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ISSUE NO.24



# PHARMACY AND POISONS BOARD

NEWSLETTER

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



**Kenya Collaborates with USP  
to Enhance Laboratory Testing  
Capabilities**



REPUBLIC OF KENYA  
**MINISTRY OF HEALTH**  
**Pharmacy and Poisons Board**

**PUBLIC ALERT**

**WARNING REGARDING SUSPECTED SUBSTANDARD AND FALSIFIED (SF) RADIO CONTRAST MEDIA-VISIPAQUE (IODIXANOL) 320MG/ML VIALS**

The Pharmacy and Poisons Board (PPB) has received several complaints regarding quality defects and suspected adverse events associated with suspected substandard and falsified (SF) batches of Visipaque (Iodixanol) 320 mg/mL vial. In light of these concerns, the PPB initiated preliminary investigations, which revealed that the affected product batches had infiltrated the market illegally, having been imported and distributed through unauthorized and illegal supply chains.

The affected product batches include:

1. Visipaque (Iodixanol) 320 mg/mL manufactured by GE Healthcare Ireland, Cork Ireland: Batch Number 15950809, 15944839, 15950792 and 15906117; and
2. Visipaque (Iodixanol) 320 mg/mL manufactured by GE Healthcare (Shanghai) Co., Ltd, China: Batch Number 5389618, 15429745, 15444386, 15661498, 15904073, 15751274, 16017833, 16044911, 16085815, 16100415, 16107210 and 16177061

In an effort to safeguard public health and safety, healthcare facilities in possession of these affected product batches are urged to **immediately quarantine** the products and report to the Pharmacy and Poisons Board offices for further guidance and necessary action.

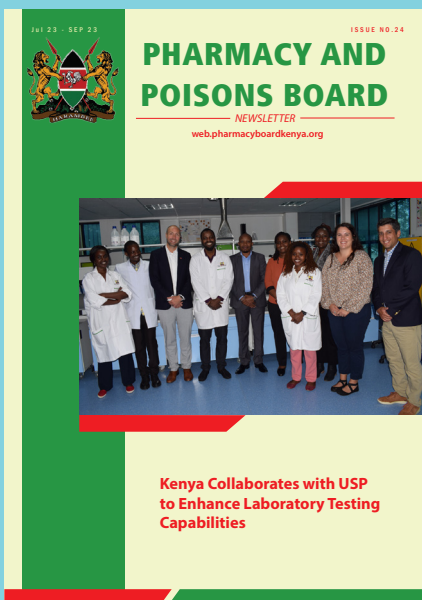
Further, the PPB strongly cautions the public against engaging in any form of trade, distribution, wholesale, retail, issuance, dispensing or use of this product due to the serious safety and health risks it poses. Any person found handling or distributing these products will be subject to legal action.

Members of the public and healthcare providers are encouraged to promptly report any suspected substandard and falsified medical product 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](mailto:pv@pharmacyboardkenya.org)
- Telephone: +254 795743049

Dr. F. M. Siyoi  
**CHIEF EXECUTIVE OFFICER**

18th September 2023



## Editorial Board

### Editorial Advisor

Dr. Obadiah Naikuni

### Editor

Judy Sirima

### Contributors

Judy Sirima

Naomi Naanyu

### 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

### Contacts

Department of Public Relations,  
Pharmacy and Poisons Board,  
Lenana Road  
P.O. Box 27663-00506 Nairobi.

**Tel:** +254-709-770-100

**Email:** pr@pharmacyboardkenya.org

**Web:** web.pharmacyboardkenya.org

### Design and Layout

Commwide Concepts

**Email:** commwideconcepts@gmail.com

# Editor's Note

## Bettering Pharmacy Services from home and abroad

Dear Readers,

We're pleased to present the 24th edition of the Pharmacy and Poisons Board newsletter. Within these pages, we highlight the significant strides and pivotal initiatives undertaken by the Board, solidifying the Board's commitment to advancing the regulation of Medical Products and Technologies.

