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PHARMACY AND POISONS BOARD

- NEWSLETTER

www.pharmacyboardkenya.org



Say No to Self-Medication: Pharmacy and Poisons Board issues urgent warning against Antimicrobial Resistance



PHARMACY AND POISONS BOARD

PRESS STATEMENT

WORLD HEALTH ORANISATION (WHO) ALERT ON PEDIATRIC MEDICINES

The Pharmacy and Poisons Board has received a medical product alert (RPQ/REG/ISF/Alert N°6/2022) from the World Health Organization (WHO) on substandard medical products manufactured by Maiden Pharmaceuticals (Haryana, India) circulating in the **Gambia Republic**.

According to WHO the laboratory analysis of the four products namely; Promethazine Oral Solution (Manufactured by Maiden Pharmaceuticals, India), Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup, and Magrip N Cold Syrup, found that they contain unacceptable amounts of diethylene glycol and ethylene glycol as contaminants.

This is to notify the members of the public that the WHO alert is specific to medical products manufactured by **Maiden Pharmaceuticals** (Haryana, India), and NOT any other manufacturing sites.

Further, the Pharmacy and Poisons would like to inform the public that the impacted products are **NOT registered** in Kenya and therefore they are **NOT available in the Kenyan market**.

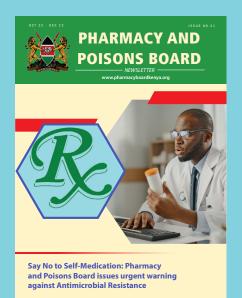
We reassure the public that there is no cause for alarm as the cough preparations (syrups) and promethazine products in the Kenyan market meet the market authorization requirements on quality, safety, and efficacy as laid out by the Pharmacy and Poisons Board.

Members of the public are however advised to be vigilant at all times and report any suspected poor-quality medicines or adverse drug reactions to the nearest healthcare facility and the Pharmacy and Poisons Board through the website https://pv.pharmacyboardkenya.org/padrs/add, mobile application: mPvERS both android & iOS and USSD code at *271# or Email: pv@pharmacyboardkenya.org

Dr. F.M. Siyoi

CHIEF EXECUTIVE OFFICER

7th October, 2022



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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 staff and stakeholders of the Board

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Editor's Note

We value you

Dear readers,

Greetings, and welcome to the 21st Edition of the Pharmacy and Poisons Board Newsletter!

In this edition, we are delighted to share with you some exciting news and updates from PPB team. Our aim is to provide you with relevant information and insights that will keep you informed about the latest industry trends and developments.

We hope you find this edition useful and engaging. As always, your feedback and suggestions are highly valued, so please do not hesitate to reach out to us at *pr@pharmacyboardkenya.org*

Thank you for your continued support!



ONGOING EVENTS

 Updating the Kenya Corrective and Preventive Action (CAPA) following the WHO Global Benchmarking Tool assessment of regulatory systems



PHARMACY AND POISONS BOARD

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Pharmacy and Poisons Board in Kenya Hosts AVAREF Assessment for Clinical Trials Oversight Improvement



The AVAREF team during a meeting at Pharmacy and Poisons Board

The Pharmacy and Poisons Board (PPB) in Kenya recently hosted the African Vaccine Regulatory Forum (AVAREF) assessment team for an audit of Clinical Trials Oversight in Kenya. As one of five African countries selected for participation in AVAREF's Clinical Trial Oversight Systems optimization program, the assessment aims to improve PPB's regulation and reduce the lead time for the review and approval of clinical trial applications.

consultation with various

stakeholders, including the PPB, the National Commission for Science Technology and Innovation (NACOSTI), and ethics committees, the AVAREF team will propose recommendations to optimize the clinical trial process.

The CEO of PPB, Dr. Fred Siyoi, welcomed the team, led by Dr. Diadié Maïga from WHO AFRO, along with Alambo Mssusa (WHO AFRO), Dr. Andrea Reias, and Dr. Barbara Bierer from the MRCT Center at Harvard.

Dr. Siyoi expressed his commitment to strengthening the regulatory systems at PPB and thanked the WHO and AVAREF for their continued support in enhancing regulatory systems in Kenya. He emphasized the importance of collaborating with all stakeholders ensure the best possible outcome for clinical trials in the country.

