



PHARMACY AND POISONS BOARD

MAGAZINE

PPB Unveils Key Guidelines



In this issue...

**93 Illegal Chemists
Closed in Coast Region**

**Kenya rolls out the world's
first malaria vaccine**



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PUBLIC NOTICE

TO ALL AUTHORIZED DEALERS IN MEDICINES

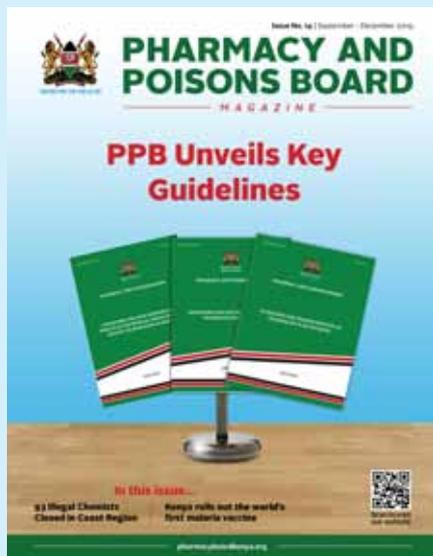
Sale of Prescription Only Medicines

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.



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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

It's encouraging to see that the topic of Universal Health Coverage has emerged from the shadows and become more widely talked about. This month in the Pharmacy and Poisons Board Magazine we highlight three key guidelines namely Guidelines on Good Distribution and Practices, Guidelines on Disposal of Pharmaceutical Waste and Guidelines on Transportation of Pharmaceuticals, which the Board has introduced to actualize its mission to protect the health of the public by regulating the profession of pharmacy and ensuring quality, safety and efficacy of medical products and health technologies in Kenya.

In this issue we recount the various projects and activities in which the Pharmacy and Poisons Board members were actively involved since June 2019. We lead our features pack with the launch of the Guidelines, roll out of Malaria vaccine, strategic planning retreat and continuing professional development stakeholders meeting among others. Our special thanks goes to all contributors for their submissions.

We remind you that this Magazine was created with you in mind. Help us make it the best it can by sharing views, inputs, suggestions and content contribution. Please keep your eyes on this magazine in the coming year for other signs of resilience and renewal as we roll out new regular features and expand our areas of coverage.

As always, drop us a line at pr@pharmacyboardkenya.org with any suggestions on topics you'd like to see us cover.

Wishing you all a memorable holiday season.

Judy



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POISONS BOARD**

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PPB unveils three key guidelines on the world pharmacists day



The Pharmacy and Poisons Board celebrated the World Pharmacists Day under the theme “Safe and Effective Medicines for All,” with a launch of three key pharmaceutical guidelines on September 25, 2019.

The Guidelines on good distribution practices, Guidelines on disposal of pharmaceutical waste and Guidelines on transportation of pharmaceuticals were launched by Dr. Rashid Aman, the Chief Administrative Secretary in the Ministry of Health at PPB offices.

Speaking during the launch, Dr. Rashid termed the guidelines a major milestone in ensuring efficient and effective drug management in the country.

Pharmacists, he argued have a crucial role to play in safeguarding patient safety through improving medicines use and reducing medication errors.

He applauded the Board and stakeholders for developing the guidelines and directed that consensus and understanding should be developed regarding the challenges faced in stopping the circulation of substandard medicines in the African continent.

“Let’s come up with a National approach to tackle this issue, since the problem of substandard and falsified medical products is global,” he urged.

He also advised on the need to support pharmaceutical industries with the necessary resources to become active participants in the global market.

“Having transparency and accountability will provide the credibility to our industries for global competition and help comply with the global requirements for export,” he said.

Speaking on behalf of the chairman of the board, Dr. Rodgers Atebe revealed that 70% of the medicines used in the country are imported with the 30% being produced locally.

He noted that all imports, including donations must obtain an import permit from PPB for them to get into the country and reminded consumers to purchase medicines from pharmacies accredited by PPB.

“The most trusted and respected means for the public to distinguish between legitimate and illegitimate drug sellers is to use the health safety code which is displayed in all registered pharmacies,” he advised.

The PPB CEO, Dr. F.M Siyoi said the Board is working on medicines track and trace system in partnership with the University of Nairobi and other stakeholders to ensure all medical products and health technologies in the market have a tracking number.



Unveiling of the 3 latest PPB Guidelines by Dr. Rashid Aman

“This will make it easy for us to identify the country of origin, manufacturer and batch of medical products and health technologies,” he noted.

The guidelines were developed with consideration of input from the key stakeholders in the industry.



PPB CEO Dr. F.M.Siyoi makes his remarks during the launch of PPB Guidelines



Chief Administrative Secretary in the Ministry of Health Dr. Rashid Aman presents his speech during the launch of PPB Guidelines

The event brought together key partners and stakeholders in the industry among them; MoH, PSK, KPA, KAPI, FKPM, KPDA, NQCL, KEMRI, KEMSA, NEMA, ICRC, RAPSK, Envirosafe, GoodLife and other manufacturing companies.

FOCUS ON WORLD PHARMACISTS DAY



PHARMACY AND
POISONS BOARD



World Pharmacists Day 2019

25 September 2019

THEME
“Safe and effective
medicines for all”

The Pharmacy and Poisons Board (PPB) is the National Drug Regulatory Authority in Kenya, established by the Pharmacy and Poisons Act, Cap 244, Laws of Kenya, mandated to regulate the profession of pharmacy and ensure quality, safety and efficacy of medical products and health technologies.