Throughout this edition, you'll discover the Pharmacy and Poisons Board's unwavering dedication to upholding the highest standards of patient safety and professional excellence. From critical discussions and collaborations to engagements with key stakeholders, we showcase our ongoing efforts to strengthen Kenya's pharmacy profession through collaborative innovation.

Furthermore, this edition unveils our international engagements, welcoming a delegation from Burundi to explore and understand the essential functions and advancements of the Pharmacy and Poisons Board. Additionally, we shed light on the continuously evolving landscape of medical device regulation and the ongoing enhancement of good pharmacy practices across Kenya.

We value your readership and warmly welcome your comments and contributions.

*Judy*

### ONGOING EVENTS

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

pr@pharmacyboardkenya.org  
info@pharmacyboardkenya.org



Pharmacy and Poisons Board



@ppbkenya



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**Ensuring quality, safe, efficacious and affordable health products and technologies in Kenya**



# The Pharmacy and Poisons Board Takes Strides Towards Medical Device and In-Vitro Diagnostics Regulation



*Pharmacy and Poisons Board Chief Executive Officer, Dr. F. M. Siyoi makes his remarks during the workshop*

The Pharmacy and Poisons Board hosted a comprehensive three-day workshop on 23rd August 2023 with a clear objective: to enhance the regulation of Medical Devices and In-Vitro Diagnostics. This initiative aims to fortify the existing regulatory frameworks governing

these essential medical products.

At the core of this workshop was the desire to harness the collective expertise of national regulatory authorities, with the ultimate goal of implementing more effective regulatory practices. This involves the adoption of quality

management systems for medical devices, as well as the proper risk classification of both Medical Devices and In-Vitro Diagnostics.

During the event, Dr. F. M. Siyoi, the Chief Executive Officer of the PPB, underscored the remarkable regulatory milestones achieved by the organization over the past decade. He emphasized the unwavering commitment to further enhancing the regulatory framework and systems related to Medical Devices and Diagnostics.

Notably, the workshop brought together regulatory professionals from various corners of the world, including representatives from entities such as the United States



*Pharmacy and Poisons Board's Head of Medical devices, Dr. Paulyne Wairimu addresses the workshop participants*



*Workshop participants follow proceedings*

Food and Drug Administration (US FDA), Health Sciences Authority of Singapore, ANVISA of Brazil, Therapeutic Goods Administration of Australia, and distinguished experts from the PPB itself. This global collaboration signifies a shared determination to collectively strengthen the oversight of these indispensable medical products.

# PPB CEO Calls for Collaboration to Strengthen Kenya's Pharmacy Profession



*Dr. Dominic Mutie, Deputy Director Pharmacy Practice and Training, makes his remarks on behalf of the PPB Chief Executive Officer during the KPA 19th, Annual Scientific Conference*

During the 19th Annual Pharmaceutical Conference on July 27th in Mombasa, the Chief Executive Officer (CEO) of the Pharmacy and Poisons Board (PPB) emphasized the pressing need for collaboration to strengthen the pharmacy profession in Kenya. The conference, hosted by the Kenya Pharmaceutical Association, provided a platform for professionals and stakeholders dedicated to advancing the field.

The CEO's speech, delivered by Dr. Dominic Mutie, Deputy Director of Pharmacy Practice and Training, commenced with a reaffirmation of the PPB's commitment to creating a conducive environment for pharmacy practice and regulation. The CEO stressed the paramount importance of a robust regulatory framework in ensuring the safety, efficacy, and

quality of pharmaceutical products accessible to citizens.

Addressing a significant challenge, the CEO called upon all stakeholders to unite in eliminating unqualified individuals and quacks from the pharmaceutical field. He

actively engage with the PPB's new guidelines, particularly those pertaining to good distribution practices, pharmaceutical product transportation, and proper pharmaceutical waste disposal.

Furthermore, the CEO advocated for a close partnership between the Kenya Pharmaceutical Association and the Pharmacy and Poisons Board, both at national and regional levels. Such collaboration, he noted, would streamline efforts and efficiently address challenges facing the profession, thereby creating a stronger, unified voice.

