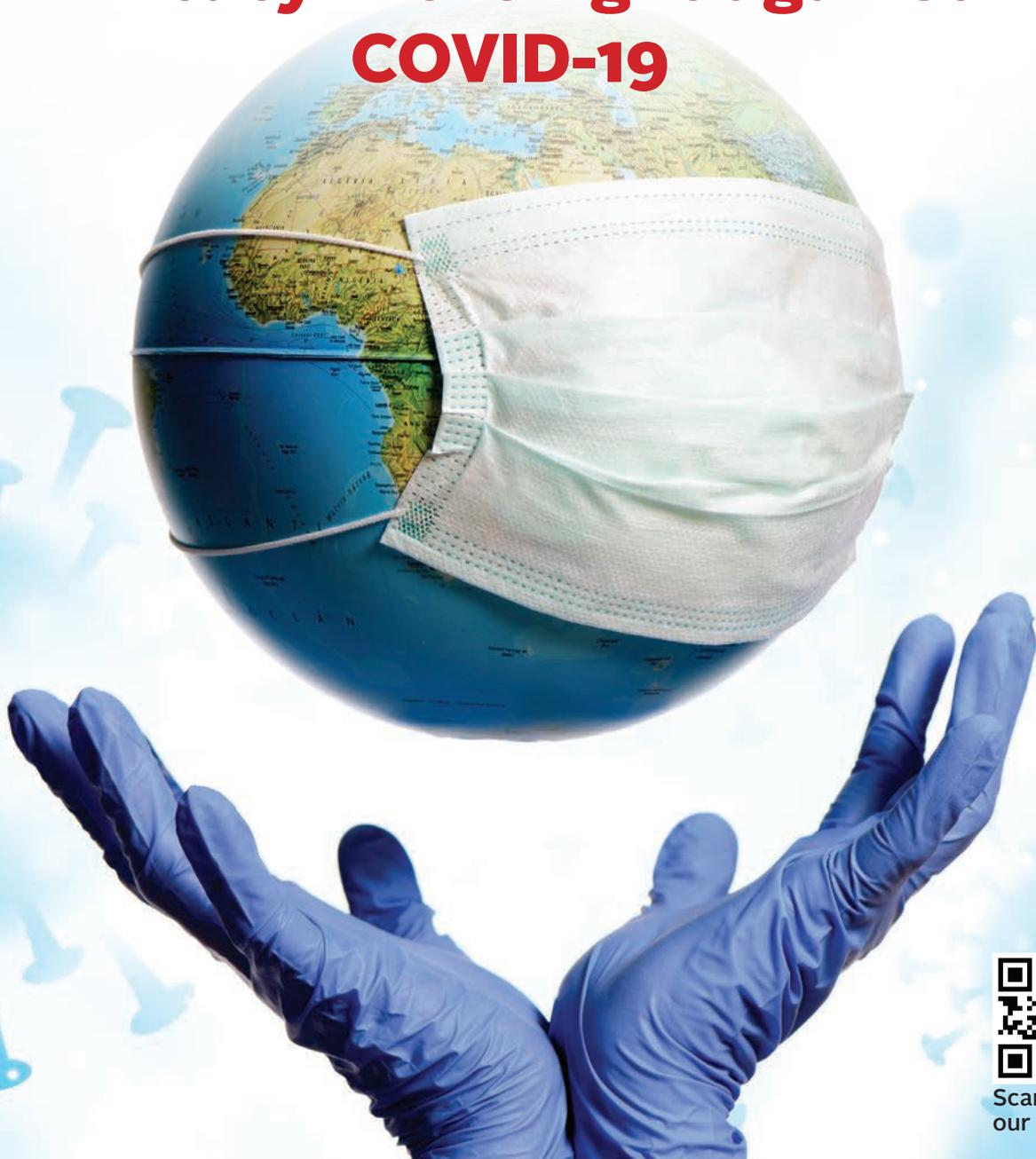




# PHARMACY AND POISONS BOARD

MAGAZINE

## Ensuring Quality, Safety and Efficacy in the fight against COVID-19



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our website



## PUBLIC NOTICE

### TO ALL AUTHORIZED DEALERS IN MEDICINES

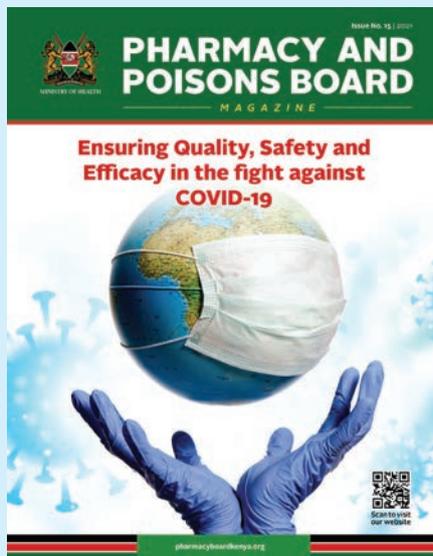
## Sale of Prescription Only Medicines

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

## Looking back and forward

COVID-19 is absolutely the biggest news story of our time. However, it is not the only news, and we are striving to make sure that relevant topics and events don't go uncovered.

In the midst of this pandemic we have found ways to carry on – at a distance and to adjust and change the way we do things. To make sure that readers stay informed and can access our Pharmacy and Poisons Board magazine, we have decided to publish the number 15 edition as a digital magazine.

That's why in our number 15 edition amidst the pandemic you will still hear stories of quality assurance, technology advancement, capacity building, inspections, and performance contract among others.

We would like to say to all our readers: Stay healthy and stay safe. On our side we will continue to keep you informed via @ppbkenya and our digital magazine.

Happy reading!

