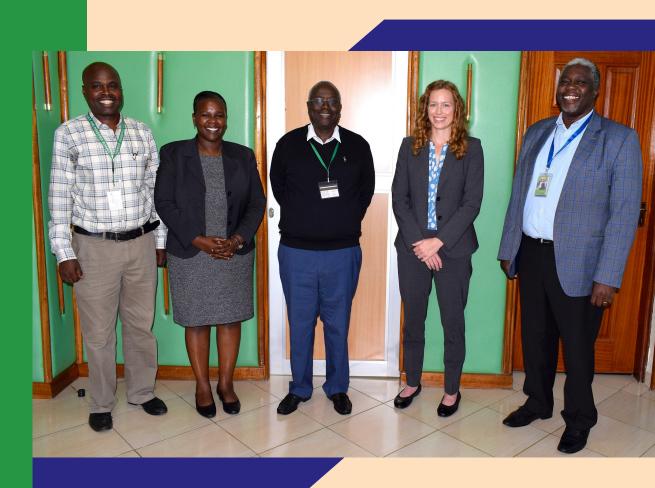


# PHARMACY AND POISONS BOARD

- NEWSLETTER -

web.pharmacyboardkenya.org



Pharmacy and Poisons Board
Hosts U.S. Delegation to discuss
Pharmaceutical Regulation and
Cross-Boarder Collaboration

→ Story Page 14

OCT 2024 - DEC 2024 ISSUE NO.29



#### PHARMACY AND POISONS BOARD

#### PUBLIC ALERT

### MANDATORY RECALL OF EFINOX 1% w/v BATCH NO. 82979 AND EFINOX 0.5% w/v BATCH NO. 82978 (EPHEDRINE HYDROCHLORIDE NASAL DROPS) MANUFACTURED BY LABORATORY AND ALLIED LTD

The Pharmacy and Poisons Board ("the Board") has mandated a recall of Efinox 1% w/v Batch No. **82979** and Efinox 0.5% w/v Batch No. **82978** manufactured by Laboratory and Allied Ltd, Kenya.

The recall is being issued due to labeling mix-ups where the correct product was identified, but the wrong strength was applied. An investigation by Laboratory and Allied Ltd revealed that there was likely a mix-up between 0.5% w/v and 1% w/v strengths of the Efinox Nasal Drops during the labeling and packing process of the above batches.

In light of this, the Board advises all pharmaceutical outlets, healthcare facilities, healthcare professionals, and members of the public to immediately **STOP** the further distribution, sale, issuance, or use of the affected product batches. The products should be returned to the nearest healthcare facility or respective suppliers.

The Board encourages the public to report any suspected cases of sub-standard medicines or adverse drug reactions to the nearest healthcare facility or the Pharmacy and Poisons Board through the following channels:

- https://pv.pharmacyboardkenya.org/users/mpublic
- USSD code at \*271#
- Mobile application: mPvERS both Android & iOS
- Email pv@ppb.go.ke or pms@ppb.go.ke
- Telephone No. 0795-743-049

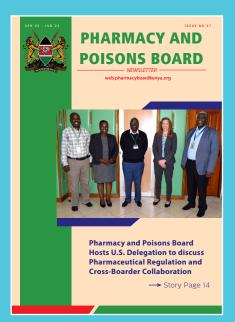
Dr. F. M. Siyoi

CHIEF EXECUTIVE OFFICER

22<sup>nd</sup> November 2024







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### **About The Newsletter**

The PPB Newsletter is a publication of the Corporate Communication Division. 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**

## Yuo can be part of us

Welcome to this edition of Pharmacy and Poisons Board Newsletter, where we share milestones and ongoing efforts shaping Kenya's pharmaceutical sector.

In this issue, we highlight our continued commitment to strengthening regulatory frameworks and ensuring access to safe, quality and efficacious medical products for all Kenyans. We thank our partners, regulators, healthcare professionals and the public for their shared dedication to public health.

Welcome contributions for future editions.