Anticounterfeit Authority and Pharmacy and Poisons Board Seek Collaboration for a Common Goal

On December 1, 2022, a historic meeting took place at the Pharmacy and Poisons Board as the delegation from the Anticounterfeit Authority (ACA), led by its dynamic CEO, Dr. Mbugua Njoroge, paid a courtesy visit to the Pharmacy and Poisons Board CEO, Dr. Fred Siyoi. The two leaders came together to explore opportunities for mutual collaboration in executing their respective statutory mandates.

This meeting marks a significant step in the fight against counterfeit products and the protection of



Pharmacy and Poisons Board Chief Executive Officer, Dr. F. M. Siyoi during a meeting with the Anticounterfeit delegation

public health. By working together, the ACA and Pharmacy and Poisons Board can leverage each other's strengths and expertise to create a more comprehensive and effective approach to achieving their goals.

With the shared mission of ensuring public safety and the well-being of Kenyan citizens, the ACA and Pharmacy and Poisons Board are committed to

eliminating counterfeit products from the market. This meeting is a clear demonstration of their commitment to working together for the greater good.

As we look forward to the outcome of this meeting, it is clear that the future of public health in Kenya is in good hands. With the ACA and Pharmacy and Poisons Board joining forces, the fight against



counterfeit products has never been stronger. Let us all support their efforts in making a safer and healthier future for Kenya and its

Say No to Self-Medication: Pharmacy and Poisons **Board Issues Urgent Warning Against Antimicrobial** Resistance

By Dr. Karim Wanga, **Head Post Marketing Surveillance**



Head of Post Marketing Surveillance at PPB, Dr. Karim Wanga

The Pharmacy and Poisons Board is sounding the alarm for all Kenyans

to stay away from self-medication and continue purchase

medicines only as prescribed by licensed healthcare professionals. The reason behind this warning is to prevent the rise of antimicrobial resistance, which is a major threat to public health worldwide.

Dr. Karim Wanga, the Head of Post Marketing Surveillance and the antimicrobial resistance (AMR) focal point at the Pharmacy and Poisons Board, stressed the dangers of self-medication with antibiotics during a speech in Nairobi during the Kenya Medical Association (KMA) symposium. He pointed out that self-medication with antibiotics can lead to numerous drug-related problems, including the emergence of antimicrobial resistance, drug overdose, drug misuse, poor treatment outcomes, and even death.

"The general public, healthcare providers, and facilities have a role to play in ensuring the appropriate medicines, of including antimicrobial agents. This can help reduce the emergence or spread of antimicrobial resistance," Dr. Wanga stated.

Dr. Wanga went on to explain that antimicrobials have saved countless lives over the years, but their

overuse, misuse, and inappropriate disposal are driving antimicrobial resistance (AMR). Indiscriminate use, misuse, and overuse in human health, animal health, crop sectors, aquaculture, and poor disposal practices are contributing factors to the rise of AMR.

Although Kenya has implemented guidance documents to prevent and contain AMR, they have not been effectively utilized. In the Pharmacy and response, Poisons Board has created new rules for the disposal of pharmaceutical waste to ensure public safety and prevent hazardous outcomes.

The health and economic impact of AMR is immense, with the annual deaths from drug-resistant infections projected to increase from the current 700,000 to 10 million globally by 2050 if action is not taken to contain it. The global economic cost of AMR is also projected to rise to 100 trillion US dollars by 2050.

the "The major concern is of emergence and spread multi-drug resistant bacteria, where it seems we are running out of treatment options," Dr. Wanga warned, adding that greater attention should be paid to the growing resistance to antimicrobials used for treatment for HIV, TB, and Malaria.

Despite the dire situation, Dr. Wanga is not giving up hope. "All is not lost in the fight against AMR. We can do something to prevent the emergence of new resistance or slowdown the spread of existing resistance," he said.

To prevent the spread of AMR, Dr. Wanga emphasized the importance of only using antibiotics when prescribed by licensed healthcare professionals and taking the of course antimicrobial prescriptions. Patients and the public are also advised to not

share antimicrobials with others, avoid self-medication and over the counter use of antimicrobials. and to implement effective hand washing and hygiene practices to prevent infections.

Healthcare workers play a role in containing AMR practicing proper hand hygiene, cleaning instruments and healthcare facilities, keeping patients' vaccinations up to date, and only dispensing antibiotics when truly necessary.

