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MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

MAGAZINE

In this issue...

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MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

Ensuring quality, safety and efficacy of medical products and health technologies

PUBLIC NOTICE

TO ALL AUTHORIZED DEALERS IN MEDICINES

Sale of Prescription Only Medicines

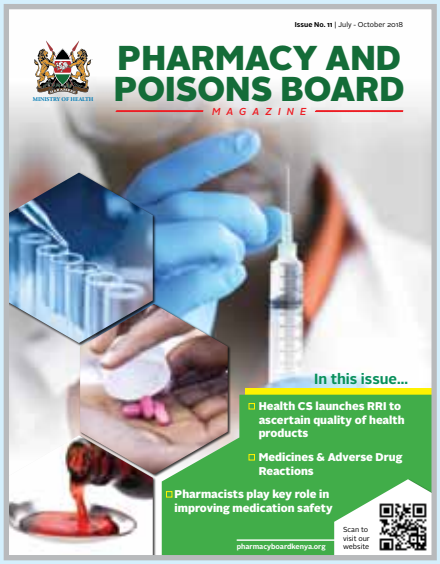
The Pharmacy and Poisons Board (PPB) is the National Medicines Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244, Laws of Kenya. The PPB is mandated to regulate the practice of pharmacy and the trade in medical products and health technologies.

In an effort to continually protect the health of the public and improve patient safety, ALL authorised dealers in medicines (wholesalers and retailers) are reminded to STRICTLY adhere to the Law governing sale of Prescription Only Medicines(POMs), more specifically:

1. Dispense **POMs ONLY** to persons in possession of a valid prescription in line with Section 29 of the Pharmacy and Poisons Act CAP 244;
2. Maintain the applicable records in line with section 30 and 31(2) of the Pharmacy and Poisons Act and provide, on demand, returns on the utilization of the above stated category of products;

Be advised that failure to comply with the Law will attract strict legal and administrative action.

Pharmacy and Poisons Board @ppbkenya info@pharmacyboardkenya.org



Editorial Board

About The Newsletter

The PPB Newsletter is a publication of the Public Relations Department. It is designed to act as a tool of communication, documenting and disseminating important news and information to the staff and stakeholders of the Board.

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Editor's Note

I am delighted to introduce the Pharmacy and Poisons Board Magazine, that provides a really exciting opportunity to publish up-to-date information alongside relevant and insightful news.

This month saw the publication of two major issues, the launch of Rapid Results Initiative on Post Market Surveillance of Health products and technologies in the Kenyan market and the Launch of the Implementation Plan for the Ethics and Anti-Corruption Commission (EACC) Report on the review of systems, policies and practices in the pricing of pharmaceutical and non-pharmaceutical supplies in the Kenya public health sector, each with potentially significant implications for the sector.

Current highlights include World Pharmacist Day 2018, establishment of PPB data Centre for online services, Pharmacy Practice and Training success story; Medicines Information and Pharmacovigilance success story, Drug Registration, Quality Control and Good Distribution Practices achievements among others.

Each of these stories speaks to our faith in the future, and we are excited to share them with you. Conventional wisdom says market competition doesn't work when it comes to medicine. Maybe we in PPB can prove otherwise by making available the information the market needs to make efficient decisions.

In this package of our latest reporting, we hope that you find a measure of quality information and useful practices.

As always, do let us know what you think

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Pharmacy and Poisons Board @ppbkenya

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Health CS launches RRI to ascertain quality of health products

Health Cabinet Secretary, Sicily Kariuki in a roundtable meeting with the private sector members during the launch of Rapid Results for Post Market Surveillance

On 27th August 2018, the Cabinet Secretary (CS) for Health, Sicily Kariuki launched a Rapid Result Initiative (RRI) on Post Market Surveillance (PMS) of medicines and medical devices in the Kenyan market with a stern warning that those found with contraband products will face the law.

The RRI will be conducted by the Ministry of Health in conjunction with the Pharmacy and Poisons Board, National Quality Control Laboratory and Kenya Medical Supplies Authority aims at establishing the quality of selected medical products and health technologies in the market in the next 100 days and will ensure that the Kenyan public has access to quality, safe and efficacious health products.

"Post market surveillance is essential because it enables the detection of Sub-standard and Falsified (SF) products; confirms the registration status of products circulating in the market and also helps to establish the effects of storage conditions on the quality and stability of products," the CS said during the launch.

The CS who was accompanied by the Chief Administrative Secretary, Dr. Raman Rashid, Pharmacy and Poisons Board (PPB) Chief Executive Officer, Dr. F.M Siyoi and Deputy Head of Public Service, Mr. Wanyama Musiambo said PMS activity will be undertaken continuously to monitor quality of medical products and health technologies post authorization.

> *"Post market surveillance is essential because it enables the detection of Sub-standard and Falsified (SF) products...*

The PPB CEO Dr. F. M. Siyoi and MoH Chief Administrative Secretary Dr. Rashid Aman consult during the launch of the Rapid Results for Post Market Surveillance in Nairobi

Health Cabinet Secretary, Sicily Kariuki addresses the media during the launch of the Rapid Results for Post Market Surveillance in Nairobi

> *"Reports by the public will go a long way in helping the ministry to monitor the quality of pharmaceutical products...*

Stakeholders at the launch of the Rapid Results Initiative at Swiss Lenana Mount Hotel, on 27th August 2018

She urged the members of the public to use the system for reporting suspected poor quality medicines whenever they come across suspicious products and adverse drug reactions. "Reports by the public will go a long way in helping the ministry to monitor the quality of pharmaceutical products," she advised.

She also called upon the public to purchase their medicines from registered facilities which can be identified through the health safety code and only buy medicines prescribed by a medical practitioner.

PPB CEO Dr. F. M. Siyoi, Health Cabinet Secretary Sicily Kariuki and board member Dr. Rogers Atebe consult during the launch of the Rapid Results for Post Market Surveillance

CS health Sicily launches a robust plan to increase access to essential medical supplies

Health Principal Secretary for Health, Peter Tum presents EACC report to Pharmacy and Poisons Board, Chief Executive Officer, Dr. F. M. Siyoi. Looking on is Health Cabinet Secretary, Sicily Kariuki, Andrew Mulwa representing the Council of Governors and Vincent Okongo EACC representative.

The Cabinet Secretary (CS) for Health, Sicily Kariuki, on 21st September 2018 launched a robust implementation plan for the Ethics and Anti-Corruption Commission (EACC) Report on the review of systems, policies and practices in the pricing of pharmaceutical and non-pharmaceutical supplies in the Kenya public health sector.

The implementation plan contains proposed actions to help bring down wastage and losses and other barriers to access for medical supplies with a direct resultant positive effect on access.

Some of the proposed actions outlined by the CS includes listing for all non-pharmaceuticals (medical devices) by the regulator, annual licensure for all medical devices (non-pharmaceuticals) distributors, reviewing and updating of all the current essential commodity lists and development of national guidelines for emergency procurement for essential medicines and other medical supplies.

The CS said the Ministry of Health will establish and operationalize Medicines and Therapeutics Committees in all Counties and Hospitals, ensure inclusion of all items listed in the essentials commodity lists in the market price index (MPI) survey and posting of updated Market Price Index data on the Public Procurement Regulatory Authority website on quarterly basis based on predetermined calendar.

Health Cabinet Secretary, Sicily Kariuki presents her speech during the handing over of Ethics and Anti Corruption Commission Report as the PPB CEO Dr. F. M. Siyoi looks on.

Other measures announced by the CS include 100% adherence to national essential lists specifications during procurement, development of generic bid documents for pharmaceuticals and non-pharmaceuticals, adoption of a comprehensive generic market survey tool(s) by all procuring entities and development of a list for essential products categorized as specialized and expensive and providing mechanism for acquisition.

The CS who was accompanied by the Principal Secretary, Eng. Peter Tum said a pricing policy for goods and services at the county and hospital levels will be developed and there will be regular review by all facilities for fees charged for health products, procedures and services to make them affordable.

She noted that the Ministry will also adopt and implement the recommendations for costing of essential health products and benefits package by the Universal Health Coverage advisory panel and enforce adherence to essential lists, clinical guidelines and protocols in prescribing.

"The budgets meant for procurement of medical products in all procuring entities will also be prioritized and electronic commodity management information system (CMIS) installed in all health facilities to link stores to all user units within the facility, KEMSA and higher levels of management," she said.

The CS said the implementing of the proposed actions will require close collaboration between the two levels of Government and even across Government Ministries, Departments and Agencies (MDA) and directed the Pharmacy and Poisons Board to develop Monitoring and Evaluation (M&E) framework for the implementation plan besides generate annual reports for the next three years.

She thanked the EACC for the informative report which had identified weaknesses in all components of supply chain cycle from selection; forecasting & quantification; procurement; distribution; storage; inventory control; information management and appropriate use by both health workers and consumers.

Health Cabinet Secretary, Sicily Kariuki presents Ministry of Health report to Vincent Okongó, the Director, Field Services, of the Ethics and Anti Corruption Commission.

Ensuring the Quality and Safety of Medical Products and Health Technologies in Kenya

Pharmacy and Poisons Board (PPB) established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya is the National Medicines Regulatory Authority mandated to oversee the quality, safety and efficacy of medical products (medicines including vaccines) and medical devices in Kenya.

The Board regulates the practice of pharmacy and the manufacture and trade in drugs and poisons. This is done through a number of activities like regulation of the investigational products during the development phase (Clinical Trials), carrying out evaluation and registration of the medicines including vaccines and medical devices before they are allowed into the market, monitoring the products during production to ensure that the manufacturing processes are carried out according to the approved processes and standards, and regulation of importation and exportation of the medical products into and out of the country.