### **UPCOMING EVENTS**

- **PSK Annual Scientific Conference**
- **KPA Annual Scientific Conference**



## **PHARMACY AND** POISONS BOARD

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Pharmacy and Poisons Board



@ppbkenya

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## Pharmacy and Poisons Board hosts a Uganda's **Parliamentary Health Committee**



A group photo of the meeting participants

The Pharmacy and Poisons Board (PPB) on November 14, 2024 hosted Uganda's Parliamentary Health Committee, led by Chair Hon. Dr. Ruyonga Joseph, for a benchmarking visit. The delegation, welcomed by PPB CEO Dr. F.M. Siyoi, received insights into PPB's mandate and its ongoing efforts toward achieving WHO maturity level 3 standards.

Key discussions included the regulation of health products and technologies, good distribution practices, traditional medicine, and veterinary products, among others. The delegation also explored regional harmonization of drug regulations in East Africa and the funding requirements strengthening regulatory for frameworks.

Dr. Siyoi expressed the Pharmacy and Poisons Board's commitment to regional partnerships, noting that such collaborative exchanges



Pharmacy and Poisons Board Director of Corporate Services shares his remarks during the meeting



Pharmacy and Poisons Board CEO, Dr. F. M. Siyoi chairs a meeting with the Ugandan delegation

play a crucial role in fostering stronger regulatory systems across East Africa.

The Ugandan legislators included Hon. Dr. Ruyonga Joseph (Committee Chairperson), Hon. Isaac Otimgiw, Hon. Dr. Batuwa



Hon. Dr. Ruyonga Joseph and his counterpart from the Uganda Parliament during the meeting

Timothy, Hon. Nebanda Andiru Florence, Hon. Ayebare Margaret, as well as Committee Clerks Ms. Nadunga Esther and Mr. Odeke Peter.

Dr. Siyoi was joined by head of corporate services Dr. Anthony Toriotich and other senior officers from the PPB.



Meeting participants follow proceedings.

### **Delegation visits Pharmacy and Poisons Board to discuss** cosmetics regulation



A group photo of the meeting participants

On November 13, 2024 a delegation from the Personal Care Products Council (PCPC) and Cosmetics Europe (CU) visited Kenya's Pharmacy and Poisons Board (PPB). Representing the cosmetics and personal care industries in the U.S. and Europe, their visit aimed to discuss potential collaboration with Kenyan authorities to enhance the regulatory framework for cosmetics and personal care products. The delegation advocates for adopting

regulatory global standards, which they have promoted in Sub-Saharan Africa and through



Delegates during the meeting at the Pharmacy and Poisons Board headquarters



Pharmacy and Posions Board Chief Executive Officer, Dr. F. M. Siyoi during the meeting

U.S. trade agreements. PPB CEO Dr. F. M. Siyoi welcomed the visitors and emphasized Kenya's commitment to ensuring public health through quality and safe products.



## Pharmacy and Poisons Board launches a nationwide crackdown on pharmaceutical malpractices



Mr. Julius Kaluai, Head Enforcement and Surveillance addresses media in Nakuru

In a move to safeguard public health, the Pharmacy and Poisons Board (PPB), in partnership with the National Police Service, on November 11, 2024 launched a nationwide crackdown to tackle the illegal distribution, wholesale, and transportation of pharmaceuticals. The intensified surveillance and enforcement efforts aimed eliminate malpractice in the sector and ensure that only safe, quality medications reach the public.

As part of the operation, PPB issued

a stern warning to unlicensed courier services, motorbike operators, and public transport providers, urging them to refrain from transporting pharmaceuticals without proper authorization



Mr. Julius Kaluai and other Pharmacy and Poisons Board staff during the media briefing



due to the risks of compromising medication quality. PPB's Head of Enforcement and Surveillance, Mr. Julius Kaluai, stressed that unlicensed wholesalers, distributors, and transporters must comply with national regulations or face serious consequences.

The crackdown followed a previous nationwide audit of health facilities aimed at identifying and addressing pharmaceutical sector malpractices. The data collected during this surveillance will help identify patterns in illegal activities, enabling more effective, intelligence-driven enforcement.

Mr. Kaluai also highlighted the need for greater collaboration PPB between and other government agencies at border points to prevent the entry of unregistered pharmaceutical

products, strengthening public health safeguards.

Additionally, PPB has warned retail outlets operating unauthorized online pharmacies to register their premises according to the services they offer, with strict enforcement measures for non-compliance.

The Pharmacy and Poisons Board is urging the public to stay vigilant and report any suspicious activity, its commitment reinforcing health reducing risks associated with non-compliant pharmaceutical distribution and transportation.

# Pharmacy and Poisons Board Steps Up Audit of **Hospitals and Wholesalers to Ensure Compliance**

The Pharmacy and Poisons Board (PPB) launched an intensive series of audits aimed at hospitals and pharmaceutical wholesalers across Kenya to enforce compliance with national pharmaceutical regulations and enhance public health safety.

comprehensive This initiative with audits commenced pharmaceutical wholesalers October 13, 2024, followed by audits of Level 4 hospitals starting on October 20, 2024. The PPB aims to ensure that all pharmaceutical practices adhere to strict guidelines governing the distribution and

handling of medicines.

In a media briefing held in Nakuru on October 28,2024, Mr. Julius Kaluai, Head of Enforcement and Surveillance at PPB, representing CEO Dr. F. M. Siyoi, emphasized the Board's commitment to addressing unlicensed activities hospital pharmacies and wholesale networks. He stated that the audits focuses on key compliance areas, including the handling of cold-chain medicines, adherence to pharmaceutical waste disposal guidelines, and ensuring that only qualified personnel manage hospital pharmacies.



Mr. Julius Kaluai, Head Enforcement and Surveillance addresses media in Nakuru

Mr. Kaluai expressed concerns staff unqualified and unregistered medicines in hospitals, warning that these issues increase the risk of medication errors, drug misuse, and improper handling pharmaceuticals, ultimately jeopardizing patient safety. He urged hospitals to register all pharmaceutical transport vessels with PPB and to maintain proper storage conditions for medicines.

The PPB also highlighted challenges related to wholesalers relocating without notifying the Board,



A group photo of PPB staff after the media briefing in Nakuru

complicating efforts to accurately map distribution networks and conduct effective audits. The issue of theft of government-supplied medicines and unauthorized sales to unlicensed outlets were identified as significant threats to healthcare integrity.

Kaluai called on private hospitals to enforce compliance by employing only licensed pharmacy staff and ensuring adherence to PPB and NEMA guidelines regarding pharmaceutical waste disposal.

The Pharmacy and Poisons Board remains dedicated to upholding high standards of pharmaceutical



Mr. Julius Kaluai and other Pharmacy and Poisons Board staff during the media briefing

quality, safety, and efficacy across essential to protecting public Kenya, with these audits being health.

# **Kenya Launches System to Monitor Antimicrobial** Consumption



Kenya took a decisive step in the battle against antimicrobial resistance (AMR) with the official launch of the Kenya Surveillance System for Antimicrobial Consumption (KESAC) on October 24, 2024. This national initiative aims to monitor antimicrobial

use and tackle the growing threat posed by AMR, which endangers health public and threatens decades of medical advancements. Spearheaded by the Pharmacy and Poisons Board, KESAC will track antimicrobial consumption throughout the pharmaceutical

supply chain, providing critical data to inform effective interventions and policy decisions.

During the virtual launch, Dr. F.M. Siyoi, CEO of the Pharmacy and Poisons Board, represented by Dr. Anthony Toroitich, Director of Corporate Services, underscored

the urgency of addressing AMR, warning that unchecked resistance could severely impact healthcare outcomes. He highlighted the necessity of collaboration among all stakeholders to ensure the successful implementation KESAC.

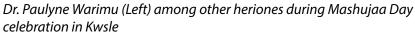
This innovative system will fill a significant gap in Kenya's ability to monitor antimicrobial consumption, allowing for the collection of data from importers, manufacturers, pharmacies, and healthcare facilities. The insights gained will guide targeted interventions to reduce irrational antimicrobial use, safeguard public health, and strengthen the country's healthcare system.

Dr. Siyoi called on healthcare professionals, pharmacists,

all stakeholders to fully embrace KESAC and join forces in the fight against AMR. The launch reflects the coordinated efforts of the Ministry of Health, the Pharmacy and Poisons Board, USAID-MTaPS, and other key partners, and Dr. Siyoi expressed heartfelt gratitude to everyone involved in bringing this vital system to fruition.