Dr. Wanga's final message was clear: "Patients and the public should only use antibiotics when prescribed by qualified and licensed healthcare professionals and they should always take the full course of antimicrobial prescriptions even when they feel better. Healthcare workers should only dispense antibiotics when truly needed and implement all necessary measures to prevent the spread of AMR."

PPB Holds Meeting with Pharma Industry Stakeholders to Disseminate New Pharmacy and Poisons Board Rules 2022

The Pharmacy and Poisons Board (PPB) held a meeting with various stakeholders in the pharma industry on October 10, 2022 to inform them about the newly enacted Pharmacy and Poisons Board Rules 2022. Dr. Jacinta Wasike, Director for Corporate Services, presided over the event on behalf of the PPB Chief Executive Officer, Dr. F. M. Sivoi. The aim of the meeting was to disseminate information about the six sets of rules, which were successfully gazetted in June 2022.

According to Dr. Wasike, the new rules will support regulatory effectiveness and help achieve global standards. She emphasized that public safety is the driving force behind the regulations and stated, "A strong regulatory system is necessary to ensure the quality, safety, and efficacy of health products and technologies."

The six rules outlined by Dr. Wasike include:

- 1. Pharmacy and Poisons (Guidelines for the conduct of Clinical Trials) Rules, 2022
- 2. Pharmacy and **Poisons** (Transportation of Pharmaceuticals) Rules, 2022
- 3. Pharmacy **Poisons** and (Pharmaceutical Waste



PPB's Head of Legal Services, Mr. Kibet Kisorio makes his presentation

Management) Rules, 2022

4. Pharmacy **Poisons** and (Pharmacovigilance and Surveillance) Post-Market Rules, 2022

- 5. Pharmacy and **Poisons** (Registration of Health Products and Technologies) Rules, 2022
- 6. Pharmacy and Poisons (Amendment) Rules, 2022.

PPB The engaged with stakeholders during the meeting to ensure the effective implementation of the new rules and to address any concerns or questions they may have.



Stakeholders and PPB staff pose for a photo after the meeting

Pharmacy and Poisons Board warns against unqualified **Pharmacists and Technologists in Healthcare**



Head of Inspectorate and Enforcement Julius Kalui and PPB Inspectors during a courtesy call on Meru Governor Hon. Kawira Mwangaza

The Pharmacy and Poisons Board (PPB) has issued a warning to county governments against employing unqualified pharmacists and pharmaceutical technologists in their health facilities. The warning came after a random verification audit by the PPB uncovered eight unqualified staff, including one pharmacist and seven pharmaceutical technologists, working in public hospitals in four counties.

The audit, which took place between October and November, was conducted following complaints about unqualified individuals working as pharmacists and technologists in some county facilities. Julius Kalaui, the Head of Inspectorate and Enforcement



PPB inspectors with Laikipia Deputy Governor during the verification audit

at the PPB, confirmed that regulatory inspectors from the board conducted the audit in seven counties and found that four of them had employed unqualified staff.

The affected counties are Meru, Isiolo, Marsabit, and Samburu. The audit involved a thorough review of personal files and payrolls, compared to the list of pharmaceutical technologists and pharmacists available at the county pharmacist office.

Kalaui advised all county public service boards to verify the enrollment status of technical staff with relevant bodies before hiring them. He emphasized that the PPB is the statutory body responsible for regulating the pharmacy profession and ensuring access to quality, safe, and affordable health products and technologies.

Unqualified staff pose a threat to public health, Kalaui warned. He urged county governments to seek guidance from the PPB's regional offices on pharmacy practice and health products and technologies. The PPB has



written letters to the affected counties advising them to recover salaries from unqualified staff and has taken two people from Meru County to court.

Kalaui hinted that the national audit will be extended to other



PPB inspectors with Nyeri Deputy Governor during the verification audit

counties to eliminate quacks and ensure that only qualified pharmaceutical staff are hired. This comes after Doctor James Mugo Ndichu, also known as Mugo wa Wairimu, was sentenced to 29 years in

jail this month for unlawfully administering drugs and raping patients at his clinic in 2015. Mugo is already serving 11 years in jail for operating unlicensed medical facilities.