> “...the Kenya National Pharmacovigilance System was officially launched in 2009...

In addition, the Board has been proactive in ensuring Kenyans have access to medical products (medicines, biologicals and vaccines) and medical devices that meet quality standards, are efficacious and safe. To achieve this, the Board has in place an elaborate pharmacovigilance and post marketing surveillance system.

The Directorate of Medicines Information and Pharmacovigilance houses the National Pharmacovigilance Centre, which is the arm of the Board that monitors the quality and safety medical products and health technologies after registration.

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems. Post marketing surveillance (PMS) on the other hand is the practice of promoting the safety of pharmaceutical drugs and medical devices after release to the market and also continuously monitoring their quality once registered.

Pharmacovigilance (PV) also plays a key role in the healthcare system through assessment, monitoring and discovery of interactions amongst drugs and their effects in human.

Pharmacovigilance aims to enhance patient care and patient safety in relation to the use of medical products and to provide reliable, balanced information for effective assessment of risk –benefit profile of medicines including vaccines

and medical devices in promotion of Public Health Programme interventions.

In order to achieve the objectives of pharmacovigilance, the Kenya National Pharmacovigilance System was officially launched in 2009, which saw the dissemination of National Pharmacovigilance Guidelines, and related forms for reporting suspected adverse drug reactions and suspected poor-quality medicinal products with the support from USAID funded Management Science for Health/Health Commodities and Services Management (MSH/HCSM) Program. To promote innovation, cost-effectiveness and sustainability, the Pharmacovigilance Centre also developed and implemented a Pharmacovigilance Electronic Reporting System (PVERS), The 1st Vigiflow compatible e-reporting system in Africa (www.pv.pharmacyboardkenya.org). Kenya is currently the 6th highest reporter of ADRs in Africa and some of the past safety alerts based on received reports can be viewed at; www.pharmacyboardkenya.org/e-shots

The Kenya PV Centre was designated a Regional Centre for Regulatory Excellence (RCORE) in Pharmacovigilance in 2014 by the New Partnership for Africa Development (NEPAD) under the African Medicines Harmonization Project. This was primarily due to the achievements in Pharmacovigilance activities that PPB attained since it started in 2009. As an RCORE, its mandate is to assist countries in Africa develop their Pharmacovigilance systems

Recognition as RCORE has spurred the centre to strive to improve the Pharmacovigilance system and has acted as a hub for good Pharmacovigilance practices by hosting Tanzania Food and Drug Authority (TFDA), Zimbabwe Medicines Authority, and Somalia through the World vision consultant. PPB is also the lead country in the East Africa Community -Pharmacovigilance and Pharmacovigilance harmonization, under the Medicine Regulation Harmonization Project.

To continuously monitor the quality of the registered products, the PPB does routine Post Marketing Surveillance (PMS) of these products. Carrying out PMS is important in that it helps in monitoring, collecting, assessing and evaluating information on medicines including vaccines and medical devices with the view to identifying any potential quality problems on medicines circulating in the market.

To help with the post marketing surveillance (PMS) activities, PPB received support from USAID funded United State Pharmacopeia (USP) Promoting the Quality of Medicines (PQM) program through the Presidential Malaria Initiative (PMI) which made it possible to procure and make available 11 minilabs that are being used in the field and ports of entry.

In the recent past, PPB has carried out PMS for antimalarials, anti-tuberculosis medicines, cough syrups, reproductive health products, antibiotics, antiretroviral (ARVs), anti-hypertensives and antidiabetic medicines. Results of the previous surveys can be viewed at www.pharmacyboardkenya.org/postmarket_surveillance

Monitoring of safety and quality of medicines, calls for a collaborative effort of all stakeholders in delivery of health care service. The patient plays a key role in ensuring that they communicate anything unusual during the cause of their treatment.

We are encouraging health care providers, patients and the general public to report all suspected Adverse Drug Reactions (ADRs), Adverse Events Following Immunization, Incidents with medical devices and all suspected poor quality medicines and medical devices to PPB through www.pv.pharmacyboardkenya.org, email: pv@pharmacyboardkenya.org, call (+254) 0795743049 or contact a health care provider near you.

This information will be treated with confidence and will go a long way in enhancing the monitoring of medicines and medical devices so as to ensure their safety, quality and efficacy.

Regulation of Medical Devices in Kenya

Millions of patients worldwide depend on an ever-widening array of medical devices for the diagnosis and management of disease. In Kenya, the Pharmacy and Poisons Board (PPB) requires manufacturers of high-risk devices to demonstrate safety and effectiveness before the devices can be marketed following the revised Cap 244 and new medical devices rules and guidelines.

The new Medical Devices regulation aims to strengthen patient safety with scrutiny of high risk devices. This Regulation aims to ensure patient safety, our number one priority, at every stage of the process from product development, to market placement and surveillance.

To strengthen patient safety and ensure the availability of medical devices, the PPB has made remarkable achievements namely;

a) **Formation of a Committee of Experts on regulation of medical devices and in vitro Diagnostics (IVDs).**
b) **Stakeholder engagement on guidelines for registration of medical devices.**
c) **Review of guidelines**
d) **Endorsement of Kenya as a member of Asian Harmonization Working Party and**
e) **Finalization and approval of guidelines on Registration of Medical Devices and IVDs in May 2018.**

Subsequently, the implementation of the Guidelines on Submission of Documentation for Registration of Medical Devices will be effective in January 2019. The Board has advised the applicants to prepare product application/s for marketing authorization using the Common Submission Dossier Template (CSDT) for Class C and D medical devices and IVDs (part of the guideline). Medical devices & IVDs class A and B will be listed as has been the case.

For more information, applicants are advised to visit Pharmacy and Poisons Board website; www.pharmacyboardkenya.org or Email: medicaldevices@pharmacyboardkenya.org

PPB establishes Research & Development Unit

The Pharmacy and Poisons Board has demonstrated a commitment to health Research and Development, by establishing the Unit of Research and development aimed at bolstering the Board's innovation agenda.

The unit is mandated to steer operational researches to help PPB improve its operations and functions under the Directorate of Quality Management Systems, Policy, Planning, Research and Regional Coordination.

The R&D unit has come up with various documents that will govern PPB in undertaking operational researches. These includes operational research policy, guidelines, protocols and manuals.

In the 2018/2019 financial year the unit has developed a robust work plan to assist PPB to operatize research. The research findings will help in policy formulation and decision-making at national level to support the achievement of Universal Healthcare Coverage (UHC) agenda.

New data centre to host PPB online services

A new state-of-the-art data centre has been established at the Pharmacy and Poisons Board (PPB) to host all activities of the Board.

The new data centre project is a vital part of the Board's plan to ensure its technology systems are robust, reliable and responsive to attainment of Universal Health Coverage (UHC).

To achieve UHC, quality data on health needs and resource requirements must be used in the pharmaceutical sector planning and budgeting. The new centre was established to address the growing demand for data management for Product Registration, Pharmacovigilance, Good Manufacturing Practice, Quality Control Lab and Post Marketing Surveillance.

The primary objective of the facility is to improve overall data centre service quality, enabling the Board to provide client-focused, integrated, accessible and cost-effective services

Increasing access to high-quality, safe health technologies across Kenya

The regulation of medical products and health technologies is a critical component of every country's public health system and ensures that high-quality, safe health technologies reach the people who need them most.

Any medical product offered for use in Kenya must be registered by the Pharmacy and Poisons Board (PPB). The product undergoes stringent regulatory procedures that require, among others, the submission of a broad range of data and evidence of quality, safety and effectiveness. The registration status is updated (retained) annually to enable the PPB to take into account any risk concerns that may arise during use as part of product lifecycle management. The responsibility of product evaluation and registration is principally undertaken by the Directorate of Product Evaluation and Registration through which the Board has made several strides.

First, Adoption of the EAC regional guidelines; the EAC Compendium guidelines for new products, Guidelines for blood and blood products, Vaccines, bio-pharmaceutics and similar bio-pharmaceutic products, which is in line with the Common Technical Document (CTD) format.

Second, the introduction of online annual retention system. Once pharmaceutical products are registered by PPB, they have to be retained annually to be in the Kenyan market. The online retention system serves as the product repository where applicants upload the Product Certificate, GMP compliance, scan of primary & secondary pack and Patient Information leaflet for review. Retention certificate is issued upon approval. The retention system is a repertoire of information and thus is very useful to the public particularly the procurement agencies and Healthcare professionals.

Third, the adoption of online applications for new products, notifications and variations. The online applications submissions system has enhanced product dossier information management including post approval changes. Further, the system has improved DPER communication to clients on the product application status. The online system is also useful for evaluators as it stores product history throughout the product life cycle.

Fourth, the adoption of guidelines for registration of medical devices. The adoption of the medical device guidelines shall enhance the Boards' capacity in ensuring quality medical devices are available in the market.

Fifth, PPB is an active participant in Joint East African community harmonized medicines regulation program. The Board has been a key participant in Regional Economic Communities (RECS) particularly the EAC and Inter Governmental Authority on Development (IGAD). PPB has been actively involved in policy formulation and development of procedures and guidelines useful in the EAC MRH Programme. Additionally, the EAC MRH has increased capacity building for the junior assessors towards reaching international standards in product assessment.

Sixth, PPB is actively involved in WHO prequalification program. The

Board has expert assessors involved in the World Health Organization (WHO) prequalification programme (WHO PQ). The experts have been the main drivers in capacity building within the Board and in the Regional Economic Communities. Partnership with WHO PQ has also aided the Board to achieve part of its training needs.