*Judy*



MINISTRY OF HEALTH

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POISONS BOARD**

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Pharmacy and Poisons Board



@ppbkenya

# CONTENTS

**6** PPB upgrades system for reporting adverse effects of medicines and vaccines

---

**8** Govt. launches pharmaceutical report to spur the industry

---

**9** Q&A with PPB CEO, Dr. F. M. Siyoi

---

**12** PPB & MOH signs performance contract

---

**12** PPB & Kemri signs agreement

---

**13** PPB sensitizes court users committee

---

**14** Protocol for risk-based PMS underway

---

**15** 68 traders arrested in crackdown on illegal pharmaceutical outlets in Western

---

**16** PPB conducts follow-up inspection of Pharmacy outlets

---

**17** PPB whips illegal outlets in South Rift

---

**18** 61 arrested in a crackdown targeting lower Eastern Region

---

**19** PPB conducts crackdown in upper Eastern Region

---

**20** PPB seize 171 cartons of assorted medicines in Nairobi and Kajiado

---

**22** 69 arrested over illegal handling of pharmaceuticals

---

**23** PPB Destroys smuggled pharmaceuticals worth over 32M

---

**27** Memorial Tributes

---



Pharmacy and  
Poisons Board



# COMMONLY REPORTED SIDE EFFECTS OF COVID-19 VACCINES



Headache



Fever



Nausea



Rash



Fatigue



Tiredness



Pain at injection site



Decreased Appetite



Vomiting



Dizziness



Body chills



Abdominal Pain

You are encouraged to report **ANY** side effect you may experience after vaccination to Pharmacy and Poisons Board through any of the channels below:

## PUBLIC/PATIENTS

Website [pv.pharmacyboardkenya.org/padrs/add](http://pv.pharmacyboardkenya.org/padrs/add)

Phone [+254 795 743 049](tel:+254795743049)

or report to the nearest health facility

## HEALTH WORKERS

Website [pv.pharmacyboardkenya.org/](http://pv.pharmacyboardkenya.org/)

Email [pv@pharmacyboardkenya.org](mailto:pv@pharmacyboardkenya.org)

Phone [+254 795 743 049](tel:+254795743049)

# PPB upgrades system for reporting adverse effects of medicines and vaccines



Health Chief Administrative Secretary, Dr. Rashid Aman

The Pharmacy and Poisons Board has launched an upgraded version of the Pharmacovigilance Electronic Reporting System (PvERS II) <https://pv.pharmacyboardkenya.org/> to strengthen safety and quality monitoring of Health Products and Health Technologies in Kenya.

The new system which, was launched on 17th March 2021 is a suite of software applications for collecting and processing of information on suspected Adverse Drug Reactions (sADRs), suspected Poor Quality Medicinal Products (sPQMPs), Adverse Events following Immunization (AEFIs), Medication errors, Incidences following use of a Medical device, and suspected Blood and Blood Products reactions.

The new system is able to receive reports from all products regulated by the PPB, it will see improved quality of reports to ensure causality assessment and signal detection are performed promptly to provide data for evidence-based decision making at policy level.

“This system is timely and I call upon all stakeholders to support this initiative as we strive to ensure that Mwananchi is using quality, safe and efficacious Health Products and Health Technologies,” said Dr. Rashid Aman, the Chief Administrative Secretary, in the Ministry of Health, when he launched the system in a virtual meeting.

He said the government is committed to providing Kenyans with safe, quality and efficacious Health Products and Health Technologies and is looking forward to great outputs from the upgraded system especially during this time when the country is still fighting the COVID-19 pandemic.

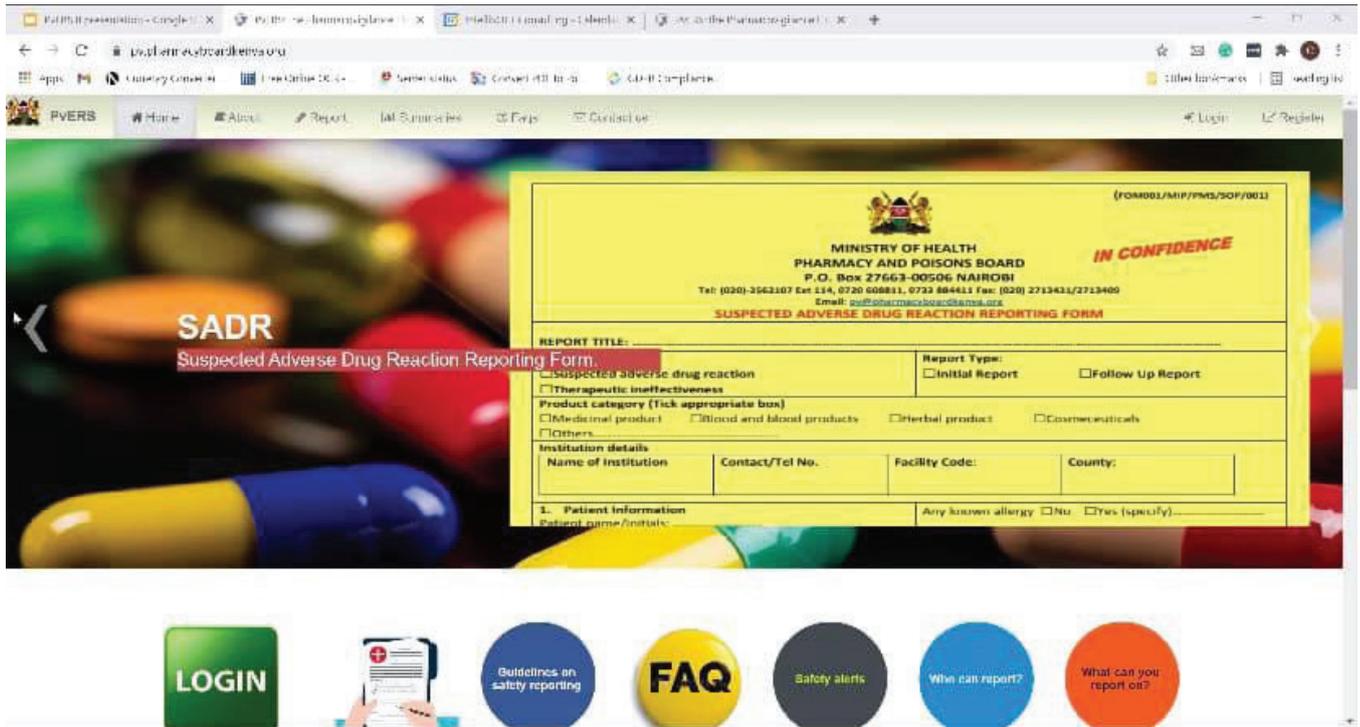
“The country is set to roll out the COVID-19 vaccines, through the Emergency Use Authorization program, this underscores the need to have a system that can quickly and effectively detect and respond to any safety concerns that may arise,” he said and lauded the Pharmacy and Poisons Board for achieving such a milestone, notwithstanding that PPB is the Regional Centre of Excellence in Pharmacovigilance in the Region.