Pharmacy and Poisons Board conducts joint inspection targeting illegal pharmaceutical outlets in Nairobi



PPB drug inspectors pack seized medicines during a crackdown

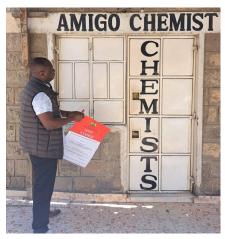
The Pharmacy and Poisons Board (PPB) carried out a joint regulatory inspection and investigation in the Nairobi region on October 30, 2022, focusing on illegal pharmaceutical outlets. The previous exercise targeted outlets that were shut down by the PPB and also profiled wholesale pharmacies that were deliberately avoiding routine audits. Julius Kaluai, the Head of Inspectorate and Enforcement at the PPB, confirmed that the Board was enforcing the closure of non-compliant premises.

The PPB is responsible for regulating the practice pharmacy and ensuring the safety, quality, and efficacy of medical products and health technologies in Kenya. As part of the investigation, the Board also engaged with stakeholders and sensitised them on its mandate, with a focus on key players in the criminal justice system such as the police, the ODPP, and judicial officers.

According to Kaluai, out of 120 pharmaceutical premises that were issued with closure notices, 79 outlets ceased operations, 11 complied with regulations, and 30 defied the order by altering the closure notice and reopening under different names. The 30 violators have been located, arrested, and their merchandise seized. They have been registered for prosecution in courts in Nairobi and Kajiado

counties. Five wholesale dealers in pharmaceuticals were also arrested for violating Cap 244 provisions, and investigations are underway to apprehend the owners and revoke their licenses.

Kaluai noted in statement that all practitioners in the affected premises will be subjected to disciplinary measures by the Board. He also issued a warning to the public to avoid chemists without names on display or signage, as this is a sign of an illegal pharmaceutical premise. The public is advised to verify the registration details of pharmacy practitioners at community pharmacies,



hospital pharmacies, and any other drug dispensing premises, which can be found at https://practice.pharmacyboardkenya.org/LicenseStatus. Any suspected practitioners can be reported via email to info@pharmacyboardkenya.org.

63 people arrested for engaging in illegal pharmaceutical practices in Kenya

A joint operation between the Pharmacy and Poisons Board and the Kenya Police Service resulted in the arrest of 63 individuals for engaging in illegal pharmaceutical practices in the Coast, Nairobi, and Central regions of Kenya. The operation, conducted from December 18th to 23rd of 2022, involved 69 targeted inspections and the seizure of 143 boxes of various health products and technologies.

The Head of Inspectorate and Enforcement at the Pharmacy and Poisons Board, Mr. Julius Kaluai, emphasized the importance of investigating, prosecuting, and reporting illegal pharmaceutical outlets and wholesalers. He also cautioned licensed practitioners against leaving their practices in the hands of unqualified personnel. "The affected practitioners will be subjected to the Board's disciplinary committee in addition to court prosecution," Kaluai



Assorted medicines seized during the crackdown

stated, and advised the public to avoid purchasing medicines from chemists with no names or signages on display. He encouraged the public to verify the registration details of pharmacy practitioners through the Pharmacy and Poisons Board's website or by reporting suspected practitioners to info@

pharmacyboardkenya.org.

The Pharmacy and Poisons Board is the National Drug Regulatory Authority in the Ministry of Health and is responsible for regulating the practice of pharmacy and ensuring the safety, quality, and efficacy of medical products and health technologies.



Closure notice on un-named chemist in Mombasa

Pharmacy and Poisons Board urges ethical practices, cautions against illegal pharmaceuticals



Seized medicines packed into cartons

The Pharmacy and Poisons Board is urging licensed pharmaceutical practitioners to maintain high ethical standards in the industry while also cautioning the public against engaging in illegal pharmaceutical practices. On December 15th, 2022, the Board's Head of Enforcement and Surveillance, Mr. Julius Kaluai, spoke about this during a joint operation with the Kenya Police Service targeting illegal pharmaceutical outlets in Nairobi and Lower Eastern Region's counties of Machakos, Kitui, and Makueni.

During the crackdown, 77 people were arrested and charged with operating unregistered premises, illegal possession of Part I Poisons, conducting business and pharmacist without proper registration. 58 of the offenders were caught in the Lower Eastern

region, while 19 were arrested in Nairobi county. A total of 81 illegal pharmaceutical outlets were closed and 134 cartons of assorted medicines were seized.

To ensure the public's safety, Dr. Onesmus Kilonzo, head of the Lower Eastern Region, advises people to verify the registration status of pharmaceutical practitioners and licensed premises through the Board's website, https://practice. pharmacyboardkenya.org/ LicenseStatus.

Illegal pharmaceutical practices in the Lower Eastern region be reported through can email at lowereastern@ pharmacyboardkenya.org or by telephone at 0702475849, while illegal pharmaceutical practices Nairobi can be reported in through email nairobi@ at pharmacyboardkenya.org or by telephone at 0702475801.



Inside an illegal pharmaceutical outlet

Kenyan Doctor recognized for exceptional contributions to healthcare



PPB's Medical Devices & Invitro-diagnostics head, Dr. Paulyne Wairimu receives her award

Dr. Paulyne Wairimu, Medical Devices and Invitro-Diagnostics Lead at the Pharmacy and Poisons Board, has received international recognition for her outstanding contributions to healthcare initiatives.

On December 19, 2022, Dr. Wairimu was awarded the Health 2.0 Outstanding Leadership Award from a pool of over 2,000 applicants at the Health 2.0 Conference in

Las Vegas, USA. The Health 2.0 Conference, a unique platform for healthcare professionals, showcases the latest advancements and innovations in healthcare and wellness from around the world.

The event promotes knowledge-sharing and networking among visionary health leaders who are working to find solutions to complex healthcare challenges. Dr. Wairimu

was honored alongside other visionary leaders and organizations that have made a positive impact on healthcare models worldwide through their remarkable contributions.

These visionaries have played a crucial role in reducing healthcare costs, improving access quality of care, and creating products and services that have enhanced the efficiency of healthcare systems in their respective regions. As the Medical Devices and Invitro-Diagnostics Lead at the Pharmacy and Poisons Board and the Chair of the African Medical Devices Forum (AMDF), Dr. Wairimu's national role and her contributions to the African continent make her outstanding. She also represents Kenya at the World Health Assembly in Geneva, the highest decision-making body for health.

"I am honored to receive this award and grateful for the recognition of my efforts to improve healthcare initiatives globally. I believe that by working together, we can create more efficient and effective healthcare systems that benefit everyone."

- Dr. Wairimu -



Dr. Fred Siyoi leads discussion on strengthening Kenya's vaccine industry with **USAID PQM+ and USP delegation**

On October 12th, 2022, the CEO of the Pharmacy and Poisons Board (PPB), Dr. Fred Siyoi, held a meeting with a delegation from the USAID PQM+ program and the United States Pharmacopoeia (USP). The purpose of the meeting was to discuss ways to enhance capacities and support Kenya's efforts in attaining World Health Organization's Maturity Level 3 (ML3) designation as a vaccine-producing country. The meeting was attended by several



PPB Chief Executive Officer, Dr. F. M. Siyoi during a meeting with the USAID and PQM+ delegation



notable figures, including Dr. Jacinta Wasike, the Director of Corporate Services at PPB, Dr. Peter Mbwiiri, Zlatka Kostova Lenard, the Director of PQM+ Vaccines, Beth Yeager, the Deputy Program Director of PQM+, and Dr. Evans Sagwa, the USP/PQM+ Director for Eastern & Southern Africa.

KPA Delegation meets with Pharmacy and Poisons Board CEO to discuss issues in pharmaceutical services

On October 18, 2022, the Chairman of the Kenya Pharmaceutical Association (KPA), Mr. Eric Seda, led a delegation to meet with the Chief Executive Officer of the Pharmacy

and Poisons Board, Dr. Fred Siyoi. The purpose of the meeting was to discuss matters related to the practice of pharmaceutical technologists, to establish

friendly working relationship, and to promote self-regulation in order to improve the quality of pharmaceutical services.



PPB CEO Dr. F. M. Siyoi, Pharmacy Practice & Regulation of Training Director, Dr. Wilfred Ochieng and Mr. Julius Kaluai, Head Inspectorate and Enforcement



KPA representatives during the meeting

Cipla Ltd and Pharmacy and Poisons Board hold sensitization meeting to enhance regulatory compliance

With the goal of improving compliance, regulatory Cipla Limited joined forces with the Pharmacy and Poisons Board Medicines Information and Resource Centre to hold one-day sensitization meeting for its marketing and regulatory affairs team. The purpose of the meeting was to educate the team on the guidelines regulations surrounding and advertising, with a focus on ensuring that all information about Cipla Ltd's medicines is accurate, unbiased, and up-to-date in its advertisements and promotions. The PPB is promoting engagement



Pharmacy and Poisons Board and Cipla Limited staff pose for a photo after the sensitization meeting

with the regulator through various channels, with the aim of increasing

compliance and safeguarding Public Health.

