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MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

MAGAZINE

PPB, a regional champion in Pharmacovigilance

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

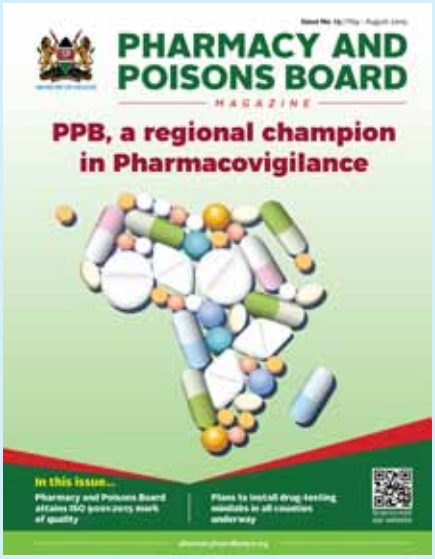
The Pharmacy and Poisons Board (PPB) is the National Medicines Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244, Laws of Kenya. The PPB is mandated to regulate the practice of pharmacy and the trade in medical products and health technologies.

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

The Pharmacy and Poisons Board (PPB), was established to promote and protect public health by ensuring that medicines, medical devices and other health technologies are safe, efficacious and of accepted quality. This type of initiative is considered relevant and a priority for Kenya.

Over the last years, the implementation of medical products traceability systems and mechanisms has been identified by National and Regional Regulatory Authorities as a useful and efficient tool to fight against the falsification and illicit distribution of medical products.

The adoption of a unit-of-sale-based traceability system for medical products brings about a series of advantages, namely:

- It helps to ensure that authorized medical products circulate only in the legal supply chain;
- It provides safety to patients who use medical products, by reducing the risks associated with SSFFC medical products, such as intoxications, adverse effects, increased number of hospitalization days, lack of response to treatment, need for alternative treatments, and even death;
- It prevents the entry and circulation of stolen and smuggled products into the legal supply chain;
- It prevents the distribution and/or dispensation of expired, prohibited or recalled products;
- It helps to ensure free medical products samples are delivered to their intended recipients;
- It favours efficient, fast and safe market recalls;
- It enables the collection of pharmacoepidemiological data and development of specific strategies based on such information;
- It favours an efficient supplies management at all health system levels;
- It contributes to reducing the expenditure on health stemming from inappropriate or unnecessary procedures such as the procurement of SSFFC medical products and the cost burden placed on the health system as a consequence of their administration

Using new innovations, we believe we can improve the overall security of PPB system and improve our ability to prevent the introduction of illegitimate products, better detect the introduction of illegitimate products, and enable stakeholders and the PPB to respond more rapidly when such products are found.

Happy reading!

Judy

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

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Pharmacy and Poisons Board attains ISO 9001:2015 mark of quality

From left: MoH Director General (Ag) Dr. John M. Wekesa, PPB Chair Dr. Jackson Kioko and PPB CEO Dr. Fred Siyoi lead other stakeholders in launching the ISO certification

The Kenya medicines regulatory authority -Pharmacy and Poisons Board (PPB), has received a quality management system (QMS) 9001:2015 certification, having met the requirements of the international standard for quality management systems. The certificate was awarded and presented to PPB by the Kenya Bureau of Standards, one of the ISO 9001:2015 certification agencies in Kenya.

The 9001:2015 ISO certification makes Pharmacy and Poisons Board one of the four national drug regulatory authorities out of seven in the East African Community (EAC) to be ISO 9001:2015 certified.

This implies that ISO certified national medicines regulatory authorities meet the ISO (International Organization for Standardization) (ISO 9001: 2015 is the 5th edition (4th Revision) of the standard) which can form the basis for harmonization and mutual recognition of regulatory outcomes, that can be used to make regulatory decisions and promote ease of doing business. It will also provide a platform for continuous improvement, and delivery of consistent and quality regulatory outcomes.

Speaking at the official hand over ceremony of the PPB ISO 9001:2015 certificate on behalf of the Health Cabinet Secretary Sicily Kariuki, Dr. John Masasabi Wekesa said that the attainment of the standardization and compliance to ISO 9001:2015 will offer convenience to both international and local markets.

"PPB attainment of ISO 9001:2015 certification is a proof of consistency in delivery of services that meet both legal, regulatory and customer requirements," he said.

Dr. Fred M. Siyoi, Chief Executive officer (CEO), PPB, said the ISO certification will not only help in enhancing PPB regulatory mandates but also in achieving efficiency in customer service delivery and promotion of both regional and international trade of pharmaceutical products, health technologies and free movement of personnel.

"The implementation of ISO 9001:2015 International Standard requirements will help in removing trade barriers and ensure free movement of pharmacy personnel as it was one of the requirements for harmonization within all the regulatory authorities in the East Africa Community (EAC) to ensure that the systems, products and services offered across board met regulatory requirements of other partner States within the region and internationally," he said.

He explained that PPB's journey to attain the ISO certification started in 2012, with the realization that the EAC community had to standardize their regulatory procedures/systems and the only way that they could achieve a harmonized system was through attainment of ISO standards.

PPB Board Chairman, Dr. Jackson Kioko, said that the attainment of the ISO 9001:215 is major milestone

in regulation as it will assure Kenyans of quality drugs, translating to improved health outcomes, quality of life and a productive citizenry.

"PPB business re-engineering started in 2010, in 2014 the quality management department was constituted with only one member of staff with an aim to establish a fully-fledged quality management and a functional registry and establish quality management systems in all the regional offices," he said, adding that "good governance and accountability has been critical in attainment of the ISO certification.

Dr. Kioko further explained that there is need for national drug regulatory authorities to strike balance between effective regulation and access, saying that if the balance is not met it might hinder universal health coverage goals of provision of affordable and accessible quality healthcare.

"We are aware that the main objective of regulation is to safeguard public health by making available safe, effective and quality essential medicines and health technologies. However, this can slow down access hence we are careful as a board to strike a balance between access and regulation in order to contribute to Universal Health Coverage (UHC) goals," he said during the launch.

PPB CEO Dr Fred Siyoi (right) and PPB Board Chair Dr. Jackson Kioko (second right) together with other guests celebrate ISO certification

Dr. Henry Rotich, Director Metrology and Testing, Kenya Bureau of Standards said that ISO 9001:2015 will enhance PPB efficiency and improve customer satisfaction and go a long way in realizing PPB vision to be center of excellence in regulation of pharmacy profession, medical products and health technologies.