He added that with the increasing access to Health products and Health technologies, there is greater need to develop/strengthen the vigilance and surveillance systems for patient safety and thus collaborative efforts between different stakeholders is key.

The PPB Chief Executive Officer, Dr. F. Siyoi, revealed that through the support of the Management Sciences for Health, the Pharmacovigilance Electronic



PPB CEO Dr. F. M. Siyoi



Reporting System (PvERS) has been in operation since the year 2013 and has seen the collection of over 14,000 reports on individual case safety reports and over 1000 suspected quality defect reports.

“These reports have been used to inform policy change, review of treatment guidelines and various regulatory actions,” he noted and acknowledged the Management Science for Health for their technical and financial support in the development of the first version of the PvERS and the World Health Organization for availing the seed fund to support part of the PvERS II particularly the vaccines safety monitoring component.

He added that in order to continuously align with best international standards and offer better usability to the stakeholders, there was need to upgrade the system to ensure it is able to collect data on all Health Products and Health Technologies that are given Market Authorisation by PPB.

“The new system will also be more interactive and allow users at a snap shot to view summaries of what is reported to PPB,” he noted.

...there was need to upgrade the system to ensure it is able to collect data on all Health Products and Health Technologies that are given Market Authorisation by PPB.

The old system had two reporting forms; one for suspected ADRs (yellow form) and one for poor quality products (pink form). The scope of pharmacovigilance has expanded globally to include safety monitoring of other health products and

technologies and more forms have been incorporated to capture information on; Medication Errors (blue form), Adverse Events Following Immunizations (white form), Incidences following use of a Medical Devices (green form) and Haemovigilance reactions due to Blood and Blood Products i.e. (cream-off white form).

The added function of user access rights allows reporters to monitor the progress of their reports, see trends across various counties and seek quick basic summary statistics of the Individual Case Safety Reports Submitted to PPB. One of the key new features is a provision for patient/consumer

reporting which is critical to ensure that each and every person is keen on their health and are able to report any concerns that they may have in regards to Health Products or Health Technologies they are exposed to.



# Govt. launches pharmaceutical report to spur the industry

**O**n 10 March 2021 the Government of Kenya launched the Pharmaceutical Industry Diagnostic Report, 2020 to make the sector more competitive.

The Kenya Pharmaceutical Industry Diagnostic Report 2020 highlights and examines gaps, challenges, and opportunities in Kenya's pharmaceutical industry and recommends steps to spur the industry's growth and make it more competitive.

The study which was commissioned by the Government of Kenya through the Ministries of Health and Industrialization and Trade & Enterprise development in collaboration with the International Finance Collaboration (IFC) found that although Kenya has competitive incentives for the pharmaceutical sector and a very good rating on the Ease of Doing Business index manufacturers are heavily dependant on imported inputs, coupled with higher cost of logistics, utilities, and packaging materials.

The study also revealed that Kenya has a shortage of well qualified personnel in industrial pharmacology, which has necessitated over-reliance on expatriates resulting in high labour costs and recommends a review of the legal landscape involving pharmaceutical manufacturing, development of an Inclusive Coordination Framework and political ownership and support among others

The report was launch by the Cabinet Secretary for Industrialization, Trade and Enterprise Development Betty Maina in a virtual meeting attended by the Chief Administrative Secretary for Health, Dr. Rashid Aman.

The launch of the report comes at an opportune time when there are serious global disruptions in the supply chain of essential health products and technologies as a result of the effects of the COVID-19 pandemic.

Dr. Rashid said a coordinated approach is required through a package of interventions to support the Kenya's effort to enhance the role of private sector in supplying good quality and affordable medicines to the Kenyan market as well as the regional market.

Some of the key interventions he recommended include building capacity for institutions responsible for training to address the skills gap and meet the demand

for skilled work force; leveraging on science, innovation and technology to improve products complexity and increase in financing for product research and development (R&D).

"In addition, we need to strengthen framework and investment in industrial infrastructure like the special economic zones as well as reducing barriers to entry and competition in pharmaceutical manufacturing," he said.

Rashid assured that the Government will endeavor to strengthen regulatory landscape as well as addressing the issues of shortage of skilled work force in the pharmaceutical manufacturing sector.

"As you are aware manufacturing has been identified as a priority in the big four agenda and one of the key sub-sectors targeted for growth is the pharmaceutical industry. This makes it a nexus for the UHC which is the other component of the big four agenda," he added.

The government of Kenya has established Export processing zones (EPZs), which are meant to create an enabling environment for export-oriented investments and promote and facilitate such investments. There are 40 gazetted zones in Kenya at different stages of development. In addition, the government has established one-stop shops to streamline processes and help organizations seeking to set up businesses in Kenya. "As a government, we encourage investors to seize these opportunities," Dr. Rashid said.

To ensure Kenyans have improved access to health services, Rashid said the government has zero-rated imports of raw materials and finished products of pharmaceuticals and also seeks to reduce the proportion of imported medical products to support local manufacturing.

"We are anticipating that the demand for medical products is expected to rise in the coming years due to increased purchasing power by citizens, increased literacy and health-seeking behavior on account of better access to information, and the roll-out of the Universal healthcare coverage by the government," he said.

To meet the demand, structured collaboration of stakeholders in the pharmaceutical manufacturing sector is required he noted.



# Q&A with PPB CEO, Dr. F. M. Siyoi

## 1. What is Pharmacy and Poisons Board?

The **Pharmacy and Poisons Board (PPB)** is the national medicines regulatory agency in Kenya, entrusted 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.

## 2. Can you explain your mandate to the people of Kenya?

The Board's statutory mandate is drawn from Pharmacy and Poisons Act Cap 244 Laws of Kenya and the rules thereunder as well as the Health Act, 2017. Amongst other functions, the Board undertakes evaluation and registration of Health Products and Technologies (HPTs); regulates pharmacy practice through registration and licensing of pharmaceutical personnel and pharmacy training institutions as well as training of pharmacy through course approvals. In addition, PPB regulates the manufacture, importation, exportation, distribution and sale of HPTs through appropriate administrative, inspectorate, enforcement and surveillance activities.



## 3. What are medical products?

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

## 4. What are health technologies?



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

## 5. What role do you play in the war against COVID-19 in the country?

The role of the Board in the war against COVID-19 is to ensure medical products and health technologies used in the management of the pandemic are of quality, safe and efficacious.