## PPB's Medical Devices and Diagnostics Head named **During 2024 Heroine**

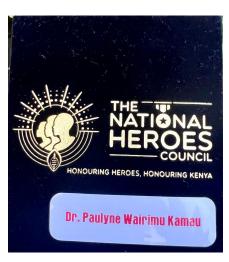




We celebrate Dr. Paulyne Wairimu Kamau for being named one of the 2024 Nominated Heroes and Heroines. As the head of the Medical Devices and Diagnostics department at Kenya's Pharmacy and Poisons Board, Dr. Kamau has made significant strides in healthcare, playing a key role in global regulatory advancements. With over 12 years of dedicated service, Dr. Kamau has developed regulatory framework medical devices, secured Kenya's



membership in the International Medical Devices Forum,





negotiated Kenya's first agreement with the USFDA. Her leadership continues to elevate Kenya's global healthcare standing.

# Pharmacy and Poisons Board GMP Inspectors Undertake Coached Audit by WHO



A group photo of the PPB staff and WHO-appointed GMP consultants

On October 16, 2024 the Pharmacy and Poisons Board (PPB) finalized a 10-day intensive coached audit for its Good Manufacturing Practices (GMP) Inspectors, aimed at



Dr. Johanna Catharina Gouws, WHO Consultant makes her remarks during the meeting



Dr. Christopher Stubbs during the meeting

enhancing their practical auditing skills.

Supported by WHO-appointed GMP consultants, the training included local manufacturing site visits to address gaps identified in the previous WHO Global



Dr. Dominic Kariuki, Deputy Director Surveillance and Enforcement makes his remarks during a close-out meeting in Nairobi

Benchmarking Tool audit.

Participants gained advanced knowledge in pharmaceutical manufacturing requirements and the latest WHO guidelines, strengthening regulatory oversight.

Dr. Dominic Kariuki, on behalf of CEO Dr. F. M. Siyoi, thanked WHO for its support in helping PPB work towards achieving WHO Maturity Level 3.

# Pharmacy and Poisons Board Unveils the 2024 PV Systems Assessment



Meeting Participants follow proceedings

The Pharmacy and Poisons Board (PPB) on October 9, 2024, unveiled findings from the 2024 Pharmacovigilance Systems Assessment, building on previous assessments from

2017 and 2020 which were conducted in collaboration with the EAC and IGAD. The 2024

assessment with support from MTaPS covered health facilities, Marketing Authorization Holders, and Public Health Programs, showing significant progress in health product safety monitoring. However, challenges like underreporting of adverse events and resource constraints continue to hinder full progress.

Stakeholders at the meeting their pledged support strengthen capacity building,



improve reporting mechanisms, and enhance collaboration with the National Pharmacovigilance

Centre at PPB to better safeguard public health.

# **Pharmacy and Poisons Board CEO Chairs an Inaugural Partners Forum**



PPB Chief Executive Officer during the meeting with partners

Dr. F.M. Siyoi, the CEO of the Pharmacy and Poisons Board (PPB), on October 9, 2024 chaired the inaugural Partners Forum aimed at enhancing collaboration among partners and stakeholders.

During the forum, Dr. Siyoi emphasized the importance of promoting a unified strategic and coordinated approach to regulatory systems to improve access to safe Health Products and Technologies (HPTs). He expressed gratitude to the partners, including the World Health Organization (WHO), the Medicines, Technologies, and Pharmaceutical Services (MTaPS), USAID, the Bill & Melinda Gates Foundation, and the United States Pharmacopeia (USP), among others, for their continued support of PPB programs in promoting the quality and safety of medicines.

Dr. Siyoi highlighted that the forum, which will meet quarterly, is designed to support PPB strategies to enhance medicine safety and advance Kenya's goal of achieving WHO Maturity Level 3 by the end of 2025.



Pharmacy and Posions Board Chief Executive Officer, Dr. F. M. Siyoi chairs the inaugral partners meeting





Partners pose for a group photo after the meeting

# Pharmacy and Poisons Board Director of Corporate Services hosts delegation to discuss KPIs



Dr. Anthony Toroitich (center) pose for a group photo with the meeting participants

On October 8, 2024 a delegation from the Bill and Melinda Gates Foundation, Broadreach, and the University of Nairobi visited the Pharmacy and Poisons Board (PPB) today to discuss the implementation of PPB's Key Performance Indicators (KPIs). The meeting, chaired by

Dr. Antony Toroitich, focused on automating KPI reporting and creating a dashboard to visualize performance metrics in line with WHO-GBT standards. This new dashboard will provide PPB staff, stakeholders, and the public with easy access to performance data, enhancing transparency and collaboration with public and private entities.



Meeting participants follow proceedings

# Tonix Pharmaceuticals, USA visits Pharmacy and Poisons Board



Dr. Anthony Toroitich, Director of Corporate Services at the Pharmacy

and Poisons Board (PPB), on October 8, 2024 chaired a meeting

with representatives from Tonix Pharmaceuticals, USA, during their familiarization visit. The discussions centered on clinical research and market authorization for vaccines. Dr. Toroitich highlighted PPB's role in ensuring that all clinical trials in Kenya meet high standards of safety, efficacy, and ethics. He also mentioned the Ministry of Health's establishment of a Clinical Trials Technical Working Group aimed at enhancing Kenya's appeal as a hub for clinical research.



Dr. Anthony Toroitich, Director Corporate Services makes his remarks during the meeting





Representatives from Tonix Pharmaceuticals, USA during the meeting

A group photo of the meeting participants

# **Pharmacy and Poisons Board Hosts** Representatives from Genetic Immunity, Hungary

The Pharmacy and Poisons Board Clinical Trials Division on October 8, 2024 hosted a meeting with representatives from Genetic Immunity, Hungary. Dr. Anthony Toroitich, representing CEO Dr. F. M. Siyoi, highlighted Kenya's regulatory framework for clinical trials and emphasized PPB's dedication to advancing healthcare through safe and ethical research. Key developments, such as the automation of clinical trial systems and global collaborations with AVAREF and WHO, were also discussed. The meeting explored potential partnerships in clinical research to enhance healthcare outcomes.



Representatives from Genetic Immunity, Hungary during the meeting



Dr. Anthony Toroitich, Director Coprorate Services during the meeting



Dr. Jonathan Meriakol makes his remarks during the meeting



# Strathmore Research and Consultancy Centre visits Pharmacy and Poisons Board



Dr. Anthony Toroitich chairs the meeting with the Strathmore team

On October 1, 2024 the Strathmore Research and Consultancy Centre (SRCC) at Strathmore University engaged in a fruitful meeting with the Pharmacy and Poisons Board (PPB) to explore collaborations focused on advancing the healthcare sector. Key areas of discussion included enhancing regulatory frameworks, fostering partnerships between industry and academia, and driving technological innovation.

Chaired by PPB's Director of Corporate Services, Dr. Anthony Toroitich, the meeting set the stage for future collaborations, with both parties committed to promoting innovation and making meaningful contributions to the healthcare industry.



The Strathmore Research and Consultancy Centre team during the meeting

# Pharmacy and Poisons Board Hosts U.S. Delegation to discuss Pharmaceutical Regulation and Cross-Boarder Collaboration



Pharmacy and Poisons Board CEO, Dr. F. M. Siyoi during the meeting

The Pharmacy and Poisons Board CEO, Dr. F.M. Siyoi, on December 3, 2024, hosted Ms. Jaclyn Stahl, an International Computer Hacking and Intellectual Property (ICHIP)

Attorney from the U.S. Embassy in Dar es Salaam, Tanzania. The visit aimed to strengthen collaboration on pharmaceutical regulatory issues and address shared challenges related to pharmaceutical crimes affecting Kenya and the United States.

Discussions focused on enhancing cross-border cooperation to prevent the entry of unregistered



PPB CEO, Dr. F. M. Siyoi, Ms. Jaclyn Stahl and Ms. Caroline Mtai during the meeting

pharmaceutical products and improving legislative frameworks to combat illicit trade.

Ms. Stahl was accompanied by Ms. Caroline Mtai, Kenya Legal Advisor with the U.S. Department of Justice's Office of Overseas Prosecutorial Development Assistance and Training, based at the U.S. Embassy in Nairobi.



A group photo after the meeting





All pharmacies and chemists must display their registration details.

Verify pharmacy practitioners here: https://practice.pharmacyboardken ya.org/LicenseStatus



Report unregistered practitioners: 0702475801 info@ppb.go.ke





More Information www.ppb@go.ke



# Pharmacy and Poisons Board collaborates with Nairobi Administration to tackle illegal pharmaceuticals in informal settlements



Mr. Julius Kaluai, head Enforcement and Surveillance makes his remarks during a meeting at Nyayo House

In a continued commitment to stakeholder engagement and promoting safe pharmaceutical practices, the Pharmacy Poisons Board (PPB) on November 25, 2024 held a strategic meeting with Nairobi County Commissioner Mr. David Wanyonyi. The session aimed to strengthen collaboration on enforcement and surveillance of illegal pharmaceutical activities, particularly in informal settlements. Attended by 12 Deputy County Commissioners from Nairobi County, the meeting addressed



Nairobi County Commissioner, Mr. David Wanyonyi during the meeting

key challenges faced during crackdowns on unauthorized pharmaceutical practices.

Mr. Wanyonyi reaffirmed the government's adoption of a multi-agency approach to tackle public health concerns and called on officials to promptly report illegal pharmaceutical activities in their jurisdictions to PPB for action. Speaking on behalf of the PPB Chief Executive Officer, Mr. Julius Kaluai emphasized the Board's

commitment to ensuring public health safety by guaranteeing access to quality, safe, and effective health products. He underscored the critical role of collaboration in regulatory compliance, noting that past surveillance efforts had significantly reduced noncompliant pharmaceutical outlets.

Mr. Kaluai highlighted the need for public awareness on the dangers of unauthorized pharmaceutical practices and urged citizens to seek medical services only from qualified professionals. He also called on the National Government Administration officers (NGAOs) to enforce permanent closures of noncompliant premises, ensure proper disposal of expired medicines, and prosecute offenders to deter future violations.

The PPB remains steadfast in its mission to safeguard public health by combating substandard pharmaceutical products and unauthorized operations in the sector.





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

**#Medicinesafety #HealthMatters** 

## **Pharmacy and Poisons Board CEO chairs a** meeting to validate SMART KPIs

Strengthening our commitment to regulatory excellence and enhancing the efficiency the pharmaceutical sector, the Pharmacy and Poisons Board (PPB) is dedicated to achieving WHO Maturity Level 3 by the end of 2025. PPB CEO Dr. F.M. Siyoi on 19th November, 2024 chaired a strategic meeting with key stakeholders to validate SMART KPIs for the board, ensuring clear performance benchmarks. The meeting was attended by consultant Dr. Peter Kithuka, Dr. Ahmed Mohamed, Director of Health Products and Technologies, Dr. Anthony Toriotich, Director of Corporate Services, Dr. Wilfred Ochieng, Director of Pharmacy Practice, and HODs.

The CEO expressed gratitude to Melinda Gates for supporting this vital initiative, which plays a key role in our goal of achieving WHO Maturity Level 3. Key Indicators (KPIs) Performance



Pharmacy and Poisons Board CEO, Dr.F. M. Siyoi makes his remarks during the meeting

are essential for measuring and tracking progress, ensuring that we meet our corporate goals and continue advancing the regulatory landscape.



Mr. Peter Kituka during the meeting





# PPB Rollls Out Advanced Pillscan Technology to **Boost Medicine Quality Control**

The Pharmacy and Poisons Board (PPB), in collaboration Missions for Essential Drugs and Supplies (MEDS), has commenced the implementation of advanced Near Infrared Technology (NIR) known as Pillscan. Acquired from Global Health Labs USA with support from the Global Fund, this cutting-edge technology is set to enhance PPB's quality control systems by detecting substandard and falsified medical products, thereby ensuring the safety, quality, and effectiveness of medicines.

The implementation phase began on December 9, 2024, at the PPB headquarters. It includes personnel





re-training conducted by software engineers from Global Health Labs USA, equipment qualification, and the development of a comprehensive library to support the technology's operation.



Dr. Lorna Wangari, Deputy Director Quality Control explains how the technology works



Mr. Luke Mayio looks on during the demonstration

# Pharmacy and Poisons Board Administers Professional Exams



Between 6th and 11th December, 2024 the Pharmacy and Poisons Board administered professional examinations to over 1,000 prospective pharmacists and pharmaceutical technologists

across six exam centers nationwide, reflecting our commitment to enhanced service access through decentralization. Your dedication and hard work will surely pay off!







# Dr. Mai Hijazi visits the Pharmacy and Poisons Board CEO

Dr. Mai Hijazi, Director of the Office of Health Systems at USAID's Bureau for Global Health, visited the Pharmacy and Poisons Board (PPB) CEO, Dr. F. M. Siyoi on December 11, 2024 to discuss critical public health issues and the role of regulation in safeguarding Kenyans' health.

During the meeting, Dr. Siyoi emphasized the PPB's regulatory role in ensuring access to quality medical products, highlighting the Board's progress in improving public health outcomes and its commitment to maintaining high standards in the country's

healthcare system. The conversation also focused on increasing the capacity of local pharmaceutical manufacturing, with more companies showing interest in establishing production facilities in Kenya.

Dr. Hijazi acknowledged PPB's



Dr. Mai Hijazi, Director of the Office of Health Systems at USAID's Bureau for Global Health



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



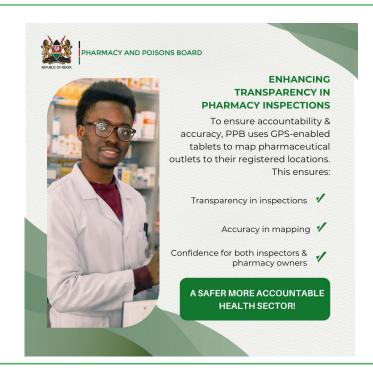
A group photo during the Quality Control Laboratory visit

efforts in optimizing resources for regulation, particularly the support local manufacturers, reiterated USAID's commitment to strengthening Kenya's regulatory framework. She praised the PPB's ongoing progress toward meeting the World Health Organization's Maturity Level 3 standards, which would enhance the country's regulatory capacity.

The meeting was attended by Dr. Mildred Shieshia, Resident Advisor for the President's Malaria Initiative (PMI), Milcah Choge from USAID, the USAID PQM+ team, and PPB's leadership, underscoring the importance of continued collaboration to improve Kenya's public health systems and regulatory capacity.



Pharmacy and Poisons Board Chief Executive Officer, Dr. F. M. Siyoi engage with Dr. Mai Hijazi during the meeting



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### PHARMACY AND POISONS BOARD

### **PUBLIC ALERT**

MANDATORY RECALL OF EFINOX 1% w/v BATCH NO. 82979 AND EFINOX 0.5% w/v BATCH NO. 82978 (EPHEDRINE HYDROCHLORIDE NASAL DROPS) MANUFACTURED BY LABORATORY AND ALLIED LTD

The Pharmacy and Poisons Board ("the Board") has mandated a recall of Efinox 1% w/v Batch No. **82979** and Efinox 0.5% w/v Batch No. **82978** manufactured by Laboratory and Allied Ltd, Kenya.

The recall is being issued due to labeling mix-ups where the correct product was identified, but the wrong strength was applied. An investigation by Laboratory and Allied Ltd revealed that there was likely a mix-up between 0.5% w/v and 1% w/v strengths of the Efinox Nasal Drops during the **labeling** and **packing** process of the above batches.

In light of this, the Board advises all pharmaceutical outlets, healthcare facilities, healthcare professionals, and members of the public to immediately **STOP** the further distribution, sale, issuance, or use of the affected product **batches**. The products should be returned to the nearest healthcare facility or respective suppliers.

The Board encourages the public to report any suspected cases of sub-standard medicines or adverse drug reactions to the nearest healthcare facility or the Pharmacy and Poisons Board through the following channels:

- https://pv.pharmacyboardkenya.org/users/mpublic
- USSD code at \*271#
- Mobile application: mPvERS both Android & iOS
- Email pv@ppb.go.ke or pms@ppb.go.ke
- Telephone No. 0795-743-049

Dr. F. M. Siyoi

CHIEF EXECUTIVE OFFICER

22<sup>nd</sup> November 2024





### PHARMACY AND POISONS BOARD

#### PUBLIC ALERT

QUARANTINE ORDER FOR SUSPECTED SUBSTANDARD FLURASTED 500 (5-FLUOROURACIL) INJECTION BATCH NO. HHP24017 MANUFACTURED BY HALSTED PHARMA PRIVATE LIMITED

The Pharmacy and Poisons Board ("the Board") orders the quarantine of **Flurasted 500** (5-Fluorouracil) Injection Batch no. HHP24017 Manufactured by Halsted Pharma Private Limited, India.

The quarantine order is being issued due to a market complaint on appearance parameter of the content. Flurasted 500 (5-Fluorouracil) Injection is used in the management of cancer.

In light of this, the Board advises all pharmaceutical outlets, healthcare facilities, healthcare professionals, and members of the public to immediately quarantine the product batch and STOP the further distribution, sale, issuance, or use of the affected batch.

The Board encourages the public to report any suspected cases of substandard medicines or adverse drug reactions to the nearest healthcare facility or the Pharmacy and Poisons Board through the following channels:

- Online https://pv.pharmacyboardkenya.org/users/mpublic
- USSD code at \*271#
- Mobile application: mPvERS both Android & iOS
- Email pv@ppb.go.ke or pms@ppb.go.ke
- Telephone No. 0795743049

The Board is committed to ensuring the safety and efficacy of medicines in the market to protect public health.

Dr. F. M. Sivoi

CHIEF EXECUTIVE OFFICER

SG/os

Fluorouracil Injection IP 500mg/10mL

FLURASTED 500 फ्लूरास्टेड For Intravenous use only

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#### PHARMACY AND POISONS BOARD

### **PUBLIC ALERT**

# RECALL OF SUBSTANDARD SURE LUBRICATED CONDOMS DOTTED, MANUFACTURED BY INDUS MEDICARE PRIVATE LIMITED.

The Pharmacy and Poisons Board ("the Board") draws public attention to the recall of the substandard sure lubricated condoms dotted, **Batch No. 2405055**, Manufactured by Indus Medicare Private Limited. The product samples did not comply with the specifications for the freedom from holes (conductivity) test performed.

In light of this, the Board advises all pharmaceutical outlets, healthcare facilities, healthcare professionals, and members of the public to immediately quarantine the product and **STOP** the further distribution, sale, issuance, or use of the affected product batch and return the product to their nearest healthcare facility or respective suppliers.

The Board encourages the public to report any suspected cases of sub-standard medicines or adverse drug reactions to the nearest healthcare facility or the Pharmacy and Poisons Board through the following channels:

- Online https://pv.pharmacyboardkenya.org/users/mpublic
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- Email <u>pv@ppb.go.ke</u> or <u>pms@ppb.go.ke</u>
- Telephone No. 0795743049

The Board is committed to ensuring the safety and efficacy of medicines in the market to protect public health.



Dr. F. M. Siyoi

CHIEF EXECUTIVE OFFICER

11<sup>TH</sup> DECEMBER 2024











## STAKEHOLDERS, **STAY INFORMED!**

The Pharmacy and Poisons Board (PPB) calls on all stakeholders to review the amended Good Distribution Practices (GDP) guidelines for pharmaceuticals.



Access the full guidelines here: https://web.pharmacyboardkenya.

org/downloads/guidel

Stay compliant, stay informed!



PHARMACY AND POISONS BOARD

### **UNDERSTANDING** THE PHARMACY **AND POISONS** BOARD (PPB)

The Pharmacy and Poisons Board (PPB) is Kenya's Drug Regulatory Authority, established under the Pharmacy and Poisons Act, Chapter 244.



### PPB IS RESPONSIBLE FOR:

PPB is committed to safeguarding public health! 🗸 🗞

Regulating pharmacy practice

Monitoring the manufacture & trade of medical products

Ensuring only safe and effective health technologies reach the





# YOU DON'T HAVE TO BE CERTAIN, JUST SUSPICIOUS!!!

Report the following to PPB using the forms available online:

- Suspected poor quality medical products
- Suspected side effectss following us eof medicines, vaccines, medical devices, blood and blood products
- Medication errors

You Can report through the channels below:

PUBLIC/PATIENTS	
Website	pv.pharmacyboardkenya.org/padrs/add
Phone	+254 795 743 049 or report to the nearest health facility
	or report to the hearest health facility

HEALTH WORKERS	
Website	pv.pharmacyboardkenya.org/
Email	pv@pharmacyboardkenya.org
Phone	+254 795 743 049

