed concern about the complexity of dealing with such products owing to the difficulty of identifyin them. He noted that the enforcement of laws against counterfeits is the shared responsibility of government, regulatory authorities, importing and exporting agencies and even the media.

During the conference the first Kenya Pharmacovigilance Newsletter and Pharmacovigilance Fact Sheet were laun officially.

.....Read More on Page 4

Patient Safety Enhanced as a Result of Pharmacovigil Reporting

Have you ever wondered whether your suspected ADR report or poor quality report any difference? While it may seem like a drop in the ocean, it definitely makes a di

The Pharmacy and Poisons Board (PPB) has taken regulatory actions to enhance pa based on the receipt of over 1400 suspected ADR reports, poor quality reports fro and results of Post Market Surveillance Surveys conducted since June 2009.

....Continued on page 2

Special Edition

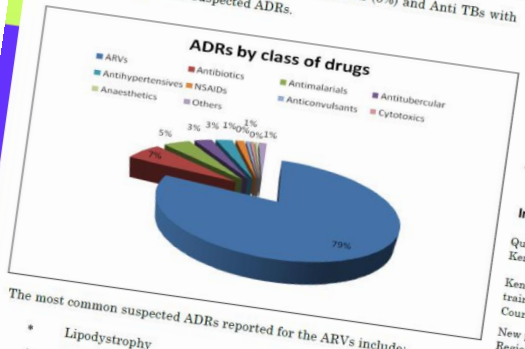
The Lifesaver

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

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

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:

Vision:

To be a global leader in the control and regulation of drugs, food supplements, cosmetics, alternative medicines, devices, poisons and medical practice of pharmacy.

Mission:

To improve the quality of life of Kenyans through provision of quality, safe and efficacious pharmaceutical products and services.

www.pharmacyboardkenya.org

THANK YOU

Asante sana…

PV mantra in Kenya

"You need not be certain…

Just be suspicious"

Report all suspected ADRs and Poor Quality Medicines to PPB

Contact us?

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