"The attainment of ISO 9001:2015 is assurance that PPB will implement the regulatory measures with an aim of achieving highest standards of safety, efficacy and quality for all drugs, medical products and health technologies that are locally manufactured, imported, distributed, sold or used to ensure the protection of consumers as envisaged by laws regulating drugs in Kenya," he said.

PPB staff pose for a photo with CEO and board Chairman during the launch

Medicines track system underway

Pharmacy and Poisons Board CEO Dr. F.M. Siyoi addresses participants during the media roundtable meeting in Nairobi

The Pharmacy and Poisons Board (PPB) is currently working on medicines track and trace system that will ensure that all medical products and health technologies in the market have a tracing number.

The system which is being developed by PPB and various stakeholders will make it easy for the Board to identify the country of origin, manufacturer and batch of medical products and health technologies.

The revelations were made on 23rd July, 2019 by the PPB, Chief Executive Officer, Dr. F.M. Siyoi during a media roundtable event at a Nairobi Hotel that drew leading health journalists from Nation Media Group, Royal Media Services, Standard Group, Medical Media Services, Radio Africa Group, as well as journalists from international media.

The CEO said PPB is now 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 (VIGIFLOW) is now a benchmark for good pharmacovigilance practices. Countries such as Tanzania, Zimbabwe, Somalia, Ethiopia, and Afghanistan have visited our offices for benchmarking," he noted.

Currently, Kenya is the sixth African Country in reporting individual case safety reports (ICSRs) to the international database and is the Lead country in Pharmacovigilance and Post Marketing Surveillance within the East Africa Harmonization under the AMRH initiatives.

He also noted that the Board has embraced the use of ICT in strengthening regulatory activities becoming the first drug regulatory authority in Africa with online systems with for regulation of medical products in accordance with the world health organization (WHO) regulatory documentation package and other relevant International guidelines and standards.

Among the systems the Board has embraced are the handheld Raman Spectrometers used by pharmaceutical inspectors to conduct instant drug tests at the ports of entry as well as during routine inspections and application of GPS based registration process for premises and their location.

"Use of ICT, such as availing reporting tools online, has made it easy for Kenyans to report ADRs," he noted.

Currently, the regulation of the pharmacy professional is online and the Board has also rolled out a Health Safety Code 21031 that allows Kenyans to verify registration status of the premises and that of superintendents before purchasing medicines.

Participants follow proceedings during the media roundtable meeting

Strengthening partnership through stakeholders engagement: Coastal region

The Pharmacy and Poisons Board (PBB) Members and Senior officials held stakeholder engagement meetings in Mombasa and Kilifi Counites in May 2019.

During the occasion the officials conducted facility visits and closed several pharmaceutical outlets that were illegally selling medical products to consumers.

"This is part of the cooperative effort, to protect the health of the public by combating the unlawful sale and distribution of medical products by unregistered outlets and personnel,"said PPB Chairman, Dr. Jackson Kioko,

Dr. Kioko who was accompanied by PPB Board Member Dr. Mary Kisingu, PPB Chief Executive Officer (CEO), Dr. F. M. Siyoi among others closed down GetWell Pharmacy outlet in Bamburi for carrying out operations without a valid licenses from the PPB plus an illegal clinic.

He observed that consumers are being put at risk by individuals who put financial gains above patient safety, and the Board will not relent until all the illegal premises are closed down.

He also put on notice the absentee superintendents who leave their licensed pharmacies in the hands of quacks or unqualified people putting Kenyans lives in danger.

"The Board has introduced the use of closure notices with unique serial numbers that will be displayed on the doors of affected chemists. The notices act as a warning to members of the public to keep off such chemist and we are advising members of the public to use the Health Safety Code displayed in registered chemists to verify their legality," he said.

PPB Chairman Dr. Jackson Kioko inspects Mevida chemist in Bamburi. The team closed Get Well Pharmacy in the same area operating illegally

PPB senior officials and pharmaceutical stakeholders during the stakeholder meeting in Mombasa County

The PPB CEO, Dr. Siyoi noted that the Board provides consumers with information on how to identify a legal pharmacy and how to buy medicine safely through the Health Safety Code, which can be assessed through a free mobile phone SMS code 21031.

The code enables any customer to ascertain the identity by name and location of legitimate pharmacists who are registered by the PPB. The free SMS code 21031 gives all the registration details of legitimate pharmacists, their premises location and aims at weeding out quacks who run illegal pharmacies or chemists that are not registered by PPB and are endangering the lives of the public, he said.

"The SMS code banner should particularly be displayed on the windows of all pharmacies premises and customers should always verify the authenticity of the outlet using the displayed banner SMS code before buying medicines," he said and advised the practitioners to pick their Banners from the Board.

Dr. Kioko also advised all practitioners who have not renewed their premise or practice license to do so. He informed the stakeholders that the Board was reviewing the guidelines on Good Distribution Practices to ensure effective regulation of pharmacies and control of the pharmacy profession.

PPB Chairman Dr. Jackson Kioko, PPB CEO Dr. F. M. Siyoi and Board Member Dr. Mary Kisingu

Eastern region

Meru County stakeholders pose for a photo with the PPB team at Alba Hotel, Meru

The Pharmacy and Poisons Board (PPB) senior management paid a courtesy call on Embu County CEC for health services, Dr. Jamleck Muturi and Eastern Regional Police Coordinator, Ms. Eunice Kihiko on 14th May 2019.

The purpose of the visit was to familiarize with the Board's regional activities and to strengthen stakeholder engagement to support attainment of Universal Health Coverage (UHC) agenda to deliver quality affordable health services to Kenyans.

Dr. Jamleck applauded PPB for sustained efforts in ensuring the quality, safety and efficacy of medicines in the county of Embu and promised the county's commitment to support the PPB to weep out unqualified personnel from dealing with medicines.

He said there is need for a sustained collaboration framework to intensify inspection, surveillance and enforcement.

The Eastern Regional Police Coordinator also called for collaborative efforts by all government agencies. "We can always use the commanders on the ground for enforcement guided by an agreed action plan," she advised.

PPB Board Member, Dr Rogers Atebe said the Board is engaging key stakeholders to discuss the challenges facing the pharmaceutical sector to resolve them.

Dr. Atebe who was accompanied by Board members Dr. Alfred Birichi and Mr Abdi Jama urged the various stakeholders in the county to remain loyal to their profession, be vigilant and always report non-professionals operating within their vicinity through "nyumba kumi" model to info@pharmacyboardkenya.org

All the stakeholders commended the Board for reviving the Enquiries and Disciplinary Committee (EDC), which is key in ensuring discipline to the profession.