Board members educated on mandate of PPB's Enquiries and Disciplinary Committee at Nakuru Workshop

On November 28, 2022, a workshop was held in Nakuru County specifically for board members to learn about the mandate of the Pharmacy & Poisons Board's Enquiries and Disciplinary Committee (EDC). The Chairman of PPB, Dr. Rogers Atebe, CEO Dr. F. M. Siyoi, EDC Chair Ms. Miriam Ndirangu, and representatives from PSK and KPA were all in attendance. Dr. Atebe highlighted the need for self-regulation within pharmaceutical industry and encouraged professionals to avoid supplying drugs to unlicensed individuals. He also called on the



PPB CEO Dr. F. M. Siyoi during the sensitizatiom workshop in Nakuru EDC to address any instances of illegal practices. professionals engaging in these

Prevention is better than Cure. When it comes to medicine safety, double check and follow instructions for a healthier tomorow.

#Medicinesafety #HealthMatters



PPB Board of Management, staff and stakeholders pose for a photo after the meeting

Atebe further called collaboration between the PSK and KPA, and the Council of Governors, Counties, and regional economic blocks, to ensure that no unqualified individuals are employed in public hospitals.

Dr. Siyoi, the CEO of the Board, also emphasized the significance of self-regulation in setting standards

and promoting patient safety. He announced that an MOU would be signed between the Board, PSK, and KPA to strengthen self-regulation within the industry.

Pictorial





From November 21st to 25th, 2022, more than 950 aspiring pharmacists and pharmaceutical technologists took the Pharmacy and Poisons Board's pre-registration and pre-enrollment professional exams at six examination centers.



On November 2, 2022, the Pharmacy and Poisons Board (PPB) organized a consultative workshop for stakeholders to review and approve the core curricula for pharmacy training programs. The core curricula serve as a reference for all pharmacy training programs in Kenya, outlining the essential knowledge, skills, and attitudes that pharmacy personnel must possess in order to effectively perform their various roles within the healthcare system and public health.

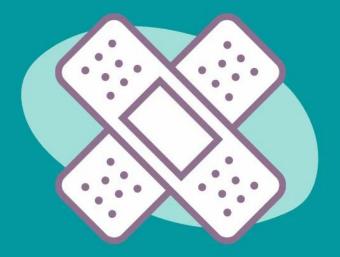
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On 13th October 2022, two individuals posing as inspectors from the Pharmacy and Poisons Board were apprehended in Nyangoma, Siaya County. The public deserves recognition for their role in the arrest of the fraudulent duo, following a warning issued by the PPB on social media.

Cervical cancer can be cured!



Regular cervical cancer screening, early diagnosis and prompt treatment can cure cervical cancer.



Get Informed. Get Vaccinated. Get Screened.



PHARMACY AND POISONS BOARD

PUBLIC NOTICE ON ILLEGAL ORAL CONTRACEPTIVE 'SOFIA'

The Pharmacy and Poisons Board (PPB) has become aware of reports in the media regarding an oral contraceptive (pill), named "SOFIA" that is suspected to be circulating in the Kenyan market.

The PPB would like to inform the public that the medical product is NOT registered by the Pharmacy and Poisons Board and therefore is NOT authorized for use or distribution in Kenya. The product is substandard and falsified (SF) and poses a great risk to the health and safety of the public.

In order to protect the safety of the public, the PPB has initiated a rapid response and heightened surveillance to confirm and check whether the oral contraceptive "SOFIA" is currently circulating in the Kenyan market with the aim of determining the source and implementing legal and regulatory actions against individuals who may be handling or distributing the product.

The PPB also warns the members of the public against trading distributing, wholesaling, retailing, issuing, or dispensing this product as it amounts to illegal activities and endangers the safety and health of the public. The PPB shall take stern legal and regulatory actions against perpetrators of such offenses.

The PPB encourages members of the public and healthcare providers to report all suspicious, substandard, and falsified medical products to the Pharmacy and Poisons Board through https://pv.pharmacyboardkenya.org/padrs/add, mobile application: mPvERS both android & iOS and USSD code at *271# or Email: pv@pharmacyboardkenya.org

Dr. F. M. Sivoi

CHIEF EXECUTIVE OFFICER

3rd October, 2022

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PHARMACY AND POISONS BOARD

PRESS STATEMENT

VOLUNTARY RECALL OF TENOFOVIR/LAMIVUDINE/DOLUTEGRAVIR (300/300/50 MG) MANUFACTURED BY UNIVERSAL CORPORATION LIMITED (UCL)

The Pharmacy and Poisons Board (PPB) and the National HIV and STI control program (NASCOP) is in receipt of several product related market complaints for Tenofovir/Lamivudine/Dolutegravir (300/300/50mg) tablets manufactured by Universal Corporation Limited (UCL).

Following the market complaints related to discoloration of induction seal and discoloration of the tablets the UCL is implementing voluntary recall of all batches of Tenofovir/Lamivudine/Dolutegravir (300/300/50 mg) tablets from the market as a precautionary measure pending the determination of the impact and extent of the quality concern by the Pharmacy and Poisons Board.

The PPB has collected several samples from healthcare facilities and they have been submitted to the Quality Control Laboratory for further analysis.

All healthcare facilities are instructed to quarantine all stocks of the product and accept the products returned by clients.

Currently, the PPB in conjunction with KEMSA and the manufacturer are coordinating the reverse logistics to ensure all quarantined stocks are mopped up and returned to a central place.

Please note that only the Tenofovir/Lamivudine/Dolutegravir (300/300/50mg) manufactured by Universal Corporation Limited is affected by this quarantine and recall.

The PPB would like to assure the public that the Pharmacy and Poisons Board has established mechanisms to ensure that medicines supplied to Kenyan market meet the required quality, safety and efficacy standards.

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We encourage the public to be vigilant at all times and report any suspected poor-quality medicines or adverse drug reactions to the nearest healthcare facility and the Pharmacy and Poisons Board through https://pv.pharmacyboardkenya.org/padrs/add, mobile application: mPvERS both android & iOS and USSD code at *271# or Email: pv@pharmacyboardkenya.org, Telephone Number: 0795743049.

Dr. F.M. Siyoi

CHIEF EXECUTIVE OFFICER

25th November, 2022



TRIBUTE

We mourn the passing of Dr. Edith Wakori, immediate former Board member, at PPB.

Our thoughts are with her family, to whom we extend our sincere condolences.

Dr. Wakori who served the Board for the period from 2017 to 2020 representing private Universities, has left an indelible imprint on the history of the pharmaceutical industry.

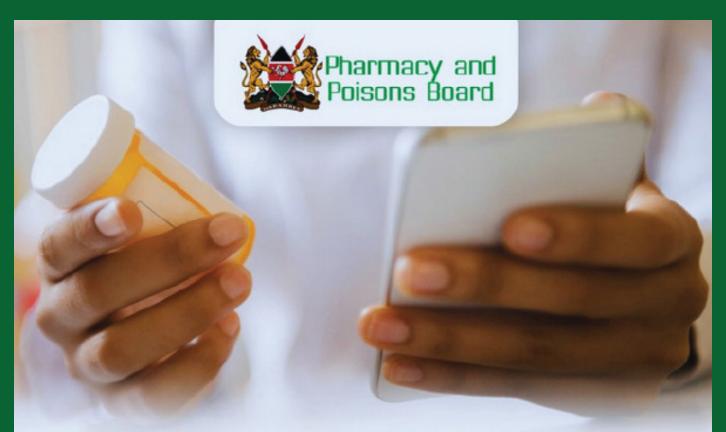
An alumnus of the University of Nairobi, Dr. Wakori was an accomplished academician and was one of the founders of the Drug Analysis & Research Unit at the School of Pharmacy, University of Nairobi. Until her demise, she was a senior lecturer at Kabarak University.

During her tenure as the chair of the Practice Committee of the Board, she facilitated the recognition of Pharmacy Specialties and improvement of Pharmacy Practice.

Her quiet demeanor, wisdom, kind words and contribution to PPB Strategic Plan 2020-25 shall always be treasured.

May the Almighty God rest her soul in eternal peace!





DANGERS OF SELF-MEDICATION

Self-medication has potential risks such as;

- Hiding of severe disease hence delay in seeking medical advice
- Wrong identification of diseases leading to wrong choice of medicines
- Can lead to side effects (mild, moderate to severe)
- Exposure to harmful medicines interactions
- Other risks include wrong dosages, wrong route of administration, risk of medicines abuse and addiction

For more information visit: www.pharmacyboardkenya.org



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PPB Newsletter

Guaranteeing Quality and Safety of Medicines