

PHARMACY AND POISONS BOARD

NEWSLETTER

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Pharmacy and Poisons Board Chairman Joins Performance Contracts Signing Ceremony



MINISTRY OF HEALTH **Pharmacy and Poisons Board**

PUBLIC ALERT

WARNING REGARDING SUSPECTED FALSIFIED THEMRA EPIMEDYUMLU MACUN ("ASALI YA WAZEE") MANUFACTURED BY VEYSI TOPUZ

The Pharmacy and Poisons Board (PPB) wishes to alert the public about a suspected falsified product, THEMRA Epimedyumlu Macun, manufactured by Veysi Topuz that is believed to be in circulation within the Kenyan market. The product, commonly referred to as "Asali ya wazee", is promoted for its alleged sexual enhancement properties and is claimed to be herbal and 100% natural.

Consequently, the PPB has conducted thorough tests on the honey-based product, and detected significant adulteration of the product with high levels of a conventional active pharmaceutical ingredient, known as Sildenafil, which is prescribed for management of erectile dysfunction and pulmonary arterial hypertension. The PPB informs the public that Sildenafil is classified as a Prescription-Only Medicine and its excessive consumption poses serious safety and health hazards.

In view of the above, the PPB strongly cautions the public against use or involvement in the trade, distribution, wholesale, retail, issuance or dispensing of this product. Any person found dealing with or distributing these products will be subjected to legal action.

Further, the PPB advises the public against use of health products that have not obtained approval from the PPB.

We encourage both the general public and healthcare providers to promptly report any suspected substandard and falsified medical products to the PPB using the following channels:

- Website: https://pv.pharmacyboardkenya.org/users/mpublic
- Mobile Application: mPvERS both android & iOS
- USSD code at *271#,
- Email: pv@pharmacyboardkenya.org
- Telephone: +254 795 743 049

Dr. F. M. Siyoi

CHIEF EXECUTIVE OFFICER

21st November 2023



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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

Our 25th Edition

Dear Readers,

In this edition we mark a significant milestone – our 25th issue of Pharmacy and Poisons Board newsletter. Thank you to our readers, contributors and supporters for your continued engagement and commitment to excellence in pharmacy and poisons management.

In this special edition, we showcase our activities dedicated to protecting public health. Explore the latest insights, initiatives and advancements shaping the landscape of pharmaceutical safety and regulation.

Asante sana..



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



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Pharmacy and Poisons Board Conducts Strategic Review to Align with National **Health Goals**



Pharmacy and Poisons Board Chairman, Board members and top management group photo.

The Pharmacy and Poisons Board (PPB) has embarked on a significant strategic review, focusing on result-oriented management and alignment with the government's Bottom-up Economic Agenda (BETA) and Universal Health Coverage. This review, which occurred from November 6 to 10, 2023, in Mombasa, brought together the PPB's Board of Directors and management to ensure that PPB 2020-2025 strategic plan is in line with national objectives.

Dr. Charles Githinji, Chairman of the PPB, highlighted several key priorities, including achieving WHO Maturity Level 3, implementing result-based management, issues related to addressing unregistered outlets, resource mobilization, and promoting teamwork. These priorities aim



to align the PPB with national healthcare objectives.

Furthermore, Dr. F.M. Siyoi, the CEO of the PPB, emphasized the necessity for change and assured that the management team is well-prepared for this transformative journey. pharmaceutical sector's crucial role in ensuring the quality, safety, and efficacy of healthcare products is essential for the nation's health and overall well-being.

PPB Director of Pharmacy Practice Presides Over Oathing Ceremony at Kenyatta University



Pharmacy and Poisons Board Director of Pharmacy Practice, Dr. Wilfred Ochieng makes his remarks during the oathing ceremony at Kenyatta University.

On December 15, 2023, Dr. Wilfred Ochieng, Director of Pharmacy Practice at the Pharmacy and Poisons Board, presided over the Oathing Ceremony for the Kenyatta University Bachelor of Pharmacy class of 2023 on behalf of PPB Chief Executive Officer Dr. F. M. Siyoi. The oath serves as a commitment to uphold professional standards and a code of ethics.