In light of the above, Pharmacy and Poisons Board developed emergency use guidelines in order to expediate the review and approval of emergency use application. A medicine or health technology is given Emergency Use Authorization (EUA) approval to enable the government deal with the public health emergencies such as in the case with COVID-19 pandemic.

In addition, Pharmacy and Poisons Board came up with guidelines to assist manufacturers of alcohol-based hand sanitizer and conducted visits to the assess them and ensure they meet standards.

Also, the Board monitored if measures for prevention & control of COVID-19 were being implemented in all pharmaceutical outlets.

To assure the safety of COVID-19 patients during their course of treatment, the PPB is also conducting countrywide pharmacovigilance of medical products and technologies used in the management of COVID-19.

The data obtained in this important retrospective and prospective study will assist the country in linking the outcomes to medications, patients factors such as, comorbidity, probability of getting adverse drug reactions or events among others, during the course of treatment of COVID-19. This data will also contribute greatly to the body of knowledge in the management of the pandemic.

## 6. How sure can a patient be sure he/she is getting the right diagnosis and medical prescription from a health practitioner for their ailment?

The Medical Practitioners and Dentists Council as well as other regulatory bodies in the Ministry of Health such as the Clinical Officers Council, Kenya Medical Laboratory Technicians and Technologists Board, the Nursing Council registers healthcare professionals and licenses medical facilities in the country.



Patients are advised to seek medical assistance only from professionals registered and medical facilities licensed by these boards and councils.

## 7. How does an ordinary Kenyan know the person behind the counter of a chemist or pharmacy is a professional?

There are currently three cadres of pharmacy professionals recognized in Kenya, i.e., pharmacist specialists (post graduate pharmacists), pharmacists (Bachelor of Pharmacy degree holders) and pharmaceutical technologies (diploma holders). All these professionals must have current practice license which, should be clearly displayed at their premises for patients to see. In addition, all licensed premises have a health safety code displayed in their premises where patients and public can authenticate the licensure status of the premise and the personnel therein. SMS the code to 21031 free of charge

## 8. What can you say of Kenya's medical research sector concerning the research for a Covid-19 vaccine?

The Pharmacy and Poisons Board recognizes the importance of research in the race to develop novel treatment and preventive remedies for COVID-19, such as drugs and vaccines. In solidarity with all countries in the world and global bodies such as the World Health Organization, the Ministry through the Pharmacy and Poisons Board is responsible for the authorization of clinical trials.

Currently, there is one approved clinical trial in Kenya for COVID vaccine being carried out by KEMRI in Kilifi county. Generally, there is a very vibrant research environment in Kenya under the leadership of KEMRI for health products and technologies. The Board has a robust clinical trial review process, undertaken by an expert committee drawn from various relevant fields.

The Board has so far, received a total of seven (7) applications related to Covid-19 clinical trials. These applications propose the use of different products including convalescent plasma, vaccine, monoclonal antibody, repurposed drugs and radiotherapy.

### 9. What message do you have for the people of Kenya in this pandemic period?

Kenyans are advised to follow the laid down guidelines by the Ministry of Health on prevention of infection and control of the spread of COVID-19.

Access to safe medical products is a cornerstone of public health around the world. The PPB has established a comprehensive and functional regulatory system to ensure that only safe, good quality and efficacious medical products are available in Kenya. Measures in place include licensing of premises, personnel and practice; inspection of manufacturing facilities and distribution channels; product assessment and registration (marketing authorization); adverse events and product quality defects monitoring; Quality Control; and control of drug promotion and advertising.

### 10. Taking medicine without a doctors' prescription may be very dangerous even for a minor ailment. What are the dangers of self-medication?

Self-medication has potential risks such as: masking of severe disease leading to delay in seeking proper medical care, poor identification of sickness resulting in the wrong choice of medicines, incorrect dosages, incorrect drug administration, risk of abuse & dependence, exposure to adverse drug reactions and exposure to harmful drug-drug interactions.

The Board urges members of the public only to buy medicines from registered pharmaceutical premises after appropriate diagnosis and prescription from a qualified medical practitioner and ensure that they are only served by qualified personnel in these premises. **Look out for the Health Safety Code displayed in the premise** and SMS the code to 21031 free of charge or scan the QR code to verify the legitimacy of the license.



## PPB & MOH signs performance contract

**O**n March 16, 2021, the Pharmacy and Poisons Board, CEO Dr. F. Siyoi officially signed the Performance Contract with the Ministry of Health in the presence of the PS Health Susan Mochache.

Performance contracting is part of broader public sector reforms aimed at improving efficiency and effectiveness in the management of the public service.



Health PS Susan Mochache and PPB CEO Dr. F. M. Siyoi signs the Performance Contract



Health PS Susan Mochache and PPB CEO Dr. F. M. Siyoi display the Performance Contract

## PPB & Kemri signs agreement

**T**he Pharmacy and Poisons Board CEO Dr. F. M. Siyoi and his KEMRI counterpart Ag. Director General Prof. Sam Kariuki on May 12, 2021 signed a Service Level Agreement (SLA) that will enable continuation of tests conducted for performance & evaluation of In-Vitro Diagnostics, that started last year when the COVID-19 Pandemic was announced.

Performance and Evaluation process is a component of regulation of medical devices, with the In-Country Support by a reference laboratory to ensure safety, performance and efficacy of diagnostics that have been given market authorization by PPB. This process safeguards the public against receiving substandard kits.



PPB CEO Dr. F.M.Siyoi and Kemri's Ag. Director General Prof. Sam Kariuki signs Service Level Agreement

# PPB sensitizes court users committee

**O**n December 4, 2020 the Pharmacy and Poisons Board conducted a sensitisation awareness on its mandate to the Court Users Committee (CUC) at Kandara Law Courts as well the Public Health Impact of crimes associated with Health Products, Technologies and the Profession of Pharmacy.

The PPB emphasized on maintaining the strong partnership existing with the Judiciary, National Police Service and the Office of the Director of Public Prosecution and other stakeholders to ensure successful prosecution of drug related offences in a bid to ensuring public health safety.



Mr. Solomon Kamau engages Court Users Committee at Kandara Law courts



Court Users Committee group photo session

## PUBLIC NOTICE

To bring public services closer to our stakeholders and the general public, the Pharmacy and Poisons Board (PPB) has opened an office in Kiambu County at the office block of the Deputy County Commissioner, Room No. 17.

This is in line with the PPB 2020-2025 Strategic Plan which calls for the decentralization of PPB services.

For any assistance or inquires the office 24/7 hotline number is +254 115 684791 or email [ppbkiambu@pharmacyboardkenya.org](mailto:ppbkiambu@pharmacyboardkenya.org).

# Protocol for risk-based PMS underway

The Kenya National Technical Working Group on Pharmacovigilance and Post-Marketing Surveillance (KTWG-PV/PMS) undertook a workshop in Machakos between January 25 – 29th, 2021.

The objective of the five-day workshop was to develop a protocol for risk-based PMS of selected medical products and health technologies in Kenya.

The major output of the workshop was the practical application of the risk-based approaches in development and finalization of the document well as the deployment of the protocol in implementation of quality survey of medical products.

The activity which was funded by the United States Pharmacopoeia (USP/PQM+) brought together key partners and stakeholders in the pharmaceutical industry among them Pharmacy and Poisons Board (PPB), Mission for Essential Drugs and Supplies (MEDS), Kenya Medical Supplies Authority (KEMSA), National Quality Control Laboratory (NQCL), Kenya Medical Research Institute (KEMRI), University of Nairobi (UON) and Public Health Programmes (Nascop, TB program, Neglected Tropical Diseases program and Reproductive & Maternal Health).



Presentation by Dr. Evans Sagwa, Director Eastern and Southern Africa PQMPlus



Group discussion

# 68 traders arrested in crackdown on illegal pharmaceutical outlets in Western

Over 68 illegal pharmacy traders have been arrested and prosecuted, in western region for illegally handling pharmaceuticals.

The operation led by the Pharmacy and Poisons Board Deputy Director of Inspectorate, Dr. Dominic Kariuki seized 133 cartons of assorted medicines and closed down over 114 pharmaceutical outlets. These include some government supplied medicines found in a private chemist at Mayoni market within Kakamega County.

“PPB calls upon the judiciary to dispense deterrent sanctions as provided under the revised pharmacy and poisons Act 2019 to the persons found guilty of contravening the provisions of the Cap 244 of the laws of Kenya,” Dr Kariuki said.

The Board, through surveillance and intelligence gathering had profiled hot spots within Western region with high levels of non-compliance to Good Distribution Practices of Medical products and health technologies.



Western region comprises the counties of Kakamega, Busia, Bungoma and Vihiga. “These were the areas that were targeted for the joint operation by PPB inspectors, national government administrative organs and the Police Service began on 17th May, 2021.

This operation targeted unlicensed premises, pilfered government drugs, illegal medicine hawkers and illegal sale

of restricted medicines in the open-air markets, general shops and kiosks within the region.

Dr. Kariuki said the enforcement of closure shall be monitored by the Police and the respective offices of County Commissioners and disclosed that registered pharmacists and enrolled pharmaceutical technologists involved in pharmaceutical malpractices have been flagged for disciplinary process at the Board.

He urged public and private healthcare facilities and those who handle pharmaceuticals to apply online through website [www.pharmacyboardkenya.org](http://www.pharmacyboardkenya.org) for disposal of any pharmaceutical waste that they may have or get in touch with PPB regional officers.

“We are also advising to members of public to report any suspected case of quacks operating within their areas as they are a danger to public health,” he noted and informed that Registered pharmacy outlets can be verified by sending the code displayed in the outlets to 21031 and it is free of charge.

The Pharmacy and Poisons Board, PPB, is the national medicines regulatory authority whose mandate is 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.



Illegal display of pharmaceuticals in open air markets in Western region



# PPB conducts follow-up inspection of Pharmacy outlets

Since July 2020 the Pharmacy Poisons Board (PPB) has sustained inspections on all pharmaceutical outlets focusing on the following key objectives.

- Market surveillance to monitor the pharmaceutical regulatory compliance levels in line with July 2019 Good Distribution Practice (GDP) guidelines.
- Conducting GDP Audit on selected public health facilities and major public procuring agencies.
- Audit of level 5, Level 4 and high-volume level 3 private hospitals in the country.
- Audit of all the six referral hospitals in the country that includes; Kenyatta National Hospital, Moi Teaching and Referral Hospital, KNH Othaya Annex, Kenyatta University Teaching and Referral Hospital, Mathari Mental and Referral Hospital and the National Spinal Injury.
- Audit of Kenya Medical supplies Agency (KEMSA) and Mission for Essential Drugs Supplies (MEDS) warehouses as the major public and private pharmaceutical procurement entities respectively.
- Monitoring if the measures for prevention & control of COVID-19 are being implemented in all pharmaceutical outlets.
- Crackdown on sub-standard alcohol-based hand sanitizers in the market (based on the PPB laboratory findings following a targeted sampling and testing conducted between March and June 2020)



PPB Drug Inspectors during an inspection activity of pharmaceutical outlets

Through this follow up inspection exercise, PPB has audited a total of 1224 pharmaceutical outlets and 49 County Referral and Sub County Hospitals as at December 1, 2020.

At the same time closed down 271 pharmaceutical outlets across the country for failure to adhere to GDP regulations. The distribution list of closed outlets per region is as follows;

- Nyanza and Western Regions - **62 pharmaceutical premises.**
- North Rift and South Rift Regions - **19 pharmaceutical premises.**
- Central and Upper Eastern Regions - **15 pharmaceutical premises.**
- Coast and Lower Eastern Regions - **71 pharmaceutical premises.**
- Nairobi Region - **83 pharmaceutical premises.**
- North Eastern Region - **21 pharmaceutical premises.**

The details of the irregular pharmaceutical outlets which have been closed were shared with the other national administrative agencies for enforcement of closure and probable prosecutions.

# PPB whips illegal outlets in South Rift

The Pharmacy and Poisons Board (PPB), is the body mandated by Cap 244 of the laws of Kenya to ensure that all Kenyans access quality, safe and efficacious medicines.

On February 12, 2021, the Board's Drug Inspectors in conjunction with Kenya Police Service carried out a targeted crackdown on illegal pharmacies within South-Rift Region covering Nakuru, Bomet, Kericho, Narok, Laikipia and Samburu Counties.

The PPB Drug Inspectors carried out total seizure of all medicines found in the illegal premises and arrested personnel operating them out of which, 116 cartons of assorted medicines were seized in the operation and put under the custody of PPB pending court directions.

The activity also saw the closure of 90 premises and an arrest of 42 persons. The list of closed premises was shared with county administration and Kenya Police Service for enforcement of closure.

PPB thanks the Kenya Police Service and the Judiciary for their cooperation during this crackdown. Those who were taken to courts were fined between Ksh. 50,000 to Ksh. 200,000 and those who pleaded guilty were fined up to Ksh. 40,000.

The Board wishes to request the courts to enhance fines for those found guilty, in line with the fines in the amended Cap 244, to act as a deterrent.



## 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**

- 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



REPUBLIC OF KENYA  
PHARMACY AND  
POISONS BOARD

**LICENSED PHARMACY  
HEALTH SAFETY CODE:**

XXXXX

**TO VERIFY  
SEND CODE TO 21031**

[www.pharmacyboardkenya.org](http://www.pharmacyboardkenya.org)

**Be safe. Buy medicines from a licensed pharmacy**

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



# 61 arrested in a crackdown targeting lower Eastern Region

A total of 95 illegal pharmaceutical outlets were closed down during a crackdown conducted by the Pharmacy and Poisons Board in conjunction with the Kenya Police Service in the Lower Eastern region on February 26, 2021.

The crackdown which kicked off on February 22, 2021 was led by the Deputy Director Inspectorate, Surveillance and Enforcement, Dr. Dominic Kariuki and covered the counties of Kitui, Makueni and Machakos.

Dr. Kariuki said the targeted pharmaceutical outlets were identified during routine inspections to have flouted regulations.

As a result of the operation, 61 persons were arrested and taken to court and 85 cartons of assorted medicines were seized. The seized medicines will be analyzed and disposed as per PPB guidelines on disposal of pharmaceutical waste, said Dr. Kariuki.

The list of closed premises was shared with county administration and Kenya Police Service for enforcement of closure.

The accused persons were charged with various offenses ranging from possession of part 1 poisons contrary to section 26(1) of the Pharmacy and Poisons Act and carrying out the business of a pharmacist/pharmaceutical technologist in premises not registered among others.

Those who pleaded guilty were fined up to Ksh. 240,000 or imprisonment of up to 18 months.



PPB Drug Inspectors seize medicines in illegal outlets in Lower Eastern Region



Assorted medicines seized during a crackdown in Lower Eastern Region.

The Pharmacy and Poisons Board wishes to thank the Kenya Police Service and the Judiciary for their cooperation during this crackdown. However, the Board wishes to request the courts to enhance fines for those found guilty, in line with the fines in the amended Cap 244, to act as a deterrent.

During the crackdown, PPB officials obtained invoices, receipts and other documents from the illegal premises that will help in the identification of the licensed wholesalers of pharmaceuticals who are supplying the illegal premises. The owners of those wholesalers will be prosecuted and their licenses revoked.

PPB inspectors have observed with concern a trend where licensed pharmacy outlets are left to be manned by unqualified persons. Such absentee superintendents have been summoned for disciplinary action as per Cap 244 of the laws of Kenya.

PPB wishes to notify both public and private healthcare facilities and those who handle pharmaceuticals to apply online for safe disposal of any pharmaceutical waste that they may have or get in touch with PPB regional officers. PPB website: [www.pharmacyboardkenya.org](http://www.pharmacyboardkenya.org)

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

# PPB conducts crackdown in upper Eastern Region

At least 100 illegal pharmacy premises have been closed down in a crackdown conducted by the pharmacy and poisons board in the upper eastern region which include Meru, Embu, Tharaka Nithi, Isiolo and Marsabit Counties.

Speaking during a press briefing in Meru town on 12 March 2021 Senior Drugs Inspector, Mr Julius Kaluai said in the same exercise, a total of 90 cartons of assorted medicines were seized.

The medicine will be analysed and if found fit for use, it will be donated to public hospitals and on the contrary, disposed of as per the board's guidelines.

At least 43 persons were also arrested and taken to various courts where they were fined between Sh60,000- Sh100,000.

Mr Kaluai said the crackdown was part of their routine process of ensuring that Kenyans access quality, safe and efficacious medicines.

"This time the crackdown targeted those pharmacy outlets that had been identified during routine inspections to have flouted the regulations. In our next move we will be checking on premises that we closed previously and this has proved to be an effective way of weeding out illegal outlets," said Mr Kaluai.

He said the list of all closed premises will be shared with the county administration and the police for enforcement of closure.



Senior Drug Inspector Mr. Julius Kaluai displays a closure notice to the media at a press briefing in Meru

In the same crackdown, Mr Kaluai added, the board officials obtained invoices, receipts and other documents from the illegal premises that are helping them identify the licensed wholesalers of pharmaceuticals who are supplying the illegal premises.

Once identified, the owners of the wholesale outlets will be prosecuted and their licenses revoked.

"It is the responsibility of every medicine wholesaler to verify the documents of those who they are selling to. Failing to do this is an illegality and they will face the consequences since these documents are not private in any way," said Mr Kaluai.

Mr Kaluai said that they also observed with concern a trend where licensed pharmacy outlets are left to be manned by unqualified persons adding that such absentee superintendents have been summoned for disciplinary actions as stipulated by the law.

He advised members of the public to use health safety codes displayed in registered pharmacy outlets in order to verify the legality of the premises.

"The board wishes to notify both public and private healthcare facilities and those who handle pharmaceuticals to apply online for disposal of any pharmaceutical waste that they may have or get in touch with their regional officers for assistance," said Mr Kaluai.



Senior Drug Inspector Mr. Julius Kaluai addresses the media at a press briefing in Meru

# PPB seize 171 cartons of assorted medicines in Nairobi and Kajiado

On 22nd January 2021, the Pharmacy and Poisons Board Drug Inspectors in conjunction with the Kenya Police Service seized 171 cartons of medicines found in illegal premises within Nairobi and Kajiado counties.

The Director for Good Distribution Practice Dr. Dominic Kariuki said the confiscated medicines will be analyzed and disposed as per PPB guidelines on disposal of pharmaceutical waste.

The operation also saw the closure of 71 premises and an arrest of 49 persons. The list of the closed premises was shared with the county administration and Kenya Police Service for enforcement of closure.

The Board wishes to thank the Kenya Police Service and the Judiciary for their cooperation during the crackdown. Those who were taken to courts were given cash bail of between Ksh. 150,000 to Ksh. 500,000. Those who pleaded guilty were fined up to Ksh. 50,000.

“We are requesting the courts to enhance fines for those found guilty, in line with the fines in the amended Cap 244, to act as a deterrent,” said Dr. Kariuki.