To achieve high efficiency in meeting its regulatory obligations the Board, through its QMS department, is working towards ISO certification.

In conclusion, the Pharmacy and Poisons Board is striving towards meeting international standards in its regulatory obligations manifested by the above enumerated achievements. This will ensure that the medical products and health technologies available in the Kenyan market are safe, of good quality and safety. In addition, the Board is involved in the expansion of local pharmaceutical industry thus contributing to two of the government's big four goals; achievement of universal health coverage and Industrialization.

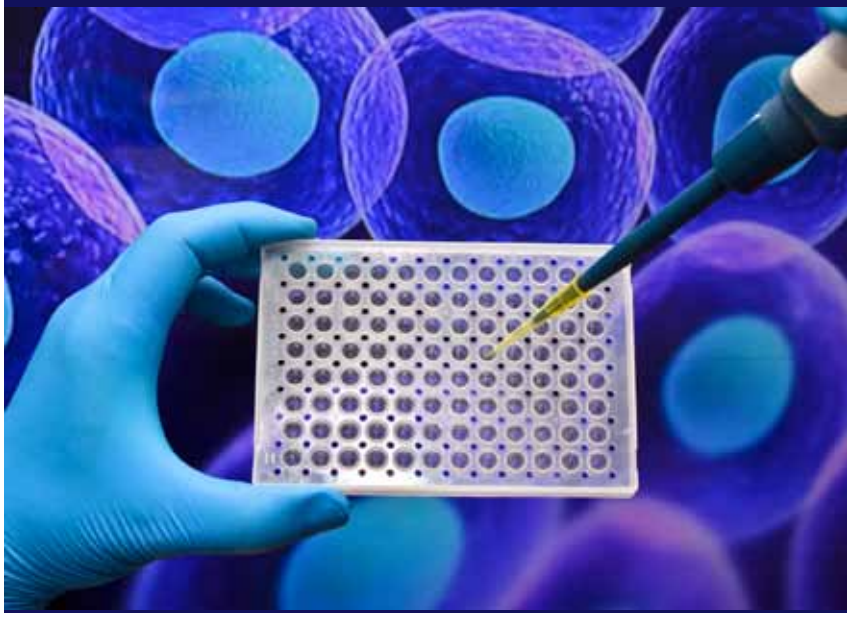
Basic screening of medicines

PPB has established a laboratory to combat the issues of Treatment failure, increased morbidity, development of drug resistance, wasted resources and effects of substandard medicines.

In its bid to envisage the mandate of quality, safe and efficacious medicines in the Kenyan Market the directorate of Quality Control and Inspectorate Surveillance & Enforcement undertook an activity on August 28th to September 10th 2018 to sample and screen medicines in the Coastal Region. Areas sampled were Mombasa, Kwale, Kilifi, Malindi, and Taita Taveta. The samples were collected from

- **Private chemists (Retailers and Wholesalers)**
- **Government hospitals**
- **Faith based hospitals**

The basic screening of the medicines was done using Handheld Raman Spectrometers and Minilab Kits. The samples screened will further be subjected to compendial testing using World Health Organization Prequalified laboratories; Mission for Essential Drugs and Supplies (MEDS) or National Quality Control Laboratory (NQCL).



Directorate of Medicines Information & Pharmacovigilance success story

The Pharmacy and Poisons Board (PPB), the Kenya National Medicines Regulatory Authority was established in 1957 under the Pharmacy and Poisons Act of the laws of Kenya.

The Mission of the Board is to protect the public by regulating the profession of pharmacy and ensuring quality, safety and efficacy of medical products and technologies, which gives it the mandate to implement and maintain a Pharmacovigilance System designed to monitor the safety of authorized medicinal products and detect any change to their risk-benefit balance.

In line with this mandate and by applying systemic approach model of institutionalization; PPB established the National Pharmacovigilance Center (NPC) in 2004 as department under the Product Registration Directorate.

Through the support of Management Science for Health/ Health Commodities and Services Management (MSH/HCSM) Program, PPB implemented the nationwide Pharmacovigilance system, that was officially launched in June 2009 by the Ministry of Health.

A national rollout plan was conceptualized and implemented focusing on capacity building of focal champions and regional trainers, dissemination of guidelines, reporting tools and job aids and In-service trainings and sensitization of HCWs.

This activity led to the NPC being able to collect and submit a total of 145 Individual Case Safety Reports (ICSRs) to the World Health Organization International Drug Monitoring Programme which enabled the PPB become the 98th Full official member of Uppsala Monitoring Centre in May 2010.

To continuously monitor the quality of medical products and health technologies in Kenya and coupled with complaints arising from the public about substandard and falsified medicines, introduction of new medicines/regimens and the experience growth of the pharmaceutical sector, the PV department in 2010, developed a Marketing Surveillance Strategy with key criteria being medicines used in Public Health Programmes and medicines Susceptible to being Substandard and Falsified.

With increasing workload and scope of the department, this has seen its growth from a one-man department to a now fully-fledged directorate with key divisions namely; Clinical Trials, Medicines Information, Pharmacovigilance and Post Marketing Surveillance.

MIPV Milestones

a) Systems Strengthening/Systemic Capacity building;

- To promote innovation, cost-effectiveness and sustainability, PPB with support from HCSM Program developed and implemented a Pharmacovigilance Electronic Reporting System, the 1st Vigiflow compatible e-reporting system in Africa (www.pv.pharmacyboardkenya.org) in the year 2013. The system allows for reporting of suspected ADRs and poor quality medicines and has seen the increase in reporting of adverse drug reactions (ADRs) up from 1459 in September 2011 to over 12,000 and from 3 in 2008 to over 1,000 of suspected Poor Quality Medicinal Products in 2018. Safety updates based on these reports are available at www.pharmacyboardkenya.org/e-shots
- In the same year 2013, through the EDCTP Grant the Clinical Trials Registry was launched (http://www.ctr.pharmacyboardkenya.org) and submission and evaluation of clinical trials applications. So far 205 Clinical Trials Application have been reviewed and processed from 2013 to date.
- The development of Guidelines for advertisement and promotion of medicines and medical devices in Kenya has led to the review 968 applications on advertisement and promotion of medicines from 2011 to July 2018.
- With the development of the Post Marketing surveillance strategy; there has been surveys carried out to continuously monitor the quality of Antimalarials, AntiTB, Antiretroviral and reproductive health medicine, anti-hypertensive and diabetics medicines among others. The routine surveys have shown improved quality of medicines following post market activities leading to improved compliance to regulatory requirements. Reports of these surveys are available in the website. www.pharmacyboardkenya.or/Postmarket-Surveillance

b) Capacity Building;

- Through technical assistance from HCSM, World Health Organization and other stakeholders, the Kenya PV system has borne fruits including implementation of national PV guidelines and training package. Over 15,000 healthcare providers and undergraduate students have been sensitized and trained in PV and PMS since 2010. PPB also collaborated with University of Nairobi, HCSM, University of Washington and SIAPS program to implement a Post Graduate Masters course in Pharmacoepidemiology and Pharmacovigilance (EPIVIGIL). Almost 60 graduates of EPIVIL are currently implementing PV activities in public health programs, PPB, at national and county levels. PPB has 5 EPIVIL specialists.
- • To build capacity in assessment of clinical trials regulations, there exists a functional experts committee on clinical trials that reviews the clinical trial applications.

Success stories

- Kenya was designated a Regional Centre of Regulatory Excellence (RCORE) in Pharmacovigilance in 2014 by the New Partnership for Africa Development (NEPAD), under the African Medicines Harmonization Project. This was primarily due to the regional Centre's ideal location and the quality of services it provides. The Kenya PV-RCORE continues to strive for excellence to serve as a hub for good Pharmacovigilance practices in the continent and as the technical lead country for Pharmacovigilance and Post Marketing Surveillance in the East African Community under the Medicine Regulation Harmonization Project.
- The multi-pronged approach to PV system strengthening in Kenya has led to increased reporting of adverse drug reactions (ADRs) up from 1459 in September 2011 to over 12,000 reports in 2018. These reports have informed several decisions including review of Kenya ART guidelines in 2011 and improved monitoring of patients on Isoniazid Preventive Therapy.

- **National and Regional Collaborations**
  - Enhanced collaboration with Public Health Programmes; Currently the PV department in collaboration with the HIV Program are carrying out Cohort Event Monitoring of antiretroviral medicines with support from the Global Fund; with financial support from MSH and technical support from Uppsala Monitoring Centre, PPB is finalizing the development of an active surveillance data management tool for collecting and analyzing all active surveillance studies in Kenya.
- The strong PPB-led Pharmacovigilance system have attracted countries to visit and learn from Kenya including: Afghanistan, Angola, Tanzania, Zimbabwe and Somalia.
- Kenya Spearheaded the development of the East Africa Community Pharmacovigilance Strategic Business plan 2018-2023 that will oversee the strengthening of PV in the region.
- Successfully hosted the Hosted African Society of Pharmacovigilance Conference in 2016

The future of MIPV

- The directorate has developed and is in the process of reviewing some of its key guidelines to ensure optimal operation in ensuring quality, safety and efficacy of medicines including;
  - Medicines and scheduling guidelines
  - Implementation of the newly approved QPPV Guidelines as from October 2018
  - Review of the National Pharmacovigilance Guidelines to include all medical products and health technologies regulated by PPB.
- In order build capacity and optimize review of safety data the following proposed actions are ongoing
  - Expansion of the experts committee on clinical trials to increase the scope of expertise and ensure effective and efficient review of applications.
  - Constitution of the Pharmacovigilance Risk Assessment and Advisory committee
  - Constitution of the technical working group on PV and PMS.

PPB steps up surveillance at the Ports of Entry

In a bid to protect the safety of the public, the Division of Ports of Entry (POE) at the Pharmacy and Poisons Board ensures quality standards of imported healthcare products comply with regulatory framework.

The Board is continuously improving and strengthening the pharmaceutical management structures to make them more responsive to achievement of Universal Health Coverage (UHC)).

Medical products imported into the country pass through designated Ports of Entry where PPB officers, along with other border control agencies, are deployed to inspect and authorize imports and exports.

Eleven Ports of Entry (PoE) have been gazzetted namely Kilindini Port, Lunga Lunga, Namanga, Jomo Kenyatta International Airport, ICD Embakasi, ICD Pepe Athi River, EMS City Square, Isebania, Busia, Malaba and Eldoret International Airport.

Reproductive Health Drugs (Postinor 2) intercepted at Inland Container Deport- Embakasi

Plans are underway to designate nine more POEs namely: Taveta, Moyale, Mandera, Kisumu Airport, Lokichogio, Liboi, Nadapal, Wilson Airport, Moi International Airport Mombasa and General Post Office Mombasa.

Pharmaceutical packaging materials seized at the Eldoret International Airport.

and the consignment was handed over to PPB for destruction.

Similarly, the Board inspectors at the Eldoret International Airport, seized a consignment of empty pharmaceutical packaging materials and are in the process of establishing local owners. According to the Head of PoE Mr. Peter Kiptoo all pharma-packaging materials and patient information leaflets must be accompanied by necessary authorizations from the PPB.

Mr. Kiptoo also affirms that only licensed pharmaceutical manufacturers are allowed to import such materials to be used in the packaging of their products that must be authorized by Pharmacy and Poisons Board.

Eleven counties have been equipped with Minilabs to promote the Quality of Medicines (PQM) program.

Due to thorough scrutiny of medical products at the Ports of Entry PPB Inspectors at Inland Container Depot-Embakasi (ICD-E) in partnership with other government agencies have managed to intercept a huge consignment of reproductive health products Postinor-2 valued at Ksh. 19,800,000. Currently, the board is gearing for the destruction the contraband product.

In addition, a foreigner was caught by the Jomo Kenyatta International Airport Inspectors together with Anti-narcotics Police Unit trying to smuggled out of the country 33,450 capsules of Tramadol Hcl 100mg to Norway. The foreigner who could not produce export documents was arrested and arraigned at JKIA Law Courts where he pleaded guilty. The court fined him Ksh 60,000

33,450 capsules of Tramadol Hcl 100mg, intercepted at Jomo Kenyatta International Airport

Machakos Agricultural Society of Kenya Show








PPB staff engage with visitors during the Machakos ASK Show on 29th June 2018

Mombasa Agricultural Society of Kenya Show

PPB drug inspectors sensitizes visitors at the Mombasa ASK Show on 29th August 2018

Nyeri Agricultural Society of Kenya Show

Sensitization session at the Nyeri ASK Show on 12th September 2018

Quality assurance for pharmaceuticals

The Pharmacy and Poisons Board has established a quality laboratory to combat the issues of treatment failure, increased morbidity, development of drug resistance, wasted resources and effects of substandard medicines.

The laboratory shall be performing chemical, biological, biochemical, physiological and pharmaceutical evaluation; testing of locally manufactured and imported drugs or medicinal substances with a view to determining whether such drugs or medicinal substances comply with the acceptable standards.

The laboratory which is based at PPB shall also be testing medical devices, Herbal medicines, cosmetics, food supplements and Radiation emitting substances

Major achievements of the Directorate of Quality Control

The laboratory has been equipped with state of the art cutting-edge instruments designed in full compliance with the specifications as defined in the United States Pharmacopeia (USP) and other Pharmacopeia.

- 6 Raman Spectrometers
- 4 HPLC's
- Dissolution testers
- Weighing balances
- FTIR Spectrometer
- UV-Vis Spectrometer
- Disintegration Tester
- Friability Tester
- Multi Tester
- Auto Titrator
- Vacuum Oven
- Media Preparation Station
- Atomic Absorption Spectrometer (AAS)

Dr Obadiah Naikuni, Quality Control Director

The equipment has been qualified by certified engineers and the analysts have been trained on operation and maintenance.

The medical products to be tested using this equipment include Tablets, Capsules, Boluses, Pessaries, Suppositories, Sachets, Creams, Ointments, Herbal products, Suspensions, Syrups, Infusions, Injections and inhalers.

The tests that will be carried in the laboratory include; Identification and Quantification; Dissolution; Friability; Disintegration; Hardness; Dimensions and Weight.

Screening of medical products

The Board through the Directorate of Quality Control has purchased Minilab kits and distributed them to regional offices in Nairobi, Kisumu, Kisii, Sirare, Mombasa, Kericho, Nakuru, Busia and Eldoret. Four Handheld Raman Spectrometers have also been purchased and dispatched to the Ports of Entry at JKIA, Kilindini Port, Eldoret and Kisumu and the inspectors trained on how to use them.

The lab has activated and strengthened the mini lab activities. It has carried out three successful screening with mini labs and two with Raman spectrometers. The handheld Raman spectrometers have established classified libraries of medical products such as the Anti-malarials, Anti-TB's, ARV's, Antibiotics, Sex Enhancers, Anti-diuretics, Antidiabetics, Antihypertensives, Reproductive Health products among others.

Eastern and Central Kenya Region Crackdown

A total of 83 people have been arrested for operating illegal pharmacies in eastern and central Kenya, in a crackdown conducted by the Pharmacy and Poisons Board drug inspectors between 24th -27th 2018 September. Out of the number, 37 were arrested in Central region, 23 in Lower Eastern and 23 in Upper Eastern said senior drug inspector Julius Kaluai, Head of inspectorate Nairobi region, while addressing the media in Meru town. According to Kalui there has been a reduction in the number of quacks in the business and the board will note relent to ensure all illegal premises are closed countrywide. Those arrested were arraigned in various courts and fined with various offenses. He cautioned registered pharmacists against employing quacks to stand in for them, which is illegal according to set standards and regulations. He cautioned the owners of premises which were found closed during the to crackdown and urged them surrender to the authority. "All outlets where quacks were arrested will remain closed until qualified pharmacists are engaged," he said.

Good Distribution Practices 2017/8 achievements

Universal Health Coverage (UHC) is one of the big four agenda of president Uhuru Kenyatta alongside manufacturing, affordable housing and food security.

Availability of quality, safe and efficacious medical products and health technologies is a key pillar in realizing the Universal health coverage.

To protect the health of the public and improve patient safety, Pharmacy and Poisons Board, the National Medicines Regulatory Authority must continually survey the market for unregistered products and personnel handling medicines since their presence can undermine the realization of Universal Health Coverage.

Likewise, the Good Distribution Practices (GDP) division being one of the divisions under Inspectorate Surveillance and Enforcement was created to oversight distribution outlets namely distributors, wholesalers, retailers, hospital/ clinic pharmacies both private and public facilities.

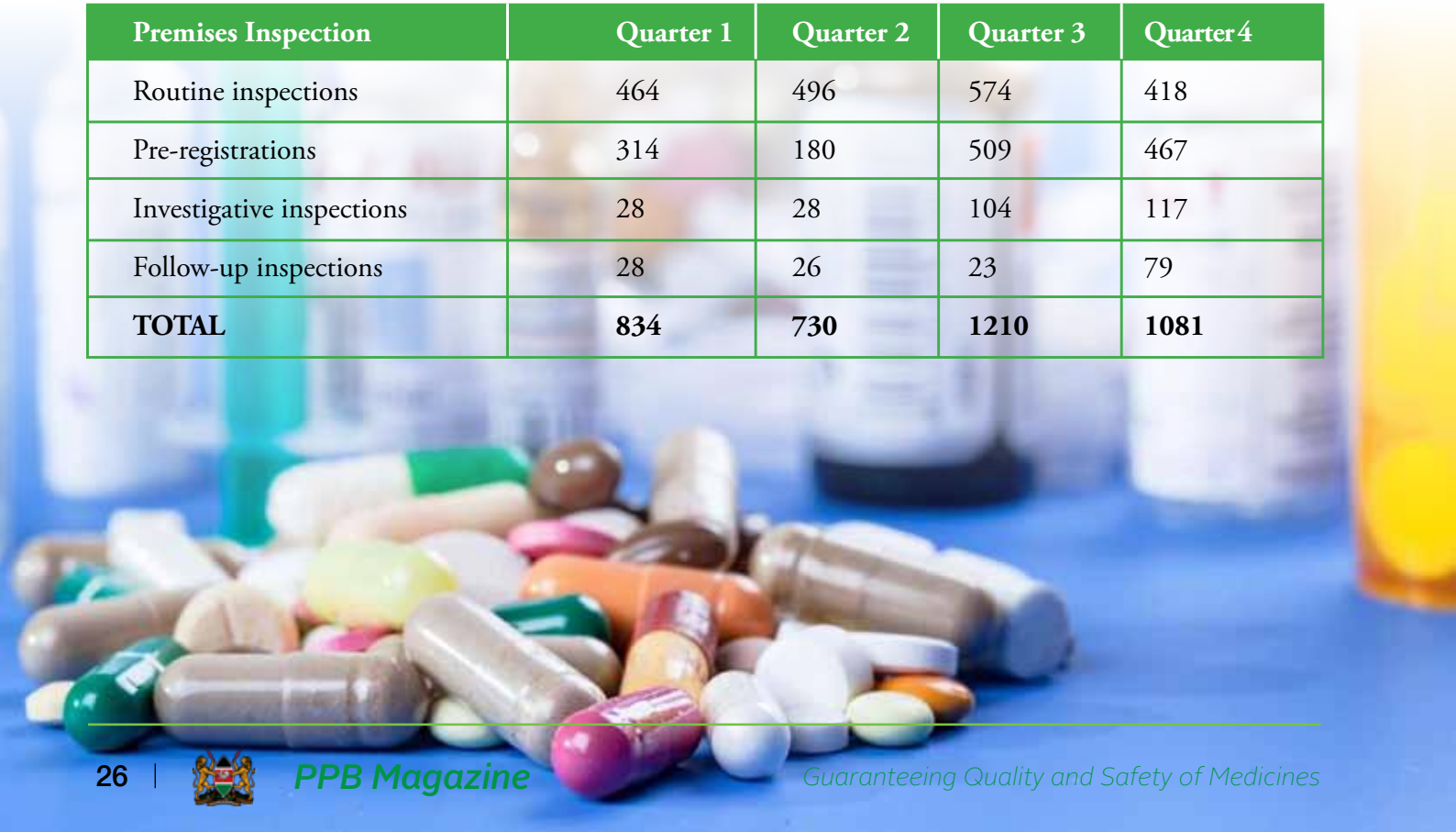
According to the Head of GPD, Dr. James Owuor, the division conducts through planned and ad hock inspections to these facilities to enforce Good Pharmacy Practice and in addition conduct market surveillance to detect and eliminate unregistered, suspected poor quality, spurious and falsely labelled medical products and technologies.

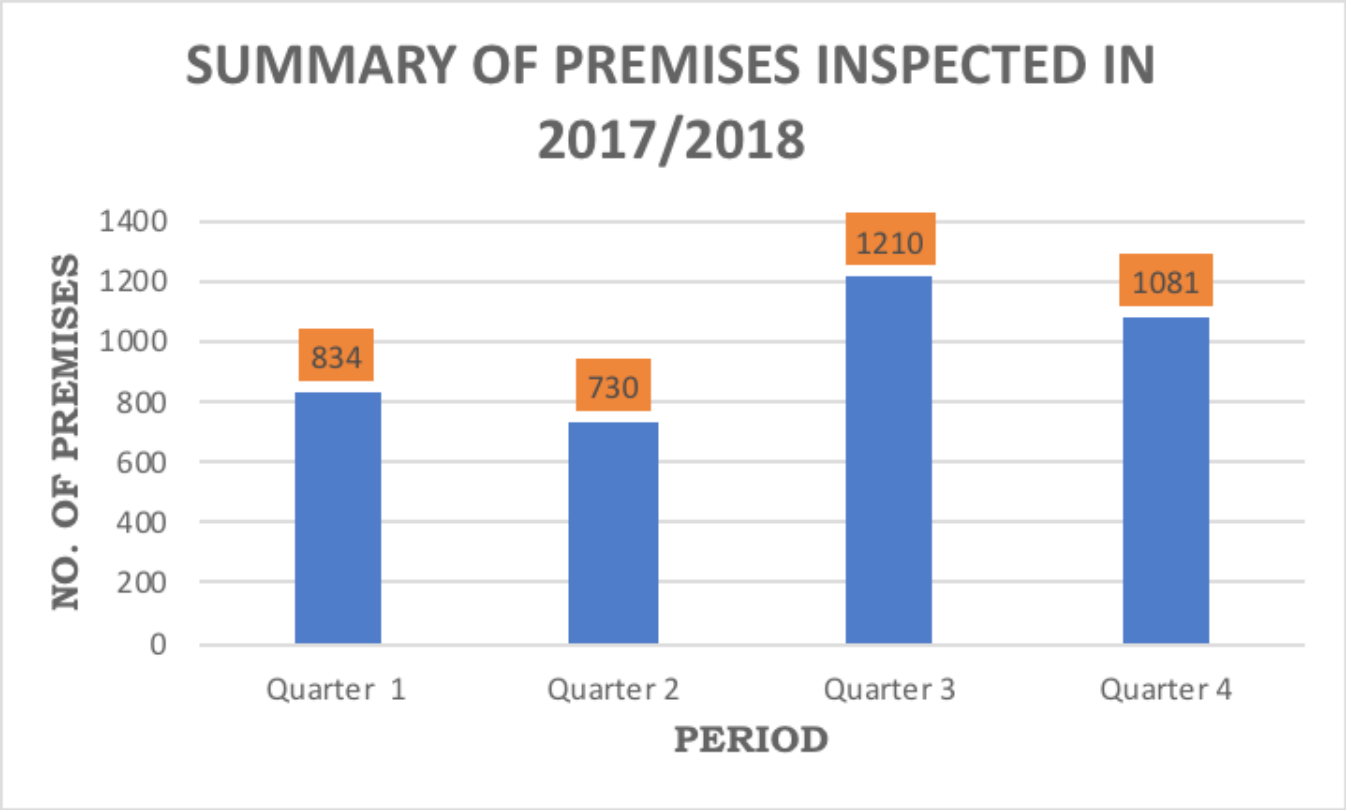
To ensure decentralization of services, PPB established 10 regional offices across the country, each region comprising of 2 to 7 counties. Inspectors are deployed in the regions from where they develop plan of activities to be undertaken.

Some of the achievements during 2017/2018 Financial year include:

a) Inspection of Distribution Outlets

Premises Inspection	Quarter 1	Quarter 2	Quarter 3	Quarter4
Routine inspections	464	496	574	418
Pre-registrations	314	180	509	467
Investigative inspections	28	28	104	117
Follow-up inspections	28	26	23	79
TOTAL	**834**	**730**	**1210**	**1081**





b) Review / Development of New Documents

The directorate in line with 2017/2018 Annual Operation Plan Implementation Log Frame held a review workshop for key documents touching on GDP. The workshop was held between 18th-24th February 2018 at Gelian Hotel, Machakos and the following documents were reviewed and developed. The same have been shared with stakeholders for comments

i. Guideline for Good Distribution Practices
ii. Guideline for Transportation of Pharmaceuticals
iii. Pharmaceutical waste disposal guideline

c) Joint Crackdown Activities

Since May 2016, Inspectorate Directorate has carried out 14 Crackdown exercises on illegal pharmaceutical outlets in the following regions:

- South Rift Region (22nd-27th May 2016)
- North Rift Region (20th -24thJune 2016)
- Nairobi Region (22nd-26th August 2016)
- Coast Region (31st Oct-4th Nov 2016)
- South Rift Region (5th -9thDec 2016)
- Central Region (20th-24th Feb 2017)
- Nyanza Region (3rd-7th April 2017)
- Western Region (3rd-7th April 2017)
- Lower Eastern (5th-9th June 2017)
- Upper Eastern (5th-9th June 2017)
- Coast Region (4th-8th Dec 2017)
- Nairobi & South Rift (12th-16th February 2018)
- Nyanza & Western (19th-23rd March 2018)
- North Rift & South Rift (7th-11th May 2018)

The aim is to weed out unlicensed outlets that are mainly run by unqualified people. These outlets pose a great danger to members of the public as they can potentially end up giving wrong medications, wrong dosage, poor quality medicines or misadvise the public with regards to medicines they are taking.

The exercises have so far been successful, since a total of 994 outlets have been closed in the process and 881 have been arraigned in court and their products confiscated as shown below.

S/N	REGION TARGETED	PERIOD CARRIED OUT	RESULTS	
			No. Arrests	No. Closed
1	South Rift Region	22nd-27th May 2016	65	70
2	North Rift Region	20th -24th June 2016	69	74
3	Nairobi Region	22nd-26th August 2016	89	105
4	Coast Region	31st Oct-4th Nov 2016	62	65
5	South Rift Region	5th -9th Dec 2016	72	81
6	Central Region	20th-24th Feb 2017	80	85
7	Nyanza Region	3rd-7th April 2017)	53	56
8	Western Region	3rd-7th April 2017	58	63
9	Lower Eastern	5th-9th June2017	30	35
10	Upper Eastern	5th-9th June2017	34	36
11	Coast region	4th-8th December 2017	52	60
12	Nairobi & South Rift Regions	12th-16th February 2018	64	79
13	Nyanza & Western Regions	19th-23rd March 2018	84	95
14	North Rift & South Rift regions	7th-11th May 2018	69	90
		TOTAL	**881**	**994**

c) Audit of Wholesalers and Distributors

In quarter 4, the division organized for audit of registered wholesalers and distributors for GDP compliance country-wide. Registered wholesalers' country-wide were audited as follows and various recommendations made.

S/N	REGION	No. AUDITED
1	COAST	12
2	UPPER EASTERN	8
3	NYANZA	5
4	WESTERN	10
5	NORTH RIFT	9
6	NAIROBI	44
7	SOUTH RIFT	9
	TOTAL	**97**

e) Stakeholder meetings/ Sensitization

During the year, a number of stakeholder meetings/ sensitizations were held by the division in various regions as follow:

S/N	Date Held	Venue	Stakeholder group
1	7th November 2017	PPB Hq	Representatives from waste disposal companies, KPA and PSK
2	12th April 2018	Swiss Lenana Mount Hotel, Nairobi	Training/meeting with Investigating officers and ODPP personnel within Nairobi region
3	4th -8th October 2017	Nairobi	Nairobi Agricultural trade fair

Emerging issues

- **Imposter inspectors**
- **Absentee superintendents**
- **Non-medical use of prescription drugs**
- **Medicine hawking**

Challenges

- **Some of the challenges encountered during 2017/2018 Financial year include:**
- **Extended electioneering period that resulted in less activities done in Quarter 1 and Quarter 2.**
- **Flooding in various parts of the country that made it impossible to access certain areas. Some field activities planned for in Q4 were deferred to July 2018.**

PPB Medical Camp



Pharmacy and Poisons Board staff undergo medical screening on 25th September 2018 at the PPB offices

Pharmacy practice and training achievements

The Pharmacy and Poisons Board (PPB) regulates the training and licensing of pharmacists and pharmaceutical technologists and the licensing of pharmacy wholesale and retail outlets, to ensure that medical products are distributed and dispensed according to required standards.

a. Accreditation of Training:

PPB approves courses for pharmacy degree or diploma training and accredits training institutions offering the courses in Kenya. Only trainees from accredited institutions are eligible for registration or enrolment by the PPB. Currently, 20 training institutions are accredited to offer Diploma in Pharmacy program, and seven Universities to offer Bachelor of Pharmacy programs in Kenya. Accredited institutions are regularly inspected to ensure conformance with standards. The list of approved training institutions is published on the PPB website.

b. Licensing of Practitioners:

Only Registered Pharmacists and Enrolled Pharmaceutical Technologists can be licensed to operate a pharmacy outlet; and the license-holder is required to be present on the premises whenever it is open to the public. Annual Practice Licenses are issued with the photo of the responsible professional for each premise; and the details can be verified electronically through Quick Response (QR) codes or Health Safety Code which must be conspicuously displayed at the premise for the public to see and verify legality of the premise. This has made it easy to identify expired licenses or forged codes. It has now become easier to detect criminals and quacks attempting to forge licenses.

In addition, PPB regularly inspects pharmacy outlets – either alone or jointly with other health regulatory bodies and it is applying GPS mapping to enhance efficiency.

c. Continuing Professional Development:

In executing its broad mandate of regulating the pharmacy profession, PPB has made tremendous gains in licensing to ensure only legitimate practice by pharmacists and pharmaceutical technologists. The latest entry is the implementation of Continuing Professional Development (CPD). The Board has taken a strong decision to implement CPD. The guidelines for implementation of CPD for Pharmacy and Practitioners have been developed and effective 2019, only those who have undertaken adequate CPD will have their licenses renewed.

Every pharmacist and pharmaceutical technologist has now been empowered to take charge of their own CPD activities with minimal intervention from the Board. The recent launch of the CPD module is part of regulatory Human Resource Information Systems (rHRIS), the online system for management of licensing. The system enables each practitioner to choose from a list of approved programmes/activities, subscribe, undertake the CPD and get points allocated automatically upon verification of

participation or completion of the activity/program.

Furthermore, each practitioner can plan for the whole year and monitor their progress and compliance as time goes by to ensure compliance by the time they are applying for license renewal.

To support this initiative, the Board is calling on eligible CPD providers to develop adequate programmes/ activities which upon accreditation shall ensure members have a rich basket of activities to pick from.

We commend the Pharmaceutical Society of Kenya (PSK), Kenya Pharmaceutical Association (KPA) and Hospital Pharmacists Association of Kenya (HOPAK) for taking the lead in this area.

Automation in management of training and practice:

The Pharmacy and Poisons Board (PPB) recognizes that customers want superior service and ease of doing business. Consequently, the Board is leveraging on technology to better manage its mandate and achieve greater customer satisfaction.

In this era of technology explosion where uptake of smartphones has been projected to be over 70% of the Kenyan population, web-based solutions are probably the easiest way to reach customers. It is also interesting that the way we communicate has also been largely affected by social media.

The PPB has successfully adopted automated online systems for premise registration and licensing, indexing of pharmacy students and application for professional examinations. More recently, the application for internship placement has been added to the list of services that PPB offers without requiring all applicants to travel to Nairobi.

The benefits of automation are enormous. "We have seen improved access to services and increased efficiency as less time, effort and other resources are spent by both our staff and customers in addressing the issues," Head of Training Dr. Wilfred Ochieng said.

According to Dr. Ochieng the waiting time for new licenses, inspection of premises has tremendously reduced. Renewal of licenses has become one of the easiest annual task for professionals and has improved compliance. "Applications can be made any time, in any place and approval can be within 72 hours," he noted.

Behind all this is a dedicated team of staff that responds to customer needs and queries. Kudos to the SWAT team.

Pharmacy workforce development to support Universal Health Coverage

As Kenya strives towards achievement of Universal Health Coverage (UHC), there is need for a strong workforce to support service delivery. The number of pharmacists and pharmaceutical technologists who are competent and fit to practice will be a critical factor in ensuring access to quality pharmaceutical services, especially considering their deployment at different facility levels.

The good news is that Kenya has experienced a steady increase in number of pharmaceutical practitioners. There are currently seven local universities offering Bachelor of Pharmacy degree. "In addition, we receive quite a good number of foreign trained pharmacists returning to join the local workforce," the Director of Pharmacy Practice and Training, said Dr. Ochieng. The growth in local training capacity has also been seen with Diploma in Pharmaceutical Technology.

Through a robust evaluation and assessment method, coupled with supervised internship, PPB has ensured a competent workforce is available. The Board conducts two examinations per cadre every year in April/May and in October/ November. The Stage 1 examination for pharmacists is administered before candidates proceed for a compulsory one-year supervised internship program. The Stage 2 examination is administered after the successful completion of internship and examination of the candidate's knowledge of applied clinical and pharmaceutical sciences. The candidate is also examined on the relevant laws and ethics that govern the practice of pharmacy, he noted.

Similarly, pharmaceutical technologists undergo Level I exams before undergoing a supervised seven-month attachment and subsequent Level II exams to assess their competence and readiness to practice. In each series of exams, the board examines approximately 1000 candidates, about 300 pharmacists and 700 pharmaceutical technologists.

World Pharmacists Day 2018

Pharmacists Play Key Role in Improving Medication Safety

Dr F.M. Siyoi, the Pharmacy and Poisons Board Chief Executive Officer, flags off the World Pharmacists Day walk at PPB offices.

On 25th September 2018, Pharmacists in Kenya marked the World Pharmacists Day in a bid to sensitize the public on the role they play in the pharmaceutical sector.

The walk which started at Pharmacy and Poisons Board headquarters along Lenana road and ended at the Pharmaceutical Society of Kenya Offices was flagged off by the Pharmacy and Poisons Board, Chief Executive Officer, Dr. F. M. Siyoi on behalf of Ministry of Health, Chief Administrative Secretary, Dr. Rashid Aman.

Dr Siyoi applauded the Pharmacists for the role they play in ensuring public safety and urged those in the community pharmacies to give pharmaceutical care to patients when dispensing medicines.

"Patients have rights and they should be given information on all drugs they receive. Any Adverse Drug Reactions should also be reported to the regulator," the CEO advised.

He also cautioned absentee pharmacists and emphasized

self-regulation through Nyumba Kumi initiative.

Speaking at the event, Dr Wilfred Ochieng, Director of Pharmacy Practice and Regulation of Training at Pharmacy and Poisons Board advised the pharmacists to guard and value their profession. "We need to focus on quality

Patients have rights and they should be given information on all drugs they receive. Any Adverse Drug Reactions should also be reported to the regulator

and put forward home grown solutions to curb quacks menace," he said.

Dr. Ochieng warned the pharmacists against trading their licenses and stressed that those found guilty will be arrested and charged in a court of law. "Let us be proud of our profession and offer superior services to mwananchi," he urged.

This year's World Pharmacist Day, was hosted by the the Pharmaceutical Society of Kenya in partnership with PPB and other pharmaceutical companies. The focus is on providing the public with free medication reconciliation, which entails looking at all medications a patient is taking and checking whether the patient is taking them as per the doctor's recommendations.

PPB CEO, Dr F.M Siyoi pose for a photo with participants before the walk to mark the World Pharmacists Day

Dr Wilfred Ochieng addresses Pharmacists at the PSK offices

Participants follow proceedings after the Pharmacists Day walk at the Pharmaceutical Society of Kenya offices

Pharmacists participate in the awereness walk to commemorate the World Pharmacists Day

The patient's will be counselled about timings of medication and whether any of the over the counter medicine, herb or supplement they have at home will interact with the prescription product. This will minimize Adverse drug-herb, drug-food and drug-drug interactions. The process will end with a Medication Action Plan & Comprehensive Medication Review Record that the patient will share with their physician at next visit.

MEDICATION SAFETY

Medicines are compounds used to treat diseases, manage symptoms of chronic illnesses and help relieve pain and suffering, among other uses. Medicines are generally safe when used as prescribed or in accordance with their label instructions. There however, are risks that may be associated associated with any medicine if not used in the right way.

The following precautions can be observed in an effort to reduce the risk of harm from medicines:

- Use the right medicine for the right conditions as directed on the label or as instructed by a doctor or pharmacist for example, antibiotics treat bacterial infections but not viral ones. Most colds, coughs, flu and sore throats are caused by viruses. Taking antibiotics for these infections will not keep others from contracting the illness, or help your child feel better.
- Use **prescription** and **over-the-counter medicines** only when needed and this should be done in consultation with your health care provider.
- Do ***not*** ask for antibiotics when your doctor says they are not needed.
- If your child is prescribed an antibiotic, make sure they take all the medicine as prescribed, even if they feel better.
- Do ***not*** save antibiotic medicine "for later" or share with someone else "with a similar condition"
- Do not give children medicine that is packaged for adults unless specifically told to do so by a physician.
- Always store medicines in tamper proof containers and out of the reach and sight of children.
- Store medicines as described by the manufacturer. This information can be obtained from the insert in the medicines' package.
- Do ***not*** use medicine past their expiry dates.

It is important that patients and their care givers by medicines from the **Pharmacy and Poisons Board (PPB)** approved health facilities to ensure you get expert advice on your medicines.

Ensure you are only served by qualified personnel in these premises. All pharmacies have been issued with **health safety code** and you can SMS the code to **21031** free of charge to verify the registration status of the pharmaceutical outlet.

Always check with the doctor if you're unsure whether symptoms require treatment with medication. To ensure the safe use of prescription or over-the-counter (OTC) medicines, discuss your symptoms with your doctor and pharmacist.

In the event of any safety or quality concerns arise in the cause of your medicines you, you are advised to seek medical attention immediately. Your doctor or pharmacist will instigate management and inform us the Pharmacy and Poisons Board. You can also call us on directly **+254 795 743049** or send us an email with the details of the concerns at **pv@pharmacyboardkenya.org.**

Alternatively you can visit us to report in person at our offices along Lenana Road or any of our regional offices countrywide or Visit PPB **website, www.pv.pharmacyboardkenya.org.**

Remember "Pharmacists are your medicines experts"

The role of the Pharmacy and Poisons Board is to safeguard the health of the public by ensuring safety, quality and efficacy of the medicines in Kenya.

REPUBLIC OF KENYA

PHARMACY AND POISONS BOARD

Ensuring Safe, Quality and Efficacious Medical Products in Kenya

Everyone knows that it is impossible to buy health. But you can buy medicines that can help to improve your health

REPUBLIC OF KENYA
PHARMACY AND POISONS BOARD

LICENSED PHARMACY
HEALTH SAFETY CODE:
XXXXX
TO VERIFY
SEND CODE TO 21031

www.pharmacyboardkenya.org

Be safe. Buy medicines from a licensed pharmacy

- Before making any purchase check if the Health Safety Code is displayed. SMS the code to 21031 free of charge or scan the QR code to verify the legitimacy of the license.
- If the pharmacy is licensed, the message will indicate the location and the name of the superintendent.
- Always insist on talking to the pharmacist or pharm-technologist about your medicines
- Report any unlicensed premise or pharmacist/pharm-technologist to 0702475824 or email info@pharmacyboardkenya.org

PLEASE DON'T IGNORE BUT SHARE THIS INFORMATION WITH THOSE YOU CARE FOR

Medicines & Adverse Drug Reactions

Q&A

Pharmacy and Poisons Board (PPB) established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya is the National Medicines Regulatory Authority mandated to oversee the quality, safety and efficacy of medical products (medicines including vaccines) and medical devices in Kenya.

In the course of our lives, we are likely to be given medicines including medicines for the prevention or treatment of various infections. Most of us may not experience any problems when using these. However, all medicines have some risks and some people may develop unwanted effects (also known as adverse reactions).

What is an adverse drug reaction?

An adverse reaction (ADR) is defined as a 'response to a medicinal product which is unwanted and unintended'. This definition includes any harm associated with the use of a medicine including use following a normal dose, overdose, misuse or error.

In many cases, side effects which are generally expected when taking medicines are mild and you can continue to take the medicine. However, some people may experience adverse drug reactions that may need a change in their medicines or, in rare cases, some additional medical treatment.

It is important to look at the risks associated with a medicine in the context of the overall benefit of the medicine to your health and the condition being treated ;where a reaction to a particular medicine is severe, it may still be better to continue the treatment and to manage the unwanted side effects/ adverse drug reactions with consultation from your doctor or pharmacist.

Where can I get information on adverse drug reactions?

The package leaflet that comes with a medicine tells you about the product. A Section of the leaflet talks about ***the possible*** adverse drug reactions. Some of the information at times may be written on the package of the medicines.

It is important to read this information. You are also advised to talk to your doctor or pharmacist about the possible adverse drug reactions of medicines they are recommending for you.

What should I do if I think I have had a reaction?

If you are worried that you may have had a reaction to a medicine, contact your healthcare professional. They will tell you if you need any medical care. They will also consider if you need to change your treatment or if you need a different treatment.

How can I report an adverse reaction?

You can report a drug reaction by:

- Contacting your healthcare professional who can notify the Pharmacy and Poisons Board;
- Calling PPB on **0795 743 049** or sending an email to pv@pharmacyboardkenya.org or fill in the forms at www.pv.pharmacyboardkenya.org
- Visiting PPB offices to report in person along Lenana road or any of PPB regional offices countrywide.

Who can report an adverse drug reaction?

- Doctors, pharmacists, dentists, nurses and other healthcare professionals.
- Patients and other members of the public if the side effect happened to:
  - ***themselves personally;***
  - ***their child;***
  - ***some other person they are responsible for, such as a spouse, a young adult or an elderly person; or***
  - ***Someone who has asked that they make a report on their behalf.***

Why is it important for me to report suspected adverse drug reactions?

Patients are in an ideal position to identify the impact of medicines they have taken, particularly on their quality of life. The patients' role in reporting adverse drug reactions is a key element in building an improved pharmacovigilance system.

The Board encourages you to report suspected adverse drug reactions so that we have more information available about the use of medicines and collect any new safety concerns that may arise with they use helps us to monitor them better.

When PPB gets a report of a suspected adverse reaction, the Board reviews all the details including the possible impact of the medicine. If PPB established that the medicine has played a role, it examines to see if this may be a new safety concern or if similar cases have been reported. The Board also have access to global safety information which helps us to identify emerging safety issues.

Where a serious safety issue emerges with a medicine, the Board may take regulatory actions that include issuing safety alerts, recall or withdrawal of the medicines.

What can I do to minimize the risk of adverse drug reactions?

It is important that you always follow the advice given to you by your health professional on the recommended storage, dose and length of time you should take a medicine. Make sure you tell your healthcare professional about any other medicines you are taking including any allergies. Some medicines can react with other medicines and this could be a health risk. It is also important that you do not self-medicate.

About Pharmacy and Poisons Board (PPB)

What is Pharmacy and Poisons Board?

The Pharmacy and Poisons Board (PPB) is the National Regulatory Authority for Medical Products in Kenya. It is a Government Agency under the Ministry of Health, established in 1957 under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya, to regulate the profession of pharmacy and the manufacture and trade in drugs and poisons. The mandate of the PPB is to promote and protect public health by ensuring that medicines, medical devices and other health technologies are safe, efficacious and of accepted quality. The PPB also advises government entities and the public on matters of safety, quality and effectiveness of medical products.

What are medical products?

Medical product refers to any product used specifically for health care purposes, i.e. to prevent, diagnose, treat, monitor, or alleviate disease or injury, or for related purposes. This includes medicines for humans and animals, medical devices, and biological products. Other terms like therapeutic products, medicinal substances or health technologies may also be used.

What are health technologies?

Health technology refers to *the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life.* Healthcare has evolved into a highly complex technological field, with new products constantly being introduced or old ones modified to deliver multiple solutions. Just like in ICT, technology is advancing and converging in healthcare. A medicine may be integrated into a medical device to be administered in a controlled manner (e.g. pre-loaded insulin syringe or a contraceptive implant; or a medical equipment may have integrated functions for diagnosis, administering medication, monitoring vital signs and recording data. This trend requires regulators to constantly adapt their competencies and systems in order to effectively assess the safety, quality and efficacy of emerging health technologies.

Why regulate medical products?

Every medicine is a potential poison, and every medical product has the potential to cause harm to humans, depending on how it is manufactured, handled or used. The main focus of the regulator is to minimize the risk of harm from medical products, to ensure that health benefits outweigh the risks and to provide clear and objective information about such risks and benefits. This facilitates consumer access to high quality, safe and efficacious medical products, while restricting access to products that are unsafe or have unproven therapeutic benefit.

What specifically does a medical products regulator do?

To assure the safety, efficacy and quality of a medical product, regulatory oversight is required throughout the product chain, i.e. from the research stage until the product becomes obsolete. This oversight occurs through eight critical functions, each targeting an aspect or attribute of product safety, efficacy or quality: -

a) Control of clinical trials
b) Inspection of manufacturing facilities and distribution channels
c) Product assessment and registration (marketing authorization & de-authorization)
d) Laboratory testing and lot release (where necessary)
e) Post-market surveillance of quality & safety; includes monitoring adverse reactions
f) Control of imports and exports, including control at points of entry and exit
g) Control of product promotion and advertising
h) Consumer education

What resources does a medical products regulator require?

A medical products regulator is a scientific institution, because regulatory processes and decisions must be underpinned by science and evidence. Key resources required include scientific & regulatory expertise, finances, equipment (laboratory, transport, ICT) and information. Regulation also requires a clear legal framework – defining a clear mandate and authority to set standards and enforce them; and mechanisms for accountability for regulatory decisions and actions.

Does the PPB perform all these regulatory functions?

Yes. The PPB undertakes the full scope of regulatory oversight for the products it regulates. The PPB aims to implement the appropriate regulatory measures to achieve the highest standards of safety, efficacy and quality for all medical products; and to minimize potential harm to humans in the use of such products. The operations and decisions of the PPB are underpinned by science and evidence, to ensure the protection of the consumer as envisaged by the laws in force in Kenya.

What measures are in place to assure that medical products in Kenya are safe?