The Board regulates;

- Professional practice of pharmacy i.e. the registration and licensing of pharmacies and pharmacy practitioners.
- Pharmacy training institutions.
- The quality, safety and efficacy of all medicinal substances i.e. Conventional and/or complementary products, dietary supplements and medical devices/ vaccines/ Herbal.
- Import and export of all medicinal substances
- Advertisement and promotion of all medicinal substances in the country.

Overtime the mandate of the Board has expanded to include the regulation of medical devices, health technologies, nutritional supplements, cosmetics, vaccines, blood and blood products, and herbal products.

PPB Vision

To be a center of excellence in regulation of pharmacy profession, medical products and health technologies

PPB Mission

To protect the health of the public by regulating the profession of pharmacy and ensuring quality, safety and efficacy of medical products and health technologies

What specifically does PPB do?

To assure the safety, efficacy and quality of medical products and health technologies, regulatory oversight is required throughout the product life cycle and supply chain. This oversight occurs through nine 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 (Pharmacovigilance)
- f) Control of imports and exports, including control at points of entry and exit
- g) Control of product promotion and advertising
- h) Registration and licensing of pharmacists
- i) Consumer education

Essential medicines for Universal Health Coverage

Health products and technologies are essential components of healthcare service delivery. Sustainable Development Goal 3.8 specifically mentions the importance of “access to safe, effective, quality and affordable essential medicines and vaccines for all” as a central component of Universal Health Coverage (UHC) and Sustainable Development Goal 3.b emphasizes the need to develop medicines to address persistent treatment gaps.



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

Some of the key interventions the PPB has initiated include;

- Development and implementation of a five-year Strategic Plan 2014-2019 now under review
- GPS mapping of registered premises
- Innovation and Technology:
 - *Adoption of automated online systems for premise registration and licensing, indexing of pharmacy students, application for professional examinations and internship placement*
 - *Application of GPS mapping of pharmacy premises to enhance efficiency and Quick Response (QR) codes*
 - *Roll out of the Health Safety Code 21031 for verifying registration status of premises and superintendents prior to purchasing medicines.*
 - *Online reporting system www.pv.pharmacyboardkenya.org for reporting any suspicious product for the PPB to take action(s)*
- Inspection of manufacturing sites to ensure they comply with Good Manufacturing Practices
- Issuance of import permits for Pharmaceutical Products including donations
- Deployment of drug inspectors to all Ports of Entry
- Active and Proactive Post-market surveillance of registered pharmaceuticals
- Collaboration with International and Bilateral organizations e.g. the Interpol and WHO in the fight against Substandard/Spurious/Falsely labelled/Falsified, counterfeits (SSFFCs) medical products.
- Sharing of the Post Market Surveillance results to ensure continued collaboration. (pharmacyboardkenya.org)
- Investment in formal training of key staff and skills upgrading in collaboration with WHO and other partners.
- Application of international standards generated through standard-setting mechanisms like the WHO Prequalification Programme, the Global Vaccine Safety Forum and the International Medical Device Regulators Forum.

PPB milestones

- The Board has established systems that have increased efficiency in business processes and customer satisfaction leading to the recent award of ISO 9001:2015 by Kenya Bureau of Standards (KEBS).
- The use of ICT, such as availing reporting tools online, has made it easy for Kenyans to report ADRs and increased the level of transparency, traceability of documents and accountability, thus making it easy to adhere to international standards.

- PBB is the first National Medicines Regulatory Authority (NMRA) in Africa to employ the use of online systems for regulation of medical products in accordance with the World Health Organization (WHO) regulatory documentation package and other relevant International guidelines and standards;
- The Board is making waves internationally as a center of excellence as per the recognition by the Regional Centre for Regulatory Excellence (RCORE) in Pharmacovigilance by NEPAD under the African Medicines Harmonization Project. The digital pharmacovigilance system (PVERS) is now a benchmark for good pharmacovigilance practices. Countries such as Tanzania, Zimbabwe, Somalia, Ethiopia, and Afghanistan have visited our offices for benchmarking.
- Kenya is currently the lead country in Pharmacovigilance and Post Marketing Surveillance within the East Africa Harmonization under the AMRH initiatives
- Establishment of a post market surveillance Quality Control Laboratory
- Establishment of Enquires and Disciplinary Committee to ensure compliance with the laws and regulations pertaining to the profession and practice of pharmacy.
- Establishment of 10 Regional Offices in Mombasa, Nyeri, Embu, Kakamega, Eldoret, Nakuru, Machakos and Garissa to ensure decentralization, effective and efficient service delivery to PPB clients and stakeholders,
- Establishment of a Research and Development Unit to assist in policy formulations and decision making towards achievement of Universal Health Coverage

Upcoming technology

We are currently working on medicines track and trace system in partnership with the University of Nairobi and other stakeholders to ensure all medical products and health technologies in the market have a tracking number. This will make it easy for us to identify the country of origin, manufacturer and batch of medical products and health technologies.

We want to thank all stakeholders and members of the public for the support towards realization of His Excellency the President's Big Four Agenda in attaining the Universal Health Coverage (UHC) and promotion of local pharmaceutical manufacturing.



Kenya rolls out the world's first malaria vaccine

On September 13, 2019 Kenya in partnership with the World Health Organization (WHO), rolled out the world's first malaria vaccine in a landmark phased introduction programme that took place in some parts of Homabay, Kisumu, Migori, Siaya, Busia, Bungoma, Vihiga, and Kakamega counties.