Assorted herbal medicines seized during a crackdown in Nairobi and Kajiado



PPB Drug Inspector displays assorted herbal medicines seized during a crackdown in Nairobi and Kajiado

During the crackdown, invoices, receipts and other documents from the illegal premises were obtained to assist in identifying the licensed wholesalers of pharmaceuticals who are supplying the illegal outlets. The owners of those wholesalers will be prosecuted and their licenses revoked.

Meanwhile the Board wishes to notify the public and private healthcare facilities handling pharmaceuticals to apply online for disposal of any pharmaceutical waste that they may have or get in touch with PPB regional officers. (PPB website: [www.pharmacyboardkenya.org](http://www.pharmacyboardkenya.org))

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



## PPB arrests 58 in the Coast Region



A closed premise in Mombasa

Mombasa, March 26, 2021- At least 58 people have been arrested and arraigned in court in a crackdown targeting illegal pharmacies in the Coast region which include Mombasa, Kwale, Kilifi, Taita Taveta and Tana River counties.

The operation conducted by the Pharmacy and Poisons Board drug inspectors in conjunction with Kenya Police Service targeted pharmacy outlets that had been identified during routine inspections to have flouted regulations.

During the activity, 124 illegal pharmacies were closed down and 48 cartons of assorted medicines were seized, said Dr. Dominic Kariuki, Deputy Director, Inspectorate Surveillance and Enforcement.

The medicines will be analyzed and disposed as per PPB guidelines on disposal of pharmaceutical waste.

Dr. Kariuki said those who pleaded guilty were fined of up to Ksh.40,000 or imprisonment of up to 5 months. He further said the Board wishes to request the courts to enhance fines for those found guilty, in line with the fines in the amended Cap 244 (to Ksh.1,000,000) to act as a deterrent.

The list of closed premises has been shared with county administration and Kenya Police Service for enforcement of closure.

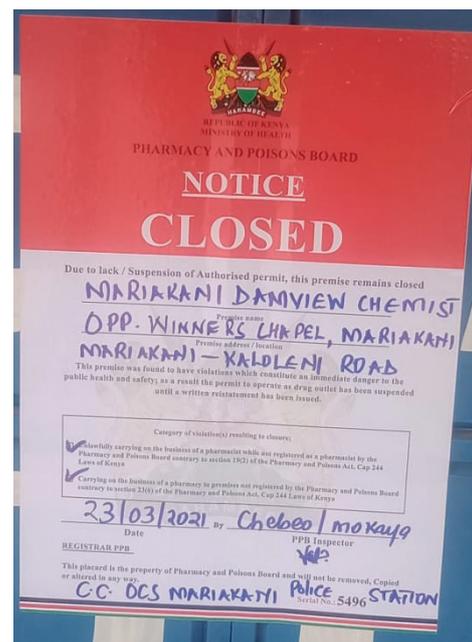
Dr. Kariuki said they have observed with concern a trend where licensed pharmacy outlets are left to be manned by unqualified persons adding that such

absentee superintendents have been summoned for disciplinary action as per Cap 244 of the laws of Kenya.

He urged public and private healthcare facilities and those who handle pharmaceuticals to apply online for disposal of any pharmaceutical waste that they may have or get in touch with PPB regional officers.

The guidelines are available on the PPB website: [www.pharmacyboardkenya.org](http://www.pharmacyboardkenya.org)

The Board advises members of the public to use health safety codes displayed in registered pharmacy outlets to verify their legality. Send SMS free of charge to 21031.



Closure notice displayed in an illegal premise in Mariakani

# 69 arrested over illegal handling of pharmaceuticals

The Pharmacy and Poisons Board is the national medicines regulatory authority whose mandate is 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 light of the above, PPB drug inspectors conducted an intensive surveillance and enforcement operation within Kakuma Refugee camp, Kakuma town, Kanamkemer market and Lodwar town within Turkana County.

The activity which started on April 26, 2021 aimed at countering the mushrooming of medicine hawkers and unsuitable storage practices for pharmaceuticals within the county.

The operation is part of targeted pharmaceutical enforcement surveillance within the North Rift Region covering the Counties of West Pokot, Trans Nzoia,



Cartons of seized medicines



Assorted medicines seized during a crackdown in Kakuma

Nandi, Baringo, Elgeyo Marakwet, Turkana and Uasin Gishu.

At least 69 people were arrested for illegally handling pharmaceuticals and 80 cartons of assorted medicines were seized. The arrested persons have been booked for prosecution in various courts within North Rift region.

Details of 95 premises that were closed down in the operation were shared with the national government administrative agencies and the respective county governments for enforcement of closure.

PPB calls upon the judiciary to dispense deterrent sanctions to the persons found guilty of breaching the requirements of cap 244 to ensure preservation of public health.

The public and private healthcare facilities and those who handle pharmaceuticals are notified to apply online for safe disposal of any pharmaceutical waste that they may have or get in touch with PPB regional officers. PPB website: [www.pharmacyboardkenya.org](http://www.pharmacyboardkenya.org)

Members of the public are advised to use 'Health Safety' codes displayed in registered pharmacy outlets to verify legality of the premises. Send SMS free of charge to 21031.



Inside illegal shelters where medicines are stored

# PPB Destroys smuggled pharmaceuticals worth over 32M

The Pharmacy and Poisons Board is the national medicines regulatory authority whose mandate is 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.

On April 14, 2021 the PPB drug inspectors jointly with the Judiciary, Department of Crime Investigations (DCI) and the Office of the Director of Public Prosecutions (ODPP) supervised the destruction of 346.3 kilograms of assorted pharmaceuticals all valued at Kshs.32,324,515 following a court order requiring that drugs produced in Court be forfeited to the state for destruction through incineration under the Court's supervision.

The consignment of medical products in question was being smuggled through JKIA as personal luggage. The PPB inspectors seized the medicines and the owners arrested following a joint intelligence exercise with customs and DCI in 2018.



Joint inter-government agencies officials before the destruction exercise



Sacks of assorted pharmaceuticals before destruction



The products which were wrapped in sacks included mifepristone tablets and other assorted medicines mixed in sacks.

The case was finalized and the three accused persons were fined Kshs. 700,000 each while the exhibits were forfeited to the state for safe disposal through incineration.