Access to safe medical products is a cornerstone of public health around the world. The PPB has established a comprehensive and functional regulatory system to ensure that only safe, good quality and efficacious medical products are available in Kenya. Some of the measures in place include:

1. **Expertise:** A key asset for the PPB is the expertise of its technical staff. The PPB invests in formal training of key staff through sponsorship to post-graduate courses in regulatory science, and also skills upgrading in collaboration with WHO and other partners.
2. **International Standards:** The PPB applies and adapts international standards generated through standard-setting mechanisms like the WHO Prequalification Programme, the Global Vaccine Safety Forum and the International Medical Device Regulators Forum. To engender confidence in these standards, PPB experts actively participate in these initiatives - as assessors, inspectors or in consultative forums.
3. **Regulatory Harmonization:** The actions of a national regulator are part of a global system of trade in goods and services. To minimize the risk of substandard or counterfeit products moving across borders, national systems for regulation and law enforcement must be seamlessly linked. The PPB collaborates with International, Regional and Bilateral organizations like the Interpol and WHO in the fight against substandard medicines.
   - The PPB is part of an ongoing East African Community Medicines Regulation Harmonization Project (EAC MRH) to improve access to safe, efficacious and good quality essential medical products within the EAC. The EAC project is part of a broader initiative between
   - The PPB works closely with other government agencies and regulators (e.g. KRA, ACA, KEBS, KENTRADE) in ongoing initiatives to streamline cross-border trade.

4. **Product Registration:** Any medical product offered for use in Kenya should be registered by the PPB. The product undergoes a stringent procedure which requires the submission of a broad range of data and evidence of quality, safety and effectiveness. PPB dossier assessors review these data to determine the benefit-risk profile of the product, and this guides the PPB on whether to issue a marketing authorization, and the conditions or restrictions attached to it. The registration status is updated (retained) annually to enable the PPB to take into account any risk concerns that may arise during use. The PPB publishes on its website the list of all registered products www.pharmacyboardkenya.org.

5. **Laboratory Testing:** Regulatory decision-making requires laboratory testing of products to assess quality standards. The PPB undertakes such testing in WHO-prequalified laboratories. In Kenya, the two pre-qualified laboratories are the National Quality Control Laboratory (NQCL) and the MEDS laboratory. The PPB may also use other laboratories, e.g. KEMRI of KEBS for specific testing needs.

6. **Inspection of Manufacturing Sites:** PPB Inspectors routinely visit manufacturing facilities for medical products to ensure they comply with Good Manufacturing Practices (GMP). Where possible, such inspections are performed jointly with WHO or other regulators. In any case, as part of technical collaboration and regulatory harmonization, the PPB shares and receives confidential information about regulatory inspections or other significant findings by regulators worldwide.

7. **Control of Imports and Exports:** The PPB has an elaborate border control system to ensure that only approved medical products cross our borders.

- Any medical product imported into or exported out of Kenya (including donations) should be authorized by the PPB.
- Medical products imported into the country should only pass through designated Points of Entry (POE) where PPB officers, along with other border control agencies, are deployed to inspect and authorize imports and exports.
- PPB has gazzetted eleven (11) Ports of Entry namely: Kilindini Port, Lunga Lunga, Namanga, Jomo Kenyatta International Airport, ICD Embakasi, ICD Pepe Athi River, EMS City Square, Isebania, Busia, Malaba and Eldoret International Airport. Plans are underway to designate nine (9) more POEs namely: Taveta, Moyale, Mandera, Kisumu Airport, Lokichogio, Liboi, Nadapal, Wilson Airport, Moi International Airport Mombasa and General Post Office Mombasa

8. **Post market surveillance:** The PPB monitors the safety of a medical product after it has been released on the market, as an important part of pharmacovigilance. This is achieved through various activities, e.g.

- The PPB Pharmacovigilance Centre enables healthcare providers or the public to report suspected poor quality products or adverse

reactions. The Centre is linked electronically to the WHO Collaborating Centre for International Drug Monitoring in Uppsala, Sweden; and this enables real time exchange of safety data on products across the world. Anyone can report any suspicious medical product online at www.pv.pharmacyboardkenya.org. Such information assists PPB to determine whether a product should retain its registration, or to impose restrictions on its marketing and use.

- Sampling and testing of products to ascertain compliance with quality specifications. Such studies have been carried out on Anti-malarial, Anti-TB and Anti-Retroviral drugs between 2012 and 2015, and they show a downward trend in the failure rates to about less than one 1%. Similar studies for antibiotics and reproductive health medicines are underway.

9. Control of Clinical Trials: Regulatory control of clinical aims to ensure that decisions related to the safety and efficacy of vaccines, drugs and medical devices for use by populations are supported by the best available evidence. The clinical trial stage is very critical to product safety – disclosure of results from clinical trials for medical products, whatever the result, is critical to preventing harm. The PPB controls the conduct of any studies in Kenya involving the use of a medical product on human participants, including the recent trials for malaria and Ebola vaccines. An electronic application platform and a clinical trial register assist the approval and monitoring process.

10. Control of Pharmacy Profession: The PPB also regulates the training and licensing of pharmacists and pharmaceutical technologists; and the licensing of pharmacy wholesale and retail outlets, to ensure that medical products are distributed and dispensed according to required standards.

- Accreditation of Training: PPB approves courses for pharmacy degree or diploma training, and accredits training institutions offering the courses. Only trainees from accredited institutions are eligible for registration or enrolment by the PPB. Currently, 23 to training institutions are accredited offer Diploma in Pharmacy program, and 5 Universities to offer Bachelor of Pharmacy programs. Accredited institutions are regularly inspected to ensure conformance with standards. The list of approved training institutions is published on the PPB website.
- Licensing of Practitioners: Only Pharmacists and Pharmaceutical Technologists can be licensed to operate a pharmacy outlet; and the license-holder is required to be present on the premises whenever it is open to the public. Annual Practice Licenses are issued with the photo of the responsible professional for each premise; and the details can be verified electronically through Quick Response (QR) codes. The PPB regularly inspects pharmacy outlets – either alone or jointly with other health regulatory bodies; and it is applying GPS mapping to enhance efficiency.

11. Enforcement: The PPB is empowered by law to investigate and prosecute crimes related. This may entail arresting offenders, confiscating products or closing down premises. In 2013/2014 the percentage of inspections to court cases was 65.74% and in 2014/2015 the percentage was 59.12%.

Officers inspect medicine suspected to be counterfeited

12. Centre of Excellence: The PPB was designated a Regional Centre for Regulatory Excellence (RCORE) in Pharmacovigilance in 2014 by the New Partnership for Africa Development (NEPAD), under the African Medicines Harmonization Project. This makes the PPB a model Pharmacovigilance Centre for training and expertise for other African Countries. Similarly, the WHO-Prequalified National Quality Control Laboratory offers other countries for quality control and training services.

Courtesy call

Burundi Ambassador to Kenya courtesy call

Burundi Ambassador to Kenya H.E. Rémy Barampama courtesy call on PPB CEO, Dr. F. M. Siyoi on 28th August 2018.

The Burundi Ambassador to Kenya H.E. Rémy Barampama paid a courtesy call on the Pharmacy and Poisons Board CEO, Dr. F. M. Siyoi on 28th August 2018.

His agenda was to pave way for the Burundian parliamentarians to visit Pharmacy and Poisons Board to learn more about Kenya's experience in Regulation of medical products and health technologies. This is in line with East Africa Community Medicine Regulatory Harmonization (EAC-MRH) initiative agenda.

Economic Counsellor at the Jordan Embassy courtesy call

The Pharmacy and Poisons Board, Chief Executive Officer, Dr. F. M Siyoi hosted the Economic Counsellor at the Jordan Embassy in Kenya, Engineer Wesam Akroush on July 24, 2018. He was accompanied by the pharmaceutical Investors Dr Mustafa Shawayat, Head of Sales & Marketing at Savvy Pharma and Mr. Sultan Farray, Country Manager Africa, Pharma International Company (PIC).

The meeting centered on prospects of Jordanian pharmaceutical companies setting up manufacturing plants besides distribution of pharmaceutical products in Kenya, the Kenyan regulatory systems and the perception of the Jordanian pharmaceutical products in the East Africa market.

The Economic Counsellor at the Jordan Embassy in Kenya Engineer Wesam Akroush courtesy call on PPB CEO Dr. F. M Siyoi on 24th July 2018

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

Ensuring quality, safety and efficacy of medical products and health technologies

PUBLIC NOTICE

Report suspected adverse events and poor quality medicine

The Pharmacy and Poisons Board (PPB) is the National Medicines Regulatory Authority for Medical Products in Kenya. The mandate of the PPB is to promote and protect public health by ensuring that medicines, medical devices and other health technologies are safe, efficacious and of accepted quality.

To continuously monitor the quality and safety of medicines circulating in the Kenyan market, PPB has established a strong national Pharmacovigilance system that helps to track, monitor and evaluate quality, and safety of medicines.

You can report: suspected side effects from medicines, adverse events from vaccines, incidents with medical devices and suspected poor quality medicines online at **www.pv.pharmacyboardkenya.org; email pv@pharmacyboardkenya.org or call (+254) 0795743049.** You can also contact any health care provider near you to report.

This information will be treated with confidence and will go a long way in enhancing the monitoring of medicines and medical devices so as to ensure their safety, quality and efficacy

Pharmacy and Poisons Board @ppbkenya info@pharmacyboardkenya.org

REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

Ensuring quality, safety and efficacy of medical products and health technologies

PERFECT BINDING

- When you visit your local pharmacy to buy medicines, look out for the **Health Safety Code.**
- Type the **code** and SMS it to **21031** to verify the registration status of the pharmaceutical outlet. You'll receive a message confirming the registration status of the outlet. SMS is free.
- For your own safety, always buy your medicines from a registered pharmaceutical outlet.

For more information visit: www.pharmacyboardkenya.org

info@ pharmacyboardkenya.org Pharmacy and Poisons Board

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