Kenya Celebrates Ratification of African Medicines Agency (AMA) Treaty



Meeting participants pose for group photo.

On November 25, 2023, Kenya marked a significant milestone with the ratification of the African Medicines Agency (AMA) treaty. This treaty aims to ensure the availability of safe health products Africa and enhance local manufacturing capacities. Represented by Dr. Wilfred Ochieng, Director of Pharmacy Practice, the PPB CEO, Dr. F. M. Siyoi, emphasized the importance of this achievement, highlighting



Dr. Wilfred Ochieng makes his remarks on behalf of the Chief Executive Officer, Dr. F. M. Sivoi.

Africa's commitment to providing high-quality health products.

As a key pharmaceutical hub in the region, Kenya aims to bolster local production and streamline regulatory frameworks in line with its national health policies. The operationalization of AMA anticipated to strengthen Kenya's clinical trials, improve manufacturing standards. and elevate regulatory bodies



Dr. Paulyne Wairimu makes her remarks during the meeting.



on a global scale. The event witnessed the participation of diverse stakeholders, indicating broad support for healthcare advancements in Kenya.

Left: Participants follow proceedings during the meeting.

Pharmacy and Poisons Board CEO Engages at USTDA Event on Healthcare Product Regulation



Pharmacy and Poisons Board, Chief Executive Officer, Dr. F. M. Siyoi shares his insights during a panel discussion.

On November 13, 2023, Dr. F.M. Siyoi, Chief Executive Officer of the Pharmacy and Poisons Board, participated in the U.S. Trade and Development Agency (USTDA) event focusing on regulatory convergence for healthcare products in East/Central Africa.

At the event, Dr. Siyoi shared valuable insights and lessons learned from the successful implementation of EAC Harmonization. He highlighted the advantages of harmonization, such as accelerated review processes for market authorization applications, strengthening National Regulatory



Authorities (NRAs) in the region, increasing market access

for products through the EAC harmonization program.

Pharmacy and Poisons Board Chairman Joins Performance Contracts Signing Ceremony



The Ministry of Health Cabinet Secretary, Susan Nakhumicha (Right) and Pharmacy and Poisons Board Chairman, Dr. Charles Githinji (Left) sign the Performace Contract at Afya House.

On November 10, 2023, Dr. Charles Githinji, Chairman of the Pharmacy and Poisons Board, along with Board Member Mr. Bernard Maiyo, participated in the signing of the 20th Cycle Performance Contracts at Afya House Annex. The signing ceremony, attended by Cabinet Secretary Nakhumicha S. Wafula, aligns with the Universal Health Coverage (UHC) agenda.

Accompanied by Principal Secretaries Mary Muthoni and Harry Kimtai, CS Nakhumicha encouraged the chairpersons of the Ministry Health Semi-Autonomous of Government Agencies (Sagas) to cascade targets within their institutions. She emphasized the crucial role of performance contracting in government



The Ministry of Health Cabinet Secretary, Susan Nakhumicha, Pharmacy and Poisons Board Chairman, Dr. Charles Githinji and Board member Mr. Bernard Mayio, pose for a photo after the Performace Contract signing Ceremony.

accountability and transparency, a tool for establishing clear and highlighting its significance as concise targets in the public 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 Hosts Africa CDC's **Advisory Committee to Enhance Regulatory** Framework



Pharmacy and Poisons Board Director of Health Products and Technologies, Dr. Ahmed Mohamed and Professor, Sikhulile Moyo during the meeting.

On November 18, 2023, Dr. Ahmed Mohamed, Director of Health **Products** and Technologies at the Pharmacy and Poisons Board, hosted experts from the Africa CDC's Diagnostics Advisory Committee (DAC). Their visit aimed to gain insights into the diagnostics regulatory framework within

a National Regulatory Agency (NRA).

The team dedicated time to explore the PPB laboratory systems supporting Performance and Validation of In-Vitro Diagnostics as part of the Market Authorization process. Present at the meeting were Dr. Noah Fongwen, Diagnostics





A group photo of the meeting participants.

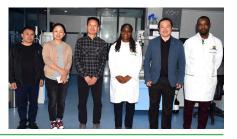
Access Lead at Africa CDC, Dr. Yenew Kebede, Head of Division for Laboratory Systems at Africa CDC, Prof. Hicham Oumzil, Chair of the Diagnostics Advisory Committee, and Dr. Paulyne Wairimu, PPB's Head of Medical Devices and Diagnostics.

PPB Hosts Delegation from Wuhan Institute to Enhance Collaboration

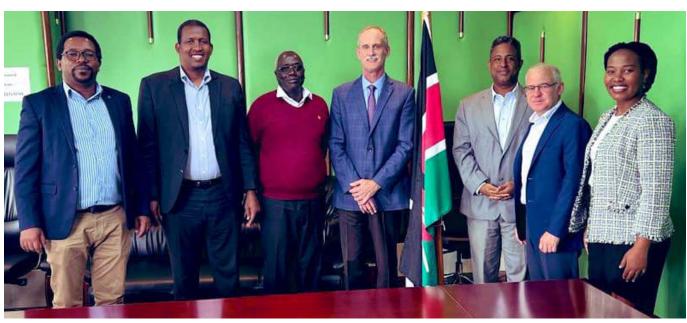


The Wuhan Institute delegation at the Pharmacy and Poisons Board Quality Control Laboratory.

On November 18, 2023, the Pharmacy and Poisons Board (PPB) welcomed a delegation from the Wuhan Institute of Biological Products in China, visiting the PPB laboratory. The meeting aimed to explore collaboration opportunities between PPB and the institute, focusing on enhancing capacity building and fortifying the country's testing capabilities for vaccines and other biologicals.



PPB Engages with US-FDA Representatives to Foster Collaboration



Pharmacy and Poisons Board Chief Executive Officer, Dr. F. M. Siyoi with the US-FDA Representative.

On November 14, 2023, Dr. F. M. Siyoi, Chief Executive Officer of the Pharmacy and Poisons Board, met with US-FDA representatives,

including Dr. Douglas Shaffer, Joseph Reiras, and Peter Mamacos, the Kenya US mission representative. The discussions centered on exploring areas of cooperation between PPB and the US FDA.

Pharmacy and Poisons Board Advocates for Local Manufacturing at East Africa Pharma Expo



The Pharmacy and Poisons Board (PPB) took center stage at the 7th East Africa Pharma Expo, organized by GPE at KICC.,

Nairobi, on October 3, 2023. Dr. Mikal Ayiro, representing PPB CEO Dr. F.M. Siyoi, reiterated the Board's dedication to bolstering local manufacturing in Kenya during the event's official opening.

PPB's initiatives to bolster Kenya's pharmaceutical sector have produced notable outcomes, attracting manufacturing investments and positioning Kenya as a regional pharmaceutical hub. Dr. Mikal highlighted key insights into PPB's regulatory framework, including oversight to ensure the suitability of premises, personnel, and manufacturing manufacturers' activities, responsibilities within the National Pharmacovigilance



Dr. Mikal Ayiro makes her remarks on behalf of the Pharmacy and Poisons Board Chief Executive Officer, Dr. F. M. Siyoi.

manufacturers' System, obligations to the Post-market



Dr. Allan Wambua addresses particpants during the Expo.

surveillance system (and the harmonization of data collection

for locally manufactured HPTs through Batch declaration.

The expo conference, attended by Dr. Tom Menge from the Ministry of Health, Dr. Allan Wambua from PPB, and industry leaders such as the Kenya Association of Pharmaceutical Industry (KAPI) and the Kenya Pharmaceutical Society (PSK), aimed to tap into East Africa's pharmaceutical markets' untapped potential, explore new opportunities, and accelerate pharmaceutical manufacturing through technology exhibits.

Cabinet Endorses Kenya Health Project to Strengthen Local Health Systems



President William Samoei Ruto chairs the Cabinet meeting to fortify Local Health Systems.

On October 9, 2023, the Cabinet approved the Kenya Health **Emergency** Preparedness, Resilience Response, and Project, marking a significant milestone in fortifying health systems and advancing Universal Health Coverage (UHC). This groundbreaking initiative, in collaboration with the World Bank, encompasses various pivotal components:

- I. Establishment of in-country capacity for 'fill-and-finish' production of human vaccines at the Kenya BioVax Institute.
- II. Empowerment and enhancement regulatory capabilities within the Pharmacy and Poisons Board.
- III. Augmentation Quality Control and Assurance capacity at the National Quality Control Laboratory.

- IV. Reinforcement of the capabilities of the National Public Health Institute.
- V. Promotion of human resources capacity, learning, development, technology and transfer bio-manufacturing.

This multifaceted program is poised to champion the 'one health' approach, highlighting local production, research, and innovation as integral components of enhancing the social determinants of health in Kenya.

alianment with this comprehensive approach, the Cabinet issued a directive to Kenya Medical Supplies Authority (KEMSA), emphasizing prioritization of locally manufactured pharmaceutical products imports. over directive resonates with the core principles of the Buy Kenya Build Kenya initiative, a cornerstone the Bottom-Up Economic Transformation Agenda (BETA).

Pictorial...

Proffessional Exams





Professional Exams Administration: Between November 6 and 10, 2023, the Pharmacy and Poisons Board conducted professional exams for 1,191 aspiring pharmacists and pharmaceutical technologists nationwide, across nine examination centers.

Universal Healthcare











Universal Healthcare Exhibition: On October 17, 2023, Principal Secretary for Public Health and Professional Standards, Mary Muthoni, visited the Pharmacy and Poisons Board exhibition stand at the Universal Health Coverage event at Kapkatet Stadium in Kericho county.

Pictorial...

Tree Planting









Tree Planting Initiative: Pharmacy and Poisons Board staff, led by Chairman Dr. Charles Githinji, joined the Ministry of Health Principal Secretary for the State Department of Public Health and Professional Standards, Ms. Mary Muthoni, in a tree planting exercise at Aramaket ECD, West Pokot County, on November 13, 2023, to boost forest cover and contribute to climate change mitigation.

PPB's Commitment to Local Manufacturing and **Quality Healthcare Support**



Pharmacy and Poisons Board chief Executive Officer, Dr. F. M. Siyoi among other pannelists during the UHC Expo at KICC.

On October 13, 2023, Dr. F. M. Siyoi, Chief Executive Officer of the Pharmacy and Poisons Board, played a pivotal role in a panel discussion focused on 'Spurring Local Manufacturing for the supply of affordable and quality essential health products and technologies to achieve UHC goals.'

During the discussion, the CEO underscored the Board's unwavering commitment supporting local manufacturing, guided by fundamental principles of quality, efficacy, and safety that every product in the market must meet.



Customer engagement at the PPB exhibition booth.

"We prioritize accessibility, particularly for local manufacturing, and are offering reduced fees and expeditious evaluations to manufacturers. The Board is dedicated to providing technical



assistance to enhance product quality as well," he said.

Furthermore, the CEO said through the East African Community (EAC) treaty, the PPB facilitates joint evaluations, simplifying registration processes across countries and expanding market



opportunities.

He said PPB is dedicated to achieving WHO Maturity Level 3, signifying a stable and consistent authority in the production and regulation of resources, with meticulous evaluation of all nine regulatory functions.

Pharmacy and Poisons Board CEO Collaborates with Local Manufacturers to Enhance Local Health Products for UHC



Ministry of Health, Principal Secretary for the State Department of Medical Services, Mr. Harry Kimtai, during a meeting with Local manufacturers of Health Products and Technologies.

On October 9, 2023, Dr. F.M. Siyoi, Chief Executive Officer of the Pharmacy and Poisons Board, participated in a consultative meeting convened by Mr. Harry Kimtai, Principal Secretary for the State Department of Medical Services, alongside local manufacturers of Health Products and Technologies (HPTs).

The meeting aimed to prepare for an upcoming two-day exhibition showcasing locally manufactured



Pharmacy and Poisons Board Chief Executive Officer, addresses the meeting participants.

health products and technologies, highlighting their crucial role in advancing Universal Health Coverage (UHC).

Dr. Siyoi underscored that promoting local manufacturing not only ensures availability and affordability but also enhances the country's resilience against unforeseen emergencies and global disruptions.

Under the Bottom-Up Economic Transformation Agenda (BETA), the

PS reaffirmed the government's steadfast commitment to promoting investment and growth in local health product manufacturing.

This strategic initiative seeks to ensure commodity security, directly contributing to the realization of UHC. Additionally, local manufacturing has the potential to improve health outcomes, stimulate economic development through job creation, and enhance Kenya's competitiveness both regionally and globally.



Kenyan and Chinese Universities Collaborate with PPB on Herbal Medicine Advancement



Pharmacy and Poisons Board Chief Executive Officer chairs a meeting with the delegation.

On October 24, 2023, a delegation from Kenyatta University and Shadong University of Traditional Chinese Medicine visited Dr. F. M. Siyoi, Chief Executive Officer of the Pharmacy and Poisons Board, to discuss the promotion and advancement of herbal and complementary medicines Kenya.





The Shadong University delegation during the meeting at PPB Headquarters.

Pharmacy and Poisons Board and Kenya Bureau of Standards Collaborate to Enhance Cosmetic **Regulation Framework**



Pharmacy and Poisons Board Director of Health Products and Technologies Dr, Ahmed Mohamed and Dr. Allan Wambua during the meeting.

On October 9, 2023, the Pharmacy and Poisons Board (PPB) and the Kenya Bureau of Standards (KEBS) convened at KEBS' offices to strengthen the Cosmetic RegulationFramework. The meeting aimed to comprehensively review the existing framework, taking into



Ms. Lucy Ikonya, Manager at Kenya Bureau of Statistics during the meeting.

account recent adjustments to the East African Community (EAC) standards for cosmetics.

Leading the collaborative effort was Dr. Ahmed Mohammed. representing PPB CEO Dr. F. Siyoi, while Mrs. Esther Ngari, the Acting Managing Director of KEBS, led the KEBS team. This joint

endeavor underscores PPB and KEBS dedication to ensuring that cosmetic products in Kenya adhere to the highest safety and quality standards.







MINISTRY OF HEALTH Pharmacy and Poisons Board

PUBLIC NOTICE ON FALSIFIED BATCHES OF TRUVADA (EMTRICITABINE/ TENOFOVIR 200MG/300MG) PRODUCT

The Pharmacy and Poisons Board (PPB) wishes to alert the public about suspicious batches of falsified and substandard (SF) Truvada product suspected to be circulating within the Kenyan market. The product batches in question are TRUVADA 200mg/300mg tablets (*Emtricitabine 200mg/Tenofovir Disoproxil 300mg*) manufactured by Gilead Sciences Inc. bearing the Batch numbers B4033894D and B425875D.

The public is notified that these product batches are illegally in the market as they have FAILED to meet the approved marketing authorization requirements evidenced by **falsified** packaging and labelling. Consequently, the PPB cautions the public against use of these specific product **batches number B4033894D and B425875D** as their safety, quality and efficacy cannot be assured.

In view of the above, the PPB will take stern legal and regulatory action against any person found to be engaged in any form of trading, distribution, wholesale, retail, issuance, or dispensing of these product batches.

Further, in an effort to safeguard public health and safety, the PPB has initiated a rapid response and heightened surveillance to verify whether the SF Truvada product is presently circulating in the Kenyan market. The PPB assures the public that other batches of this product currently in circulation in the Kenyan market meet the required marketing authorization requirements on safety, quality and efficacy.

We urge members of the public and healthcare providers to report all suspicious, substandard, and falsified medical products to the Pharmacy and Poisons Board through the following channels:

- Website: https://pv.pharmacyboardkenya.org/users/mpublic,
- Mobile Application: mPvERS both Android & iOS
- USSD code at *271#,
- Email: <u>pv@pharmacyboardkenya.org</u>
- Telephone: +254 795 743 049

Dr. F. M. Siyoi

CHIEF EXECUTIVE OFFICER

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