PPB wishes to notify both public and private healthcare facilities and those who handle pharmaceuticals that they should apply online through website [www.pharmacyboardkenya.org](http://www.pharmacyboardkenya.org) for disposal of any pharmaceutical waste that they may have or get in touch with PPB regional officers.

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.

## PUBLIC NOTICE

### Regulatory guidance for Healthcare Professionals on appropriate use of antimicrobial medicines

The Pharmacy and Poisons Board (“the Board”) is the National Medicines Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board regulates the Practice of Pharmacy and the trade of Medical Products and Health Technologies in Kenya.

The Board aims to implement appropriate regulatory measures to achieve the highest standards of safety, efficacy and quality for medical products and health technologies to ensure the protection of the consumer as envisaged by the laws regulating medicines in Kenya.

The Pharmacy and Poisons Board would like to notify all healthcare professionals that there is increasing resistance to antimicrobials in Kenya and globally. The World Health Organization (WHO) has declared AMR as one of the top ten (10) global public health threats facing humanity.

The Kenya National Policy and Action Plan documents on the Prevention and Containment of Antimicrobial Resistance (2017-2022) recognize that the misuse and overuse of antimicrobial medicines in humans, animals and food production poses a high risk of resistance to the health of the public considering that very few new antimicrobial medicines are being discovered over time.

In light of this, the Pharmacy and Poisons Board would like to guide as follows;

1. All antimicrobial medicines shall be prescribed by duly registered prescribers as outlined in the Medical Practitioners and Dentists Act, Chapter 253 and the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya.
2. All antibiotic medicines shall be prescribed according to the Access, Watch, Reserve (AWaRe) classification outlined in the Kenya Essential Medicines List, 2019.
  - **Access** antibiotics have activity against a wide range of commonly encountered susceptible pathogens while showing low potential for development of resistance.
  - **Watch** antibiotics have higher resistance potential or higher toxicity concerns and should be prioritized as key targets of national, county and healthcare facility antimicrobial stewardship programs and monitoring.
  - **Reserve** antibiotics should be reserved for treatment of confirmed or suspected infections due to multi drug-resistant organisms and treated as ‘last-resort’ options. They should be protected and prioritized as key targets of national and international antimicrobial stewardship programs, involving monitoring and utilization reporting, with the aim of preserving their effectiveness.
3. All antimicrobial medicines shall be dispensed from duly registered pharmacies / chemists and healthcare facilities.
4. Healthcare professionals are advised to educate patients and the public on the risk of antimicrobial resistance and appropriate use of antimicrobial medicines.

## PUBLIC NOTICE

### Regulatory guidance for the **General Public** on use of antimicrobial medicines

The Pharmacy and Poisons Board (“the Board”) is the National Medicines Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board regulates the Practice of Pharmacy and the trade of Medical Products and Health Technologies in Kenya.

The Pharmacy and Poisons Board would like to caution the general public over the increasing resistance to antimicrobial medicines (antibiotics, antivirals, antifungals and antiparasitics) both in Kenya and globally. These medicines are used to prevent and treat infections in humans, animals and plants.

Antimicrobial Resistance (AMR) occurs when bacteria, viruses, fungi and parasites no longer respond to these medicines. The World Health Organization (WHO) has declared AMR as one of the top ten (10) global public health threats facing humanity.

The Kenya National Policy and Action Plan documents on the Prevention and Containment of Antimicrobial Resistance (2017-2022) recognize that the misuse and overuse of antimicrobial medicines in humans, animals and food production poses a high risk of resistance to the health of the public considering that very few new antimicrobial medicines are being discovered over time. Antimicrobial resistance leads to inadequate treatment of infections, longer hospital stays, higher medical costs and increased deaths.

In light of this, the Board would like to advise the public as follows;

1. The public is discouraged from self-medication with antimicrobial medicines.
2. The public should **ONLY** access antimicrobial medicines using valid prescriptions from registered pharmacies/chemists, clinics and hospitals.
3. Antibiotics are a class of antimicrobial medicines that are only effective against bacterial infections. Antibiotics are **NOT** the solution for infections caused by viruses such as common colds or flu. The correct diagnosis and the decision about whether antibiotics are necessary can only be made by a qualified healthcare professional.
4. The public should ensure that they complete the full dose of prescribed antimicrobial medicines.
5. Unused antimicrobial medicines should **NOT** be disposed of in toilets or waste bins but returned to the pharmacy/chemist where it was obtained from or taken to the nearest clinic/hospital.
6. Antimicrobial medicines should **NOT** be stored at home for purposes of future use.
7. The public should **NOT** share antimicrobial medicines with friends or relatives.
8. For more information on antimicrobial resistance, you can contact the Pharmacy and Poisons Board at [pv@pharmacyboardkenya.org](mailto:pv@pharmacyboardkenya.org) or call +254 795 743 049.



Pharmacy and  
Poisons Board



# HAVE YOU EXPERIENCED ANY **SIDE EFFECTS?**

The Pharmacy and Poisons Board encourages you to report any suspected side effects following use of medicines or vaccines.

You can report through the channels below:

PUBLIC/PATIENTS	
Website	<a href="http://pv.pharmacyboardkenya.org/padrs/add">pv.pharmacyboardkenya.org/padrs/add</a>
Phone	<a href="tel:+254795743049">+254 795 743 049</a> or report to the nearest health facility

HEALTH WORKERS	
Website	<a href="http://pv.pharmacyboardkenya.org/">pv.pharmacyboardkenya.org/</a>
Email	<a href="mailto:pv@pharmacyboardkenya.org">pv@pharmacyboardkenya.org</a>
Phone	<a href="tel:+254795743049">+254 795 743 049</a>



# *In Loving Memory*



*Dr. Edwin  
Osano*



*Mr. James  
Kariuki Thuo*

*We are all deeply saddened by the tragic and unexpected loss of our wonderful friends and colleagues, Dr. Edwin Osano and James Kariuki Thuo.*

*It was a privilege for us at the Pharmacy and Poisons Board to have been a part of Osano and Thuo's life.*

*Your sudden death has touched our lives and hearts dear colleagues. The way you have inspired us has touched us even more.*

*Your friendship was a blessing. You brightened up our days. You lifted our spirits. But we should never question what God has planned.*

*So as we remember our beloved brothers, we have to keep telling ourselves that we will meet again.*



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](http://www.pharmacyboardkenya.org)



[info@pharmacyboardkenya.org](mailto:info@pharmacyboardkenya.org)



Pharmacy and Poisons Board



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