Present in the stakeholder's forum were PPB Directors Dr. Jacinta Wasike and Dr. Stephen Kimathi, County Pharmacist, PSK & KPA members in the public and private sector.

On 15th May 2019, the Pharmacy and Poisons Board members and senior management paid a courtesy call on Meru County CEC member, department of health services, Mr. Misheck Mutuma to explore areas of collaboration.

The discussion centered on modalities on how devolved units can be engaged to ensure quality medicines are dispensed to the public by qualified personnel.

Mr. Mutuma thanked the Board for the initiative and urged PPB to increase surveillance in the region because it has a high population to ensure the medicines are of good quality, safe and efficacious.

The PPB Board Member, Dr. Birichi emphasized the need for a collaborative framework between the PPB and the county government with focus on key areas with challenges namely drug abuse; substandard medicines and unqualified personnel who are dispensing medicines.

He also urged the county government to always ensure that the suppliers of medicines are duly licensed by PPB.

The Board also held discussions with key stakeholders in the region drawn from the County Government, PSK, KPA, Public & Private Hospitals and the Judiciary.

The Director of Medicines Information and Pharmacovigilance Dr. Stephen Kimathi welcomed the participants on behalf of the Board CEO, Dr. F. M. Siyoi and noted the importance of stakeholder engagement as a key aspect for policy considerations. The meeting also delivered on the need to create focal points at the county referral hospitals.

Embu region stakeholders group photo during the Board members regional visits

Post marketing surveillance and pharmacovigilance workshop

The Pharmacy and Poisons Board Chief Executive Officer (CEO) Dr. F.M. Siyoi opened the Technical Working Group (TWG) Workshop on post marketing surveillance and pharmacovigilance at the Board officers on Lenana Road on 2nd April, 2019.

TWG works together with the Board to ensure quality, safety and efficacy of medical products and health technologies in a bid to build and maintain confidence of citizens in the healthcare systems.

At the event the CEO emphasized that National Medicines Regulatory Authority for Kenya, PPB carries out regular post marketing surveillance of medical products and health technologies circulating in the Kenyan market towards ensuring patient safety.

He thanked the United States Pharmacopoeia/ Promoting the Quality of Medicines Program (USP/PQM) for collaborating with PPB in monitoring the quality of medicines and specifically anti-malarials for the last nine years since 2009.

Participants engagement session during the Technical Workshop Group (TWG) on post marketing surveillance and pharmacovigilance at PPB offices.

"This has helped to build the capacity of PPB in the use of minilabs in screening of antimalarial medicines," he noted and urged the participants to share ideas on to how to improve and carry out PMS and PV activities for greater impact to Kenyans and their health.

Engaging stakeholders

To ensure quality, safety and efficacy of medicines in the market the Pharmacy Board held a stakeholder engagement forums with several government agencies in Garissa County.

The forum was aimed at creating awareness about the mandate of the Board plus enhancing protection of public health through partnerships.

Among the critical issues that were discussed includes pharmaceutical drugs abuse specifically codeine containing formulations and Cozepam tablets commonly referred to by the locals as "Taptap."

In attendance was the Deputy Governor Garissa County, Abdi Dagane, County Health Management Team, representatives from Pharmaceutical Society of Kenya (PSK), Kenya Pharmaceutical Association(KPA) and County security team headed by the County Commissioner.

Stakeholders engagement session in Garissa County

Public awareness campaign kicks off

Dr. F. M. Siyoi, CEO PPB flags off public sensitization campaign on 21st May 2019

The Pharmacy and Poisons Board (PPB) has kicked off a sensitization campaign aimed at encouraging the public to only buy medicine from registered outlets in the country.

The campaign, packaged in a series of roadshows set to be conducted country wide, kicked off in Nairobi's informal settlements where PPB staff reached out to the public to report suspected unregistered outlets in the areas.

PPB Chief Executive Officer, Dr. Fred Siyoi while flagging off the roadshow revealed that the Board is planning to conduct joint inspections of health facilities with other health regulatory authorities to ensure that the public access quality medical products.

Dr. Siyoi warned illegal chemist/ pharmacy owners of immediate prosecution and closure of businesses adding that PPB is involved in a continuous inspection exercise aimed at weeding out illegal premises and practitioners.

He also urged the public to report any suspected Adverse Drug Reactions (ADRs) or poor-quality medicines adding that such reports help PPB improve surveillance on the effects Kenyans experience from using drugs.

Speaking in Gikomba market on May 22, 2019 PPB inspector Mr. Elijah Mburu urged residents to collaborate with PPB inspectors in the region by providing information on suspected outlets.

Mr. Mburu said all registered chemists/pharmacies have been issued with a "Health Safety Code banner" placed at a visible position upon entry to an outlet. He added that all practitioners are also required to display the premise license.

"Before buying medicine, remember to verify the registration status of the outlet. Send the unique code on the banner to 21031(toll free) to get details on location of the outlet and name of the superintendent," said Mburu urging the public to provide information on any outlet where the location, name of superintendent does not agree with PPB details.

Mr. Mburu further urged the public to always check for expiry date of the medicine they purchase reminding them that expired medicines can deteriorate health and even increase healthcare costs.

PPB is a regional champion in Pharmacovigilance – International Society

The International Society of Pharmacovigilance (ISoP) has hailed the Pharmacy and Poisons Board for putting in place a "strong pharmacovigilance system."

Speaking in Nairobi during ISoP's mid-year training, the Society's President, Sten Olsson urged other countries in Africa to emulate Kenya's Pharmacovigilance system. "The Pharmacy and Poisons Board (PPB) has put in place a robust pharmacovigilance system that has made Kenya a champion of Pharmacovigilance in Africa," Olsson said.

He applauded PPB for active participation in organizing ISoP's first training in Africa, adding that about 94 pharmacovigilance professionals drawn from 19 countries got skills and shared experiences in conducting pharmacovigilance activities. The participants were drawn from regulatory agencies, pharmaceutical companies, academia, hospitals and community settings.

The ISoP Symposium and Training Course, with the theme, **"Pharmacovigilance in Africa beyond spontaneous reports"** was held on 6th – 8th May, 2019 at Panafric Hotel, Nairobi. The course provided an open platform for pharmacovigilance professionals to share ideas on how to improve the different components of safety regulation systems and practices.

Dr. Olsson said that ISoP organizes meetings and trainings in all continents and draws its members from around the world. "The ISoP Regional Chapters aid in engagement of activities supporting patient safety locally and providing a platform where like-minded experts from other countries interact."

He cited Morocco and Kenya as some of the countries in Africa that have set up strong pharmacovigilance systems but called for harmonization of medicine regulations and policies amongst countries to reduce the cost for drug manufacturers to comply with different regulations in every country.

Dr. Olsson emphasized that health care professionals have to communicate to the regulators to assist in data collection and establish the causes of some reactions that can be a result of underlying diseases noting that the next generation of patients must be protected.

ISoP president Sten Olsson making a presentation during the mid-year training held in Nairobi

It was noted that the current crop of health professionals must see beyond the current patient. Pharmacovigilance systems must learn from the reports in Pharmacovigilance centers established to identify likely patterns of reactions which calls for strong research systems in the continent.

The Society was founded by the European Society of Pharmacovigilance (ESOP) in 1992. It became ISoP in 2000 and currently has over 600 members drawn from over 75 countries.

ISOP training participants pose for a group photo after the training

Plans to install drug-testing minilabs in all counties underway

Minilab team screens samples collected in Nyeri County

The Pharmacy and Poisons Board (PPB) intends to install mini drug testing laboratories also known as **Minilabs** in the 47 counties in Kenya, a move that aims to improve the quality, safety and efficacy of medical products and health technologies in the country' says the PPB CEO Dr. F. M. Siyoi.

"To improve surveillance, the Board is investing to have Minilabs in every county in a period of five years" said the PPB CEO in an interview in Nairobi. The mini laboratories will have capacity to conduct screening quality tests for substandard and falsified products as PPB seeks to expand post market surveillance.

Acquisition of these labs will complement the already existing eleven available Minilabs situated at selected former provincial headquarters and ports of entry.

"The Board has mainstreamed post market surveillance in Kenya and through this investment patients can rest assured that only quality medicine and medical products shall be allowed into the market," Siyoi noted.

"A decade ago, post-market surveillance used to be done when necessary mostly based on reported complains from patients. Today, the board has invested in high technology equipment and well-trained personnel to regularly conduct planned post market surveillance activities," said the CEO.

"The board now carries out routine drug sampling and analysis to assure quality safety and efficacy of medical products and health technologies. This is helping patients receive high quality medicines," Siyoi said adding that the Board will continue investing in surveillance activities.

"These Minilabs are portable and can be used even in remote rural areas by trained personnel to check on the quality of products. We want to collaborate with counties to ensure uptake of these technologies and institutionalize quality assurance processes.

PPB defines post market surveillance as a "continuous process of monitoring the quality, safety and efficacy of all medical products and health technologies on the market."

Minilab Kit

Growth of clinical trials conducted in Kenya linked to an elaborate regulatory environment

Kenya has registered exponential growth in clinical trials with an average of six applications recorded monthly at the Pharmacy and Poisons Board (PPB) in the last year.

The World Health Organization defines a clinical trial as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioral treatments, process-of-care changes and preventive care."

PPB Head of Clinical Trials Dr. Edward Abwao says the growth in the number of clinical trials applications necessitated PPB to draft guidelines for conduct of clinical trials in Kenya. The guidelines came into effect in 2012 and were revised in 2016.

Today, PPB is closely working with other regulators in the regions in a bid to harmonize regulations and consequently improve the quality and integrity process of the clinical trials in this region.

"Clinical trials are key in development of medicines, medical products or even devices. As such, we have to invest in a regulatory process that conforms to global standards," says Abwao.

Clinical trials are the pipeline upon which drug development moves from confines of laboratories to human use. In recognition of this, PPB in 2012 developed guidelines for the conduct of clinical trials in Kenya.

Abwao notes that the guidelines act as a roadmap for all parties involved in the development of drugs and medical products. "The guidelines have put in place measures that ensure participants are not used for commercial gains. They clearly spell out application requirements, conduct of trials, data integrity and participants safety and the kind of laboratories to be used for the trials," he added.

The guidelines require principal investigators involved in clinical trials in the country to be Kenyans. This aims to ensure there is someone responsible for the whole process and can be held accountable by the Kenyan government.

PPB clinical trials guidelines demand "a qualified medical practitioner to be responsible for all related medical decisions and he/she should also be licensed with the Kenya Medical Practitioners and Dentists Board."

Data generated from these trials is critical and should not be abused. Anyone conducting a clinical trial in Kenya must demonstrate to PPB that they are able to keep data safely. They also need to demonstrate that the methodologies used are free from chances of data manipulation and falsification, said Abwao.

PPB may withdraw the authorization to conduct a clinical trial if the Authority is of the opinion that the safety of the study participants in the trial is compromised or that the scientific reasons for conducting the trial have changed.

The regulation of the clinical trials is done in phases and PPB is involved in every stage of the trial. Kenyans can also see all the approved clinical trials taking place in the country at **www.ctr.pharmacyboardkenya.org**, the site shows where the trials are taking place and their current status.

"Continuous inspections on the progress of trials are done to ensure that regular reports during the entire process are submitted and the purposes of the trial is not changed mid-way," he concluded.

PSK holds 39th annual Scientific Conference

The Pharmaceutical Society of Kenya (PSK) 39th Annual Symposium themed "Pharmacist championing quality patient care in UHC" was held on May 30, 2019 at Travelers Beach hotel, Mombasa with calls for revision of all insurance providers accreditation criteria.

PPB exihibitors during the Annual PSK Scientific Conference

At the Symposium PSK President Dr. Louis Machogu said the criteria will require personnel on the ground to not only have competency, but also show a valid documentation proof from health care professional bodies including PSK, Kenya Medical Association (KMA) and the National Nurses Association of Kenya (NNAK) to safeguard health care outcome, patient safety and professionalism.

Dr. Machogu noted that quality healthcare should be delivered by individuals who have subscribed to a code of professional conduct that facilitates for group governance and accountability.

He lauded the health Bill 2018 which was assented into law saying it will strengthen Pharmacy and Poisons Board (PPB) to discharge its mandate against quacks, enforcement of scheduling of medicines and levels of practice.


Delegates follow proceedings at the PSK conference

National Drug Control System moves from test stage to production

Participants pose for a photo with Pharmacy and Poisons Board CEO Dr. F. M. Siyoi during the launch of licit control unit NDS system at the PPB offices

The National Drug Control System (NDS) for Licit control at the Pharmacy and Poisons Board has successfully moved from test stage to production, ushering a new dawn in the regulation of controlled medicines.

Kenya now becomes the first country in Africa to install a comprehensive package of NDS; International Import Export System (I2ES) and Statistics and Processing Analysis (NDS SPA) as the Board bets on technology to boost regulatory activities. This system is an addition to the Board's investment in technology-aided regulatory activities that have now made PPB a regional trailblazer.

"We are happy to announce the migration of National Drug Control System (NDS) for licit control from a test environment to production," said the PPB Chief Executive Officer Dr. F.M. Siyoi on 27th June, 2019 as he presided the unveiling of the system

The PPB CEO Dr. F. M. Siyoi officially launch the licit control unit NDS system at PPB offices

According to PPB's Head of Licit Control Unit Mr. Job Kandie, the NDS system is expected to tighten the regulation of controlled medicines and improve licensing procedures at PPB.

"Application of the permits will allow clients to access global licit licensing services from the comfort of their desk, improving the customer experience as well as expanding market reach for traders," Kandie said. He also added that the system will enable PPB track quantities of drugs in the market at any given time to the specific premises stocking them.

Once operational, NDS will require importers and retailers of controlled medicines to file drug returns online, a shift from the current system replete with paper work. This, Kandie says, will boost transparency in the process of monitoring distribution of controlled drugs.

National Drug Control System is used to control Narcotics, Psychotropics and Pre-Cursor Chemical substances globally. Countries trading in controlled

substances issue permits for Export or Import to companies under their jurisdiction using the system. These permits are shared worldwide with other countries for trading purposes. To facilitate the exchange of information, United Nations Office on Drugs and Crime (UNODC) developed NDS and International Import Export Authorization System (I2ES) online system that is a secure information exchange portal hosted in Vienna by UNODC/INCB

The web interface enables users to access all the functionality of NDS and data from member countries who have signed the treaties for controlling licit products.

By implementing this system, PPB has created unlimited opportunities for traders in licit products to access any market in the world using PPB permits.

Moving to production is the third step in a long journey that began with the signing of the Service Level Agreement in November 2018 and the installation of the pre-production edition in January 2019.

Kandie said that effective use of NDS will put Kenya in a strong position to track all activities involved in the sale and use of controlled medicine adding that the NDS is safe from infiltration.

He also noted that PPB staff will undergo intensive training on handling the system for effective use. Kandie, however, remains optimistic the NDS system rollout will run smoothly.

PPB plans to list selected companies on the NDS for the pilot testing stage before a national rollout.

"At production, we will conduct test runs with selected companies. We do not expect significant changes to the system at this level," Kandie remarked.

"Part of the problem has been unethical and unprofessional handling of these drugs. Drugs in this category are prescription only but you find some practitioners mishandling laid down drug dispensing guidelines. Professional organizations also have a role to play," Kandie added.

However, he called on Pharmaceutical Society of Kenya and Kenya Pharmaceutical Association to conduct more member training on handling-controlled medicines.

Kenya sets up 24 hour Poison information Centre

The Pharmacy and Poisons Board (PPB) plans to set up a round-the-clock poisons information service that will provide urgent advice in cases of poisoning.

The regulator says that the move to set up the centre is in recognition of a need to offer informed prevention and treatment mechanisms that help in reducing the burden of mortality and morbidity as in the wake of increased rise in self and accidental poisoning cases.

According to PPB Head Medicines Information Division, Dr. Gerald Macharia, the center will not only provide advisory services that will offer home based solutions to poisoning cases but would also provide medical professionals with any assistance in handling patients of poisoning.

He explained that the centre will comprise of a 24-hour toll-free telephone call centre equipped with a toxicology library with data on local commercial products, including pharmaceuticals, as well as on natural toxins produced by local poisonous plants, industrial chemicals and venomous animals. Pharmacists will answer to questions from members of the public and medical practitioners on cases of both intentional and accidental poisoning.

World Health Organization (WHO) defines a poisons centre as a specialized unit that advises on, and assists with, the prevention, diagnosis and management of poisoning. The latest survey done by WHO in 2004 estimated that there were 3.4 deaths per 100,000 people due to unintentional poisoning in Kenya.

Dr. Macharia said the centre will have a specialized unit that will respond to cases of suspected wrong medication. The basic structure of the poisons centre will be a phone line service available 24/7, databases on poisoning, drug reactions and also the continuous and systematic collection of poison data from the library.

"The centre will help in rapid detection, verification, assessment, alert and response to chemical exposures that are threat to public health," he said. It will also have a library with standard textbooks of medicine for both general and pediatric, chemistry, pharmacology, analytical toxicology and animal and plant toxins of the region and standard medical dictionaries.

In Kenya there are two established poisons centres namely the Agrochemicals Association of Kenya (AAK) poisons centre based at Kenyatta National Hospital and the National Poison Information and Management Centre located at Gertrude's hospital.

Inspectorate directorate intensifies countrywide surveillance

The Pharmacy and Poisons Board closed down a total of 86 pharmacies in Western region in April 4, 2019 in a one-week operation that targeted Kakamega, Vihiga, Bungoma and Busia counties.

The Head of Good Distribution Practice and Ports of Entry, Dr. Dominic Kariuki said several illegal operators were arrested, arraigned in court and charged with various offences including;

- ***Possession of part 1 poisons contrary to section 26(1) of the Pharmacy and Poisons Act;***
- ***Carrying out the business of a pharmacist while not registered as a pharmacist contrary to section 19(1a) of the Pharmacy and Poisons Act and***
- ***Carrying out the business of a pharmacist in premises not registered contrary to section 23(1) of the Pharmacy and Poisons Act.***

Dr. Kariuki disclosed that PPB has introduced the use of official closure notices – banners, which are displayed on the doors of closed premises. The notices have unique serial numbers tagged to a given chemist. He warned absentee superintendents that disciplinary action will be taken.

During the operation government drugs were seized in three private pharmacy outlets within the county. Dr. Kariuki advised the public not to buy GOK labelled drugs from private chemists and report the culprits to the relevant authorities.

He revealed that in a bid to ensure quality, safety and efficacy of medicines the Board has distributed minilabs to its regional offices for random sampling and testing of medicines and is training health workers and stakeholders on how to identify and report poor quality medicines using the PPB poor quality medicines reporting tools.

Dr. Jacinta Wasike, Director, Inspectorate, Surveillance and Enforcement engages stakeholders in Garissa County after crackdown

He also urged pharmacy outlets with expired drugs to safely quarantine them and reach out to regional offices for safe disposal.

In **Garissa County** a total of 21 pharmaceutical outlets were closed down in a national crackdown operation on illegal pharmaceutical outlets that also undertook an audit of 15 premises on May 8, 2019.

During the operation the Director of Inspection, Surveillance and Enforcement ,Dr. Jacinta Wasike, said the aim of the exercise is to weed out illegal pharmaceutical outlets, audit hospitals and pharmacies for good distribution practices and evaluate storage conditions of pharmaceutical supplies in the region.

She reemphasized that PPB has introduced the use of official closure notices – banners which are displayed on the doors of closed premises.

In **Nakuru County,** the pharmaceutical Inspectors arrested 16 people for operating pharmacy outlets without valid documents on 27th May, 2019.

The culprits were arrested and arraigned at Nakuru High Court after members of the public tipped the officers of the illegal outlets which that were only operating at night.

"These are risk premises endangering public health. There is no way you can close your premise during the day and open during the night. The government has its own strategies and we shall adopt more strategies to ensure regulations are observed and drugs are dispensed by qualified people," Senior Pharmaceutical Inspector Julius Kaluai said

The officers found that most registered premises were found being operated by unqualified people while others had no valid licenses.

"All registered pharmacies are supposed to be well manned by professionals so that the public can access proper medication," he emphasized.

He said the Board has 11 gazetted Ports of Entries which, are manned by drugs inspectors who continuously conduct surveillance using the handheld Raman Spectrometers to verify drugs at the point of inspection.

On 31st May 2019 the Board closed a total of 51 illegal pharmacies in S**outh Rift** region in a crackdown that started on 1st April 2019 covering the counties of Nakuru, Kericho, Bomet, Narok, Laikipia and Samburu.

The operation targeted pharmacy outlets that were found to have flouted regulations as stipulated in Cap 244 Laws of Kenya. THe culprit's stocks were seized, owners arrested and arraigned in court and charged with various offenses, said Julius Kaluai, Senior pharmaceutical inspector at PPB.

He noted that the crackdown was carried out to augment the routine inspections that are carried out by regional inspectors and urged the courts to impose enhanced fines for those found guilty of operating illegal pharmacies to discourage this practice.

PPB inspectors during a media session in Nakuru after crackdown

"Some of the accused persons pleaded guilty and were given fines ranging from Ksh.20,000 to Ksh.60,000 which was not a deterrent enough to the weight of the crime committed," he noted.

During the crackdown, all non-compliance premises and those found closed were pinned with closure notices) which are displayed on the doors of the chemists that has been closed down.

The closure notices have a unique serial number that is tagged to a given Chemist. Copies of closure forms are given to the local police command to ensure that the said premises remain closed. The closure notices also act as a warning to members of the public to keep off such premises.

Meanwhile, the Board has distributed minilabs to its regional offices for random sampling and testing of medicines in the market to ensure that medicines in the Kenyan market are of good quality, safe and efficacious.

Health workers have also been trained and other stakeholders on how to identify and report poor quality medicines using the PPB poor quality medicines reporting tools.

Members of the public are advised to use health safety codes displayed in registered pharmacy outlets to verify legality of the premises. Send SMS to 21031 and it is free of charge.

Head of Good Distribution Practice and Ports of Entry Dr. Dominic Kariuki displays a sample of a closure banner to the media after a crack down in Kakamega

Be vigilant on herbal products, PPB warns

Herbal concoctions sold in Kenya as medicine are unsafe for human consumption, Pharmacy and Poisons Board senior inspector of drugs Mr. Julius Kaluai has warned.

Speaking in an interview at 89.5 Ghetto Radio Mr. Kaluai said the concoction, popularly known as "Maasai medicine" is not listed with the PPB noting that the herbalists expose users to risk of consuming poison.

The drug inspector also clarified to listeners that no one drug has the efficacy to heal all the diseases these "drug" vendors purport their concoctions can treat.

"The herbalists who sell the purported drugs move around also selling other goods such as shoes and belts. These traditional herbalists are the only people who know the ingredients of the concoctions. PPB will not let this habit thrive as we seek to protect the health of Kenyans," he told listeners.

Mr. Kaluai added that PPB has intensified drug inspection activities further revealing that the Board will not relent until all unlicensed people quit pharmacy practice.

Mr John Muinami during the interview

Mr Julius Kaluai during the interview

He urged the public to cultivate a culture of visiting a health facility to receive medical care cautioning that self-medication is a threat to human health.

Mr. John Muinami, also present during the interview, advised Kenyans to only purchase medicine from registered pharmacies or chemists. He urged the public to look out for the Health Safety Code banner in a pharmacy and text the code to 21031 (toll free) to verify the registration status of that particular outlet.

He further noted that the Board has capacity to regulate registered outlets but called on Kenyans to report any pharmacy operating without a Health safety code and license.

Mr. Kaluai called upon residents to collaborate with the regulator during inspections saying Pharmacy and Poisons Board is here to ensure only safe medicines are in circulation and qualified personnel administer the medicines.

One can report any unlicensed premise, pharmacist, or pharmaceutical technologist to 0702475824 / 0720608811 or email info@pharmacyboardkenya.org

PPB cracks the whip on herbalists

The Pharmacy and Poisons Board (PPB) on May 17th, 2019 seized herbal medicines and personnel working at three herbal clinics in Nairobi over substandard medicines.

The drug inspectors that raided Murugu Herbal Clinic and three other clinics within Nairobi, were checking for the quality of the herbal medicines, confirming the licensing of the clinic and how the medicines are produced from the manufacturing process to the final product.

Speaking during the inspection, Ms. Valentine Mokaya, a pharmaceutical inspector said the Board acted after the clinic refuted orders to take the herbal medicines for analysis at the PPB laboratory. This follows an array of claims that the medicines could cure incurable diseases.

Pharmaceutical inspector Mr. Elijah Mburu shows a mixture of seized unknown herbal powders at Murugu herbal clinic

During the exercise it was discovered that the herbal medicines were manufactured in complete disregard to good manufacturing practices and respect to environment, premises and personal documentation, hygiene, among others. Dr. Paddy Agoro present during the inspection said the clinic had improper manufacturing processes which can be detrimental to the human health. He also noted that the clinic was run by unqualified personnel.

The PPB inspectors found out that the medicines were stored in dirty substandard containers with no stickers that shows the names of the medicines, manufacturing details, ingredients and batch numbers which is a necessity for every medicine manufactured to ensure patients know more about the products. Additionally, there were no leaflets to show the side effects of the medicines and the directions for use to guide patients on dosage.

Officers from the Pharmacy and Poisonous Board, Dr. Paddy Agoro and Ms. Valentine Mokaya at Murugu herbal clinic during the inspection

Other clinics that the board inspected were Kamirithu, Olive and East & West Medical Centre, a Chinese herbal clinic.

Owners and people found handling the herbal medicines at the clinics were arrested and booked at Central, Pangani and Kilimani police stations respectively before taken to court.

The Board urges the public to be vigilant when visiting herbal clinics. It is important to seek medical treatment from certified hospitals.

Pharmaceutical inspector seizes substandard medicines from Murugu herbal clinic in Nairobi during the inspection

Focus on Nairobi and Uasin Gishu counties roadshows

The Pharmacy and Poisons Board conducted public awareness campaigns to help Kenyans to understand the issues of medicine safety in Nairobi and Eldoret Counties from 21st – 22nd May 2019 and 24th -25th May 2019 respectively.

The Chief Executive Officer, Dr. F.M. Siyoi flagged off the roadshows to raise awareness of the Health Safety Code and the dangers of misusing prescription medication in Nairobi county.

Dr. Siyoi said this is one of the initiatives the Board is undertaking to empower the public to report suspected medicines and quacks in the industry.

The Nairobi Roadshow

He disclosed that a joint inspection of health facilities is ongoing with other health regulatory authorities to ensure the public access quality medical products and other health services.

The roadshows were in partnership with Ghetto Radio and Kass FM.

You should only buy drugs from registered outlets, says Pharmacy and Poisons Board (PPB) during a road show caravan in North Rift region. The road show is part of a series of publicity campaigns organized by PPB to popularize the use of Health Safety Code.

"You need to verify if a pharmacy is registered before you buy medicine. Always look out for the Health Safety Code printed on a banner placed inside the facility. SMS that code to 21031 and you will receive a reply with details of the chemist, its location and the superintendent," PPB drug inspector Dr. Onesmus Kilonzo told the public.

He cautioned the public against buying expired medicines further urging them to check expiry date of the drugs before making a payment. Dr. Kilonzo asked pharmacists and pharmaceutical technologists in the region to surrender expired medicines to the PPB's regional office for safe disposal.

The Eldoret Roadshow

The Board has a mandate to make sure medicines in the country are safe for use.

Gilbert Bett, a pharmacy operator in Kapsabet hailed PPB for the roadshow citing the Health Safety Code as a measure to weed out quacks. "This works to the advantage of businesses owned by registered personnel. By creating publicity about the code, the Board builds public trust for all registered pharmacists and pharmaceutical technologists," he added.

THE ADVERTS APPROVAL

The Pharmacy and Poisons Board appeals to all healthcare stakeholders, media houses, publishers and advertisers not to run any promotion of medical products and health technologies without prior approval.

"Media outlets should be cognizant that advertisements that run without prior approval from the Board violates existing guidelines on drug advertisement standards", says Dr Gerald Machari, Head Medicines Information adding that the PPB makes it mandatory for all persons wishing to advertise medical product and health technologies to make a formal application with the regulator for review and receive a verdict before they publicize.

Cap 244 of the laws of Kenya has a legal mandate to regulate ethical promotions and advertisements of medical products and health technologies. The World Health Organization (WHO) defines the promotion of pharmaceuticals as all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and or use of medicinal drugs.

Dr Macharia revealed that the Board in conjunction with stakeholders in 2012 developed guidelines that direct the process of application, review and verdict of all promotional and advertisement materials. These guidelines stipulate that the elements of advertisement and promotion should meet some minimum threshold and shall apply to all manufacturers, wholesale dealers, retailers and any other entity involved in advertisement and promotion of medical products and health technologies.

The process of application, review and approval of all advertisements and promotional materials of medical products and health technologies is overseen by the Head medicines information to ensure that all promotional materials contain balanced and accurate information that meet legal and regulatory requirements.

The Board is concerned that some adverts do not contain accurate information therefore are likely to mislead members of the public. The guidelines on advertisements and promotional materials of medical products prohibits healthcare practitioners and celebrities to endorse medical product.

The PPB monitors all running advertisement and promotional materials to prevent running of illegal advertisements. "Regulation of herbal and complementary medicines adverts is covered under the Ministry of Sports, Culture and Youth Affairs" Macharia clarified.

Medicines and medical devices advertisements are approved by a committee that reviews and gives verdict on their suitability whether they meet legal and regulatory standards. The cost of advertisement and promotional material application for review and issuance of a verdict by the Board is Sh5000 per application per product and per medium.

"We advise the medical practitioners to abide by the legal provisions of adverts of medical products and also requests members of the public to be vigilant and report any illegal promotions" Dr Macharia, concluded.

Conditions under which drug recalls, withdrawals and quarantines happen

PPB can recall or cause to be recalled a medicinal product or medical device if it is established to be of poor quality and/or fails to comply with quality and safety specifications.

According to PPB post market surveillance officer, Dr. Vivian Rakuomi several regulatory measures can be instituted when a product is proven and or suspected to be defective based on stability studies, market complaints, and after an evaluation of benefit-risk balance.

"The quality of the products is tested per batch," he says. "A batch of pharmaceutical products that is sub-standard does not imply that the whole product brand is of poor-quality. Recalls are very necessary and part of medicines regulation. It actually implies that quality of medical products and health technologies is being monitored."

A medical product can also be voluntarily recalled because of defective labeling or packaging among other reasons submitted to PPB by the Marketing Authorisation Holder (MAH) or the manufacturer

"During recalls the public may be advised to return the batch of the affected medical product to their pharmacist or healthcare provider. Specific batches of medical products are recalled under normal circumstances.

He says that responsibility of conducting recalls lies with the market authorization holder who essentially is the owner of the product., Recalls are to be effected within stipulated time-frame and the MAHs are expected to strictly comply with the timeframes. In cases where PPB has a good reason to believe that the recall action is ineffective, the Board takes over the recall in what is called statutory recall.

Quarantine means separation of a medical product or health technology, physically or by other means from the rest of the stock and halting further issuance or distribution of the product while an investigation is being undertaken in order to determine the quality or safety of the product. Quarantine order may be lifted once a product is determined to be of the required quality and/ or safety.

Withdrawal of medical products means total removal of the product from Kenya market," he expounded.

Withdrawal may be triggered by side effects caused by the product, or evidence obtained from various sources such as, observational studies, clinical trials, systematic reviews that shows the risk outweighs the benefits on use of a particular product.

"Drug recalls and quarantine are common practices in many jurisdictions. That however is not a reason to cause panic. These are measures that regulators undertake," he said. It is important that the media accurately reports issues concerning recalls of medical products in order not to cause unnecessary panic among the public.

PPB investigates new form of pharma crime at ICD premises, Nairobi

The Pharmacy and Poisons Board is investigating cases of theft of Medicines from containers at ICD premises undergoing clearance.

The PPB action is based on complaints of some pharmaceutical importing companies of an increasing new trend of drugs getting stolen from containers at ICD while in the process of clearance.

"As from January 2019 we have received complaints from victims showing a total of 12 containers were found to have drugs stolen, which translates to at least 2 containers containing drugs being broken into per month," said Pharmaceutical Inspector Joshua Plekwa.

The stolen containers were found with tampered seals while others were found with seals different from original or fake seals which indicates involvement of an organized group or cartel.

Most of the targeted medicines are either of high value or fast moving drugs in the market. The affected companies includes Pharma Specialities Ltd , Harley's Limited, Cadila Pharmaceuticals (EA) Ltd, Surgipharm Limited, Laborex Kenya Ltd, Medisel (Kenya) Ltd and Dawa Ltd.

ICD, Nairobi

Investigation are on-going to expose these criminals whose activities are impacting negatively on legitimate traders through a Multi Agency approach.

Fake pharmacist arrested

A fake pharmacist was arrested at chemist in Westlands, on Limuru Road, Nairobi County on 8th July 2019.

Vickson Muthage Gicobi was arrested following a sting operation conducted by Pharmacy and Poisons Board Pharmaceutical inspectors attached to Drug crime investigation Unit and the police from the Special Crime Prevention Unit.

The self-confessed IT expert was found dispensing medicines at Gesam chemist which also had a falsified PPB premises and practice licenses for 2019.

The fake documents were detected through the use of a bar code reader which PPB has embraced.

He was arraigned in court and charged with forgery and pleaded not guilty and was granted a bond of Sh. 0.5 million or cash bail of Sh. 0.3 million. The next mention is on 13th August 2019.

The Board is appealing to the members of the public to be vigilant and volunteer information on such culprits to track them down.

Vickson Muthage Gicobi

New regulations in the registration of human vaccines in Kenya

The Pharmacy and Poisons Board Product Evaluation and Registration officer Dr. Jonathan Meriakol, said that the Guidelines on submission of Documentation for Registration of Human Vaccines published in August 2018 are meant to reduce new vaccines' approval times and enhance the efficiency of certain aspects of the submission process for human vaccines applications. It will also help increase timely access by ensuring that only quality, safe and efficacious vaccines are approved for registration.

"The guideline will help PPB to use the submitted information and other factors to assess the suitability of the vaccine and compliance with the regulation by facilitating the processing of applications and subsequent registration," Dr. Meriakol said. He also noted that the guidelines are subject to review after three years from the date of publication. They will require, among other things, that applicants provide documents in word format downloaded from www.pharmacyboardkenya.org -dossier requirements- in support of market authorization of vaccines.

Under the new regulations, PPB has created a strict process that strengthens the already existing supervisory system for human vaccine products, promoting accountability from applicants. Applicants are required to fill a form that is downloaded from the PPB website and fill details such as applicant information, product manufacturing information, non-clinical study details as well as clinical studies conducted.

Dr. Meriakol explains that the guidelines provide product dossier requirements in support of market authorization of vaccines with the evaluation relating to some product properties such as quality, safety, and efficacy. The approvals submission also stipulates premarketing assessment criteria that will be used to determine and ensure that the product is registered.

Dr. Jonathan Meriakol, Head Biological Product Registration

The submission forms are formatted as per the International Council for Harmonization (ICH) of the technical requirement for pharmaceuticals for human use Common Technical Document (CTD).

It also recommends that applicants reveal names of experts who performed product evaluation, a summary of academic qualification and the relationship between the experts and applicant. This is meant to prevent conflict of interest before the issuance of the marketing authorization.

"Experts in these areas pharmacists, clinicians or physicians will be making declarations of the document submitted," he said.

The guidelines further state that the request for approvals should be submitted by any legal person or entity engaged in the manufacture or the applicant for a license. The applicant takes responsibility for compliance with the human vaccine product established standards.

In the spirit of regional harmonization of processes, the new approval process takes into account the registration status of the vaccine in the East African Community (EAC). Further, PPB will be evaluating whether the vaccine has been approved in other countries.

It also requires declaration on statements whether the application for the product has been previously rejected, withdrawn or repeatedly differed in the EAC partner states.

PPB ensures quality medicines are circulating in the Kenyan market

The National Medicines Regulatory Authority in Kenya, -Pharmacy and Poisons Board (PPB) continuously undertakes surveillance of medical products and health technologies in the Kenyan market to ensure products comply with quality safety and efficacy specifications.

According to PPB Post market Surveillance officer, Dr. Vivian Rakuomi, the Board carries out routine surveillance of medicinal products, medical devices, vaccines and cosmetics in order protect the public from harmful products.

PPB has a directorate of product evaluation and registration which is responsible for rigorous products evaluation and registration that involves dossier evaluations. The register of products and their specifications are maintained at PPB.

Upon registration of a product, market authorization is granted allowing the product to be marketed in Kenya. However, this process is not an end in itself, since continuous evaluation of benefit-risk profile of products is done throughout the life-cycle of the products. This is in view of any emerging safety concerns that may affect a given product.

"To determine and reflect if the approved products adhere to acceptable level of compliance and has consistent quality standards of producing the same product as stated in its product specifications presented during its registration, PPB has put in place a robust post-market surveillance mechanism," he said.

He explains that improper product handling can compromise quality.

"To ensure consistency of quality standard products circulating in the market, PPB analyses samples of medical products and health technologies

circulating in the market through a process known as post market surveillance (PMS), Dr. Rakuomi added that samples taken from the market are tested for quality based on pharmacopeial standards and specifications as presented during the product registration.

He says that PPB conducts at least two routine Post market surveillance (PMS) surveys each year as part of the initiatives to assure quality of products in the market.

Members of the public and healthcare providers are encouraged and can voluntarily report any issues of suspected poor-quality medical products or health technologies.

In passive surveillances he explains that the Board receives and reviews market complaints from the public and healthcare professionals through the pharmacovigilance electronic reporting systems (PVERS) and also through manual reports. Once the report is received, he explains, PPB initiates investigations on the market to establish if indeed the product has quality defect (s) Depending on the outcomes of the investigations, a regulatory action is instituted.

He says some of the reports include: expired drugs sold in the market, changes in odour and color of the medicines, defects in packaging or labelling and medicines reported to be inefficacious. The quality defects can result in product quarantine, product recall or withdrawal.

"The samples collected from the market are subjected to laboratory tests at an accredited laboratory," he said.

Dr. Rakuomi added that PPB tests the samples at its technical arm, the National Quality Control Laboratory and where justified Mission for Essential Drugs (MEDS) laboratory for confirmatory tests. Both of these laboratories are WHO accredited.

Adverse events can be reported by the pharmaceutical industry, healthcare providers and consumers.

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

- 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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