The country is among three other African countries that will administer the vaccine, known as Mosquirix- RTS,S, to children up to 2 years of age, as part of the country's routine childhood immunization programme. Other countries that are rolling out the vaccine are Malawi and Ghana.

Unveiling the vaccine in Ndhiwa, Homabay county the Cabinet Secretary for Health Sicily Kariuki said the vaccine that will be offered free of charge in all health facilities, is approved, safe and effective.



Health Cabinet Secretary Sicily Kariuki oversees roll out of the world's first malaria vaccine in Nyanza region

Malaria Vaccine in Kenya



Protect your child from malaria
Bring your child for **MALARIA VACCINATION**



Ask your health care provider for more details on eligibility and availability in your area.



“Clinical trials have shown that when used alongside other recommended malaria prevention interventions, fewer incidents of malaria in children and less hospital admissions will be experienced,” she said.

The malaria vaccine, which will be delivered through the routine national immunization programmes, is given at 6 months, 7 months, 9 months and 24 months of age.

To get the most protection, a child who receives the vaccine must get all four doses and continue other practices to prevent malaria, including sleeping under a mosquito net every night and throughout the year.

The vaccine can prevent 4 out of 10 malaria infections and prevent severe malaria by more than 30 percent in the 6-24 months age group.

Accompanied by various development partners and county officials Mrs. Kariuki said Kenya’s new strategic direction for malaria eradication is to have at least 80 percent of people living in malaria-risk areas having access to appropriate malaria preventive interventions.

The vaccine will be rolled out in a phased approach and will be implemented in the eight Counties with the highest Malaria burden of up to 20 percent. These are: Kakamega, Vihiga, Bungoma, Busia, Kisumu, Homa Bay, Migori and Siaya.

The selected sub-Counties in the 8 Counties will have the opportunity to initially introduce the vaccine while the remaining ones will be introduced later.

“I therefore urge parents of children in this age group residing in the selected sub-counties to visit their nearest health facilities or selected immunization sites for vaccination to protect their loved ones from malaria,” she advised.

The CS commended the support from GAVI, the vaccine alliance, the World Health Organization, The Global Fund, UNITAID, PATH and local development Partners in Health for their role in implementation of malaria interventions.

Malaria still remains one of the top 10 causes of death in the country, and a leading killer of children under 5. The prevalence has remained high, with an incidence of up to 27% among children aged less than 5 years, especially in the lake region, where the disease is endemic.

Despite the challenges tremendous progress in the fight against malaria has been made through the scale-up of insecticide-treated mosquito nets (ITNs), indoor residual spraying with insecticides (IRS), and appropriate diagnosis and treatment using artemisinin-based combination therapies (ACTs).

“These interventions have over the last decade reduced malaria prevalence for under-fives reduced to 8 percent from 13 percent,” she said.

Promoting quality of medicines in Kenya

A program funded by the US Agency for International Development (USAID) and implemented by the US Pharmacopeial Convention (USP) dubbed Promoting the Quality of Medicines (PQM) has in the past 10 years supported Pharmacy and Poisons Board (PPB), National Quality Control Laboratories (NQCL), and the Counties to strengthen Kenya National Medicines Quality Assurance system, with the aim of improving people’s access to quality-assured medical products nationwide.

Speaking at the Closeout Event held at a Nairobi hotel on 11th September 2019, the Ministry of Health Chief Administrative Secretary, Dr. Rashid Aman said the partnership between the Kenyan government and USP/PQM has been critical in the monitoring and promotion of quality medical products and health technologies in the country through routine post-market surveillance, adding that they are essential components of healthcare services delivery.



Ministry of Health Chief Administrative Secretary Dr. Rashid Aman speaks at a Closeout event on Promoting Quality of Medicines (USP_PQM)

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Dr. Rashid lauded the USP/PQM program which has yielded key achievements among them; Formation of a Technical Working Group, establishment of 11 sentinel sites, procurement of 11 Minilabs, reinforcing PPB capacity for dossier assessment, medicines quality testing, regular post marketing surveillance, information management and supporting International Accreditation of the NQCL to meet global standards.

“Emphasis will be placed on defining Kenya’s continuous path towards attaining UHC and ensuring that the Kenyan public continuously has access to quality, safe and efficacious medical products and health technologies,” said Dr. Rashid.

The culmination of the program brought together key partners and stakeholders in the project namely; MOH, USAID, USP/PQM, NQCL, NASCOP, NMCP, MEDS, KEMSA, PSK, KEMRI, IGAD, AMREF, ICF MACRO, Health Strat among others to celebrate the achievements gained, forge stronger coordination among the partners and develop a roadmap and way forward post the program.



Participants follow proceedings during the USP_PQM Closeout Event

PPB Board Directors & Management hold strategic planning retreat to improve service delivery



PPB Chairman Dr. Jackson Kioko addresses the Board Directors and Management in Mombasa during the 2020-2024 Strategic Plan retreat.

Strategic planning is a key element of good governance. To enhance service delivery the Pharmacy and Poisons Board, the Board Directors and Management held a retreat on 28th October to 1st November 2019 to develop the 2020-2024 Strategic Plan.

The planning retreat was aimed at ensuring the Board pursues successful activities to achieve its mandate, the Chairman of the Board of Directors Dr. Jackson Kioko, said.

The chairman emphasized the need for teamwork to realign the Board's strategic plans, goals and objectives towards promotion of accountability.

"Ensuring that interventions are of high quality is an intrinsic part of PPB mission," he said.

He also highlighted the need to enhance synergy in the new strategic plan, strengthen internal audit to be able to manage risks, prudent financial management and sensitivity to public communications.

Strategic planning is an important aspect for any organization as it is the foundation for measuring performance, resource mobilization and driving development.

The Board's strategic plan for 2020 provides the management with a roadmap to align the organization's functional activities to achieve set goals.

It will also guide the management discussions and decision making in determining resource and budget requirements to accomplish the set objectives thus increasing operational efficiency.

Pharmacy and Poisons Board holds a stakeholders meeting on Continuing Professional Development (CPD)

By Dr. Wilfred Ochieng, Director Pharmacy Practice and Regulation of Training, PPB



Stakeholders pose for a photo

The constitution of Kenya provides citizens the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care. To gradually realise this right and to progress towards attainment of Universal Health Care (UHC), Kenya needs adequate numbers of well trained and deployed health workforce. Pharmacy practice is an integral part of healthcare and a strong pharmacy workforce integrated in the entire healthcare system is critical for service delivery. Pharmacy and Poisons Board has been working with stakeholders to ensure quality right from

training through to the entire professional life of pharmacists and pharmaceutical technologists.

It is the mandate of PPB to ensure pharmacists and pharmaceutical technologists are fit to practice. Apart from the initial training and registration or enrolment, each licensee is required to engage in adequate Continuing Professional Development (CPD). In recognition of this need, the Pharmacy and Poisons Act was amended in May 2019 to include a requirement of CPD as a mandatory condition for licensure. Whereas CPD guidelines were developed sometime back, licensing of

practitioners has never been fully linked to accumulation of the requisite CPD points. There has been poor uptake of CPD and generally a scarcity of CPD providers approved by the Board. In view of the foregoing, PPB decided to reduce the Continuing Professional Development (CPD) points required for renewal of 2020 practice licenses to 20 points only.

Great progress has been made in the last half of year 2019. PPB invited eligible institutions/companies/individuals to apply for accreditation and develop adequate CPD programmes/activities/events to enable pharmacists

and pharmaceutical technologists meet their CPD obligations. Provision of online CPD activities has also been encouraged to enable wider reach. The number of accredited CPD providers and programmes/activities has grown tremendously. Exponential growth has also been observed with the number of licensees taking up CPD.

In order to support and continuously integrate stakeholder views in the CPD management process, Pharmacy and Poisons Board held a stakeholders meeting at the PPB headquarters on the 4th day of October 2019. Current and aspiring CPD providers were sensitized on the CPD module which is part of regulatory human resource information systems (rHRIS), the online system for management of licensing.



Director Pharmacy Practice and Regulation of Training addresses stakeholders during a sensitization workshop on CPD module.



It is the mandate of PPB to ensure pharmacists and pharmaceutical technologists are fit to practice...

It 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.

The Board also received valuable feedback on the implementation of CPD from the stakeholders. The recommendations were taken to improve the implementation guidelines and the online system. We thank our stakeholders for walking with us as we strive to achieve the bigger goal of providing the highest attainable standard of health and Universal Healthcare.

We commend all the 29 currently approved CPD Providers for taking the lead in this area and encourage more providers to come up for accreditation. The more the approved programmes/activities the richer the basket of activities licensees can pick from to create the individual CPD portfolio for the year. We also encourage early planning and accreditation of both providers and programs/activities to avoid last minute rush.



Dr. Lily Bett engages stakeholders



Capacity building for pharmaceutical regulatory excellence: The Purdue University's MS Program

By Dr. Samuel Kerama, Dr. Ali Arale and Dr. Patrick Kibet Chebeo

The regulatory efforts developed can only produce positive results if more attention is paid to long-term capacity building with an aim of attaining regulatory excellence and fulfil the President's Universal Healthcare Coverage (UHC) through access to quality, safe and effective medical products and health technologies. Successful capacity building depends on improvement of knowledge and competences of individuals.

To achieve its mandate of ensuring quality, safety and efficacy of medical products and health technologies, coupled with its vision of becoming a leading medicines regulatory agency, the Pharmacy and Poisons Board (PPB) invests in staff capacity building through

regular short courses, workshops and specialized tertiary trainings. This is done through various avenues, especially through collaborations and sponsored programs.

In light of the above, three PPB officers were privileged to be sponsored to attend the Purdue University's MS program in Arusha Tanzania, as part of the Bill and Melinda Gates foundation capacity building programs for developing countries.

The program is an MSc degree designed to empower qualified personnel (pharmacists and industrial chemists) to regulate and manufacture quality medicines in Africa. The current cohort is supported by the Bill and Melinda Gates

foundation, with technical support from the PURDUE university (USA) and the Merck foundation.

The program admits qualified persons from across the African continent, with Kenya having a sizeable representation from the Pharmaceutical industry, Academia, community pharmacy and Pharmaceutical regulation.

The Master's program focuses on creating leaders in Biotechnology Innovation and Regulatory Science (BIRS) in relation to pharmaceuticals, medical devices and research. The topics offered address innovation and integrate emerging technologies.



PPB officers, Dr. Samuel Kerama, Dr. Kibet Chebeo and Dr. Ali Arale in Arusha TZ for the Purdue University's MS program

COURSE CONTENT AND DELIVERY

The program has been tailored to meet current trends in pharmaceutical manufacturing, regulation and trade. It is delivered as a blended online and live program in USA and Africa. This involves online sessions and face-to-face sessions that meet current sector trends.

As participants, we have drawn great knowledge, skills and expertise from the Purdue University's faculty and industry experts who have been delivering lectures and practical sessions in; Drug development and registration, Good regulatory practices, Manufacturing and quality control, Global supply chain management, Measurement and evaluation in industry and technology, Quality and productivity in industry and technology, Project management, Global technology, Medical device and vaccines regulation, Emerging world class leadership strategies and Research project

With the knowledge and skills attained, coupled with our research topics that are operational based, we are better equipped for our regulatory assignments (Product evaluation, Good manufacturing processes and Good distribution practices) and we endeavor to be change agents in regulation as we offer service to the great nation of Kenya and to the global citizens.

We look forward to the upcoming sessions and our eventual graduation after successful completion of the program in March 2020.

Our gratitude goes to;

1. *The Pharmacy and Poisons Board (PPB) for the opportunity offered to us and the support offered towards our stay during the sessions. We look forward to the support through the remaining sessions.*
2. *The BILL AND MELINDA GATES FOUNDATION who have graciously sponsored the current cohort through funding the costs of tuition and study materials including lab facilities.*
3. *The Purdue University, led by Prof. Kari, Prof Byrn, and all the faculty, industry experts, Merck Fellows and Sis. Zita who have all played a role in making this experience worth the while.*
4. *Our fellow course mates from Kenya and across the continent with whom we have shared experiences and comradeship.*
5. *The people of the United republic of Tanzania who have and continue to be wonderful hosts.*

Access to medicines critical to achieving UHC, PPB CEO says



PPB CEO Dr. F.M.Siyoi speaks at Pharma Logistics Africa (PLA2019) forum

Access to affordable quality medicine is a key mandate of the PPB and hence a strong, quality, effective and efficient procurement logistical system is critical for achievement of primary healthcare, as the basis for Universal Health Coverage, the Pharmacy and Poisons Board Chief Executive Officer, Dr. F.M. Siyoi noted said on Wednesday September, 30, 2019 during the opening of a two -ay Pharma Logistics Africa (PLA2019) forum in, Nairobi on.

The PLA2019 forum themed “A sustainable Advanced Supply Chain,” provided a platform for key Government agencies from AU Member States, Regional Economic Community leaders, like AUDA-NEPAD, United Nations, NGOs, International Agencies, Pharmaceutical manufacturers and Logistics Companies to share knowledge, best practices, new technologies and services capable of furthering the continents efforts for sustainable advanced supply chain.

The forum speakers included Alfons Can Woerkom, the Head of Supply Chain The Global Fund to fight Aids, Tuberculosis & Malaria, Dr.Isabella Ayagah , Head of Global Health Security Ministry of Health & National Focal Person Eastern Africa Regional Collaborating Centre (RCC), Dr. Ngoy Nsenga, WHE Programme Team Lead for East and Southern Africa WHO and Paul K.Tanui, Senior Programme Officer African Medicines Regulatory Harmonisation (AMRH)programme among others.

President applauds public private partnerships to improve healthcare

The Cabinet Secretary for Health Sicily Kariuki opened the 8th East Africa Healthcare Federation Conference on September 5, 2019 at Nairobi Safari Park Hotel on behalf of H.E. President Uhuru Kenyatta.

The 8th East Africa Healthcare Federation Conference provided

a platform for sharing experiences and lessons, developing partnerships and contributing to the betterment of health and the realization of UHC in the East African Community.

In his speech the President also acknowledged the role of the Public Private Partnerships in complementing government initiatives in health service delivery especially in the case of Universal Health Coverage (UHC) and cost of healthcare.

He said Kenya has realigned its healthcare system focus towards achieving Universal Health Coverage (UHC) by the year 2022, one of the government's Big Four priority agenda for development that is aimed at ensuring that no Kenyan undergoes financial hardship while seeking health care.

The Government he said has also invested in development of the East African Kidney Institute which is under development in Nairobi to improve health outcomes.



Health Cabinet Secretary Sicily Kariuki presents her speech during the opening of the 8th East Africa Healthcare Federation Conference in Nairobi.

“This is an EAC investment which is in tandem with ongoing capacity building expected to improve access to quality health care services for renal patients from countries in the region,” he said.

He also mentioned the implementing of the Managed Equipment's Service project an initiative of the national government which he said has enhanced diagnostic and specialized treatment capacity across the 47 counties.

“It is now possible to get kidney dialysis and mammography services at the County health facilities. So far II ICU centres have been distributed in the regions,” he noted.

Kenya also has registered commendable decrease in Maternal mortality rates down to 362/100,000 population thereby averting 2000 maternal deaths per year. Under-five mortality has reduced by over 50 per cent, HIV prevalence has reduced from 6 percent to 4.9 percent, TB treatment has increased from 80 to 90 percent and malaria prevalence for under-fives has reduced to 8 percent from the previous high of 13 percent.

The Free Maternity Programme which was introduced by the national government has led to an additional 600,000 deliveries under skilled care every year since inception in 2013.



Health Cabinet Secretary Sicily Kariuki tours exhibition stands during the 8th East Africa Healthcare Federation Conference

PPB Engage Medical Technology Industry committee

The Pharmacy and Poisons Board Medical Devices team on October 8th, 2019 met with the Medical Technology Industry Association of Kenya (MEDAK) committee members with a view of sharing the new developments that have been ongoing.

MEDAK will be the umbrella body representing the medical technology industry and ensure regulatory compliance through engagement between the regulator and Industry.

Speaking at the event Dr Paulyne Wairimu, a technical expert from the Board, expressed willingness to work with the new MEDAK team on creating an enabling environment for the regulatory framework of Medical Devices in Kenya.

The MEDAK team included Dr. Mercy Njuguna (Chairperson), Njambi Ouattara, (Secretary), Dr. Morris Mbulo, Dr. Wairimu Mbogo and Dr. Eva Maina.



Committee members from Medical Technology Industry Association of Kenya (MEDAK) pose for a photo with PPB staff

PPB expands the Expert Committee on Clinical Trials (ECCT)



Expert Committee on Clinical Trials (ECCT) pose for a photo

The Pharmacy and Poisons Board has expanded the Expert Committee on Clinical Trials (ECCT) by adding more disciplines in the review process in a bid to strengthen the regulatory review of clinical trials applications and assist with the monitoring of the ongoing trials.

The decision was arrived at due to the increasing complexity of investigational products and clinical trials being undertaken in Kenya. As science changes rapidly so does research.

The seven new ECCT members joined the existing five to make a total of 12 experts. The increase in the numbers and expertise will aid the Board in the quality of clinical trials applications review and meeting of the promised timelines as per the client's service charter.

Pakistan High Commissioner in Kenya visits PPB

The High Commissioner for Pakistan to Kenya Saqlain Syedah and Trade Development Officer Mahvish Malik paid a courtesy call on the PPB Chief Executive Officer, Dr. F. M. Siyoi on 18th September 2019.

The meeting centered on understanding the Pharma Regulatory framework and ways to explore future collaboration between the two countries business community.

A similar meeting was held in September 27, 2019 when delegates from Pakistan toured PPB to understand the pharmaceutical product registration process and perceptions of their products in the Kenyan market.



The High Commissioner for Pakistan to Kenya Saqlain Syedah engages the PPB CEO at his office

PPB hosts High-Level Government officials from Nigeria

The Pharmacy and Poisons Board, Chief Executive Officer, Dr. F. M. Siyoi on July 30, 2019 hosted High-Level Government officials from the Federal Republic of Nigeria who were in the country for a study tour titled 'Funding Universal Healthcare Delivery in Nigeria.'



High-Level Government officials from the Federal Republic of Nigeria at PPB for a study tour

The officials drawn from a wide range of state ministries, departments and agencies visited PPB to familiarize with the role the Board plays in realization of UHC in Kenya and its linkages with other agencies like the Kenya Medical Supplies Authority among others.

EAC NMRA's visit PPB

The Pharmacy and Poisons Board, Chief Executive Officer Dr. F. M. Siyoi on August 28, 2019 hosted a delegation of the Heads of East African Community National Medicines Regulatory Authorities (EAC NMRA's).

The EAC delegation was drawn from the Republic of Kenya, the Republic of Burundi, the Republic of Rwanda, the United Republic of Tanzania, Republic of South Sudan and the Republic of Uganda.



East Africa Community Deputy Secretary General, Hon. Christophe Bazivamo addresses a delegation of the Heads of East African Community National Medicines Regulatory Authorities at PPB



The team led by the East Africa Community Deputy Secretary General, Hon. Christophe Bazivamo, affirmed their position in adopting regulatory GMP outcome and inspections reports from other EAC NMRA's in an effort to reduce the timelines and cost of introducing medicines of priority to EAC market.

Present in the meeting were the industry representatives from both local and international companies who applauded the teams leadership role in reaching the noble decision of regulatory convergence to avoid duplication of efforts.

Representatives from USAID/Kenya and East Africa

On September 9, 2019 the PPB CEO, Dr. F. M. Siyoi hosted USAID/Kenya and East Africa, Chief of Health Population and Nutrition Office (HPN), Mr. Randolph Augustin and Mildred Shieshia, PMI Resident Advisor for an update of the support they have been offering the Board in monitoring the quality of medicines in the country for the past ten years. They also discussed areas of possible future collaborations.



Representatives from USAID_Kenya and EAC engage with the PPB CEO

PPB CEO meets WHO team on Ebola Preparedness

The PPB CEO, Dr. F. M. Siyoi held talks with the World Health Organisation Kenya officials led by Dr. Sarah Bennett from WHO headquarters on September 4, 2019.

The officials who were accompanied by Dr. Kadondi Kasera, the Head of Public Health Emergency Operation Centre, Ministry of Health, discussed Kenya's preparedness to handle Ebola Virus Disease (EVD) in case of an outbreak.

Currently, there is an outbreak of EVD in the Democratic Republic of Congo and the country is putting additional mechanisms to address any possible outbreak.



WHO representatives pose for a photo with PPB CEO Dr. F.M.Siyoi

Tunisia Delegates visit PPB



A delegation from Tunisia during a meeting with the Director of Inspectorate Surveillance and Enforcement, Dr. Jacinta Wasike

A delegation from the Tunisia Union for Industry, Trade and Handicrafts (UTICA) on October 16, 2019 visited the Pharmacy and Poisons Board to explore and understand the Pharma regulatory environment in Kenya.

The delegation led by Mr. Tarek MEJAOUEL, in charge of Development & International Cooperation in African Countries, met with the Director of Inspectorate Surveillance and Enforcement, Dr. Jacinta Wasike.

They discussed possible areas of partnerships and investment particularly in the pharmaceutical sector.

Showcasing at the Kenya Revenue Authority

5th Annual Tax Summit

PPB exhibited at The Kenya Revenue Authority - 5th Annual Tax Summit that took place at KICC between 16th & 17th October, 2019 in recognition of the collaboration towards enhancing trade facilitation in the country and combating illicit trade. The theme of the event was “*Tax Simplification and Inclusivity to Facilitate Trade and Economic Transformation.*”



PPB staff pose for a photo during the 5th Annual Tax Summit at KICC

Focus on Mombasa International Trade Fair

The PPB showcased at the Mombasa International Trade Fair Themed “Promoting Innovation and Technology in Agriculture and Trade.” The event which was held between 4th to 9th September, 2019 provided a platform for the Board to interact with the members of the public face to face.



Drug Inspector Mr. Yusuf Ndimba sensitizes visitors at the Mombasa ASK Show 2019

Showcasing at Medical Expo and Conference 2019 (AMEC)

On August 29th, 2019 the Pharmacy and Poisons Board took part in the Africa Medical Expo and Conference 2019 (AMEC) which was held at the Nairobi Hospital Convention Centre.

The event “Our Health, Our Wealth: Partnerships and Innovation Towards Universal Health Coverage” was the first in Africa to bring together International, Regional health and medical industry, the youth and medical professionals in the continent to network.

It also provided an opportunity for direct market linkages, mentorships, exchange programs, partnerships and networking with local and international investors to chart the way forward for Africa’s health systems towards Universal Health Coverage.



Drug inspector Mr. John Muinami engages visitors during the Africa Medical Expo and Conference 2019 (AMEC)

PPB Exhibits at the 8th East Africa Healthcare Federation (EAHF) Conference



Health Cabinet Secretary Sicily Kariuki addresses participants at the 8th East Africa Healthcare Federation (EAHF) Conference

On September 5, 2019 the Health Cabinet Secretary Sicily Kariuki officiated the opening of the 8th East Africa Healthcare Federation (EAHF) Conference under the theme “From Strategy to Action: Advancing Healthcare Systems in the SDG era.”

The two-day conference which took place at Safari Park Hotel, Nairobi brought together policy makers, government leaders, health advocates and entrepreneurs in the healthcare industry across the region.

The EAHF Conference constitutes the ideal platform to collaborate in addressing the most pressing healthcare issues facing the East and the wider Africa in a bid to create a strategy for amplifying financing and quality measures to achieve Universal Health Coverage.

PPB Carries out tree planting in Machakos and Nyeri offices

The President's pronouncement of a new national tree-planting drive at the beginning of his second term demonstrated the Government's commitment to reversing the country's worrying levels of deforestation.

On 20th - 21st August 2019 the PPB staff joined the new campaign and took the initiative to plant trees at Machakos and Nyeri regional offices respectively to increase the government coverage to plant an additional 1.8 billion trees in the next five years.

Conservation of trees for a green environment with added economic and medicinal values is of great necessity particularly to PPB. Under this, every staff will be expected to plant and continuously monitor the progress of a tree to ensure it survives to its maturity



93 Illegal Chemists Closed in Coast Region



Dr. Dominic Kariuki PPB head of Good Distribution Practices and Ports of Entry and Pharmaceutical Inspectors at Pharmacy and Poisons Board during a press briefing in Mombasa

A total of 71 illegal chemists in Coast Region have been closed, stocks seized and owners arrested during a crackdown carried out by the Pharmacy and Poisons board (PPB) pharmaceutical inspectors and the police under the Coast Regional Commissioner on Wednesday November 6, 2019.

Among those arrested include operators of mobile clinics using vehicles with assorted drugs and sound systems, the head of Good Distribution Practices and ports of entry, Dr. Dominic Kariuki said during a media briefing.

Out of the 71 cases 49 have been taken to court, of which 20 pleaded guilty and were given fines ranging from sh.10,000 to sh.60,000.

The charges included possession of poisons contrary to section 26(1) of the pharmacy and poisons act, carrying on the business of a pharmacist/ pharmaceutical technologist contrary to section 19(1a) of the pharmacy and poisons act and section 23(1) respectively.

Dr. Kariuki said the details of the non-compliant outlets have been shared with the regional commissioner for enforcement of the closures.

“The major challenge we are facing is licensed wholesalers who are supplying illegal chemists,” Dr. Kariuki noted and warned that the identified wholesalers will face the necessary disciplinary action.

He also lamented over lenient court fines imposed on the accused persons which he said are not deterrent enough.

He also added that access and security concerns in the coast region have been a major challenge leading to proliferation of the illegal drugs in the region.

He directed all pharmacy outlets and hospitals with expired drugs to safely quarantine them and get in touch with the regional inspectors of Pharmacy and Poisons Board for safe disposal.

“We have also distributed mini labs to regional offices for random sampling and testing of medicines in the market to ensure they are of good quality, safe and efficacious,” he said.

The PBB has also launched guidelines for good distribution practices, transportation and disposal of pharmaceutical waste which are available at the boards website www.pharmacyboardkenya.org

He called on members of the public to use health safety codes displayed in registered pharmacy outlets to verify legality of the premises they get medicines from by sending a message to the 21031 charge free code.



Some of the drugs confiscated by the Pharmacy and Poisons board during a crackdown in coast region



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



LICENSED PHARMACY
HEALTH SAFETY CODE:

XXXXX

TO VERIFY
SEND CODE TO 21031

www.pharmacyboardkenya.org

Be safe. Buy medicines from a licensed pharmacy

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

- 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
- Pass Information anonymously to the board through complaints.pharmacyboardkenya.org



The New Internship Guidelines for Pharmacists



Participants pose for a photo after a consultative workshop to discuss the draft internship guidelines for pharmacists

The Pharmacy and Poisons Board (PPB) being the National Medicines Regulatory Authority of Kenya is mandated to protect the health of the public by regulating the profession of pharmacy. The Board does this by ensuring the availability of pharmaceutical services in Kenya, which satisfy the requirement of all for the prevention, diagnosis and treatment of diseases using safe, efficacious, high quality and cost-effective medical products and health technologies.

On 18th October 2019, the PPB held a stakeholder engagement meeting attended by key stakeholders in the pharmaceutical sector to discuss the internship guidelines for pharmacists. In attendance were representatives from the Ministry of Health (MOH) Pharmaceutical Society of Kenya (PSK), Mission for Essential Medicines (MEDS), Kenyatta National Hospital (KNH), Kenya Pharmaceutical Distributors Association (KPDA), University of Nairobi (UoN), Kenyatta University, USIU Africa,

Kenya Methodist University and County Pharmacist Forum representatives from Nyandarua, Laikipia, Embu, Samburu, and Isiolo.

Internship is a compulsory experiential learning supported by the national Government under the Ministry of Health that is intended to provide pharmacists with an opportunity for consolidating and integrating knowledge acquired during college studies with clinical work experience. It is designed to allow graduates enhance their professionalism and gain career knowledge through hands on training for a period of 12 months and acquire skills to be competent pharmacists and is mandatory for one to be registered as a pharmacist by the Pharmacy and Poisons Board.

The meeting was officially opened by the Chief Executive Officer, Dr. F.M. Siyoi, who highlighted the importance of internship as an integral part of pharmacist professional training in view of the directive by the Government to all regulatory bodies to send

interns to primary healthcare facilities.

The CEO noted that the internship guidelines will go a long way in supporting the national aspirations to achieve Universal Health Coverage (UHC) by focusing on primary healthcare preventive health than curative health.

Speaking during the event the Director of Pharmacy Practice and Regulation of Training, Dr. Wilfred Ochieng said the development of the guidelines was informed by new emerging issues in particular the expansion of hospital rotation to include placement of pharmacists in Primary Health Care (PHC) for eight weeks which previously wasn't there, expansion of industrial pharmacy sites to include manufacturing industries, supply chain management institutions, pharmaceutical Quality Control Laboratories and the inclusion of more community pharmacies as internship centers as follows;



PPB CEO Dr.F.M.Siyoi engages stakeholders during a consultative workshop to discuss the draft internship guidelines for pharmacists

Rotation	Duration	Sites
Hospital Pharmacy	Six months (24 weeks)	Level 4,5 and 6 hospitals (Comprehensive primary care and secondary care hospitals; national comprehensive and specialized teaching and referral hospitals)
Primary Health Care	Two months (8 weeks)	Primary healthcare facilities; KEPH level 1 (community services); level 2 (dispensaries and clinics) ;and level 3 (health centers)
Community Pharmacy	Two months (8 weeks)	PPB approved community retail pharmacies
Industrial Pharmacy	Two months (8 weeks)	PPB approved drug manufacturing industries, Supply Chain Management Institutions and Pharmaceutical Quality Control Laboratories

Proposed Internship Structure in summary



PPB halts importation and prescription of Ranitidine products

On August 2019 the Pharmacy and Poisons Board received and reviewed information on the contamination of ranitidine products with genotoxic N-nitrosodimethylamine (N-NDMA) impurity and based on the Board's core mandate of ensuring the safety of Kenyans, the Board decided that;

- a) All ranitidine containing products shall be recalled (level 2 recall; recall up to retail pharmacies) and quarantined by their respective marketing authorization holders (MAHs) until proven to be safe.
- b) There shall be no more importation of the ranitidine products into the country or sale of ranitidine containing products pending conclusion of regulatory investigations.
- c) Doctors should prescribe the available alternatives and patients should also use alternative medicines.



Recall of Sure Lubricated condoms Dotted



The Pharmacy and Poisons Board (PPB) in collaboration with the National STI and AIDS Control Program (NAS COP) conducted a joint post-market surveillance quality survey of selected medical products and health technologies used in Kenya this year.

Among the products that were sampled and tested were male latex condoms which failed to comply with specification (s) for ISO 4074:2015 standard;

1. **Name of Product:** SURE LUBRICATED CONDOMS DOTTED
Batch Numbers: 17DN052, 17DN754
Manufacturer: Innolates (Thailand) Limited
2. **Name of Product:** SURE LUBRICATED CONDOMS
Batch Numbers: L48058, P48045, P48001, L48037, P48027, L48110
Manufacturer: HLL Lifecare Limited, INDIA
3. **Name of Product:** SURE LUBRICATED CONDOMS
Batch Numbers: 1601957422
Manufacturer: Suretex Prophylactics (India) Limited

The non-compliance is BATCH SPECIFIC and does NOT impact the entire product of SURE CONDOMS.

PPB has put in mechanisms to ensure quality and safety of condoms circulating in Kenya in addition to ordering recalls of all the affected batches of the SURE condoms.



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 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



REPUBLIC OF KENYA
MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

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



- 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

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