Adherence to pharmacy practice guidelines, especially those concerning prescription medicines and controlled substances, was emphasized as essential in maintaining public trust in healthcare providers. The delegates were reminded of the critical role



*Mr. Julius Kaluai, PPB Head of Good Distribution Practices among other conference participants*

proposed the implementation of "nyumba kumi" initiatives within communities. These initiatives aimed to identify and remove such individuals, thereby safeguarding the profession's integrity and protecting the public from potential harm.

Aligned with the PPB's mission to attain WHO Level 3 maturity, the CEO underscored the necessity of staying updated and compliant with guidelines. Delegates were encouraged to

designated superintendents play in ensuring the quality of services provided.

The conference also addressed critical issues affecting the profession, including the elevation of pharmaceutical services at level 4 hospitals and the upgrading of career conversion programs for pharmaceutical technologists. Additionally, the PPB is actively developing comprehensive Standards of Pharmacy Practice to promote professionalism across all sectors.



*Conference participants at the PPB exhibition booth*



## The Pharmacy and Poisons Board CEO Joins Key Meeting with Ministry of Health's MDAs



*Ministry of Health MDA's representatives, PS Mary Muthoni and the National Assembly Departmental Committee on Health members pose for a group photo*

On September 1, 2023, the Ministry of Health's State Department of Public Health and Professional Standards, in collaboration with various MDAs, orchestrated a significant engagement with the National Assembly Departmental Committee on Health. The meeting aimed to familiarize committee members with crucial aspects of the State Department's programs, sub-programs, activities, and projects.

Dr. F. Siyoi, the CEO of the Pharmacy and Poisons Board, participated in this event, which was chaired by Hon. Dr. Robert Pukose and hosted by Principal Secretary Mary Muthoni Muriuki. The primary objective was to provide committee members with an in-depth understanding of the State Department's multifaceted initiatives.

The discussion revolved around vital topics, including human resources, healthcare programs, and legal considerations. One central theme highlighted the indispensable role

of a well-trained and sufficient healthcare workforce in delivering high-quality healthcare services. The emphasis was placed on the imperative need to invest in this critical aspect of healthcare.

Efforts to enhance the efficiency and effectiveness of healthcare

services were given paramount importance. Diverse strategies aimed at eliminating redundancies and optimizing resource allocation were explored, all with the overarching goal of ensuring the prompt delivery of healthcare services to those in need.



*Ministry of Health, State Department of Public Health and Professional Standards Principal Secretary, Mary Muthoni Muriuki makes her remarks during the meeting*



## Pharmacy and Poisons Board (PPB) Prioritizes Patient Safety



Participants of the Patient safety Day 2023 Walk pose for a photo at PPB Headquarters

The Pharmacy and Poisons Board (PPB) holds a pivotal role in guaranteeing that patients gain access to medical products and technologies that are not

only of the highest quality but also safe and effective.

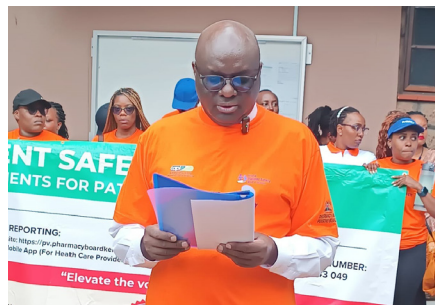
During this year's World Patient Safety Day walk on 15th September 2023, Dr. Obadiah Naikuni, representing Dr. F. M. Siyoi, the Chief Executive Officer, emphasized the paramount significance of patient safety within the healthcare sector. He said the PPB is committed to sustaining continuous surveillance activities aimed at ensuring the safety of medical products available in the market was reaffirmed.

The CEO encouraged both patients and healthcare



Patient Safety Day walk 2023

professionals to actively report any adverse events through the Pharmacovigilance initiative. He highlighted that this reporting process is facilitated by the Pharmacovigilance Electronic Reporting System (PVERS), which is easily accessible via mobile phones.



Pharmacy and Poisons Board Quality Control Director, Dr. Obadiah Naikuni makes his remarks during the Patient Safety Day walk at PPB Headquarters

## Burundi Delegation Explores Kenya's Pharmacy and Poisons Board Functions

The Pharmacy and Poisons Board (PPB) played host to a delegation from the Republic of Burundi, led by Ambassador Evelyne Habonimana. Their visit, which occurred on September 21, 2023, aimed to gain insights into the regulatory functions of the PPB and explore

potential avenues for bilateral collaboration, fostering diplomatic ties between the two nations.

During their discussions, the delegation delved into the intricacies of PPB's regulatory framework, with a particular focus on essential areas including

product registration, import-export procedures, pharmacy practices, pharmacovigilance, post-marketing surveillance, and enforcement activities.

The delegation, comprising key figures such as the Minister of Environment, Agriculture, and





*Ambassador Evelyne Habonimana (sixth from right) among the Burundi delegation during the meeting at PPB*

Breeding, Mr. Sanctus Niragira, and the Minister of Public Health and Fight against AIDS, Mrs. Sylvie Nzeyimana, was warmly received



by Dr. Ahmed Mohamed, PPB's Director of Health Products and Technologies.

Dr. Mohamed, representing Chief Executive Officer Dr. F. M. Siyoi, facilitated the visit, which also included a tour of the state-of-the-art PPB Quality Control Laboratory, showcasing the board's commitment to advanced testing capabilities.



*Pharmacy and Poisons Board Director of Health Products and Technologies Dr. Ahmed Mohamed addresses the Burundi delegation*



*A visit to the PPB's Quality Control laboratory by the Burundi delegation accompanied by PPB staff*

## Pharmacy and Poisons Board Illuminates Medical Devices Regulation



*Dr. Paulyne Wairimu shares her remarks during the Maisha Conference*

On September 1, 2023, during the Maisha Conference, Dr. Paulyne Wairimu shed light on the Pharmacy and Poisons Board's robust regulatory system for medical devices, including condoms. The board's post-market surveillance plays a pivotal role in ensuring strict adherence to quality standards

while detecting counterfeit devices, with an unwavering commitment to safeguarding public health. Dr. Wairimu also highlighted the board's responsiveness to global market demands, showcasing its adaptability and agility.

The Pharmacy and Poisons Board (PPB) has been resolute in establishing a comprehensive

regulatory framework for medical devices since 2011. This endeavor aligns with internationally recommended standards from medical device regulatory forums. Notably, the regulatory procedures have been streamlined through automation, enabling applicants to digitally seek market authorization, a testament to PPB's commitment to efficiency and modernization.



*Maisha Conference participants*



## Pharmacy and Poisons Board Enhances Good Pharmacy Practices in Kenya



*Participants follow proceedings during the workshop to review Good Pharmacy Practices in Kenya*

From the 18th to the 21st of September 2023, the Pharmacy and Poisons Board (PPB) conducted a comprehensive three-day engagement with key stakeholders. The primary objective was to engage in discussions and fine-tuning

of the Guidelines on Good Pharmacy Practices in Kenya.

These guidelines represent a concerted effort to revamp and redefine the landscape of pharmacy practice, with a sharp focus on elevating patient care, especially concerning

medication usage. They also outline the essential facilities and human resources required to uphold the standards of Good Pharmacy Practices.

Participants in this collaborative workshop held in Machakos County included officials from the Ministry of Health, the Pharmaceutical Society of Kenya (PSK), the Kenya Pharmaceutical Association (KPA), the Kenya Medical Practitioners and Dentists Union (KMPDU), the Hospital Pharmacists Association of Kenya (HOPAK), the Council of Governors, and various other stakeholders within the pharmacy sector.



## Pharmacy and Poisons Board CEO meets East Africa Pharma Expo CEO



*PPB Chief Executive Officer, Dr. F. M. Siyoi engages Mr. Paresh Jhurmarvala, CEO, East Africa Pharma Expo*

Local manufacturing has emerged as a critical priority for the Kenyan Government due to its significant

potential to enhance the quality of life and livelihoods of its citizens. On August 5, 2023, Dr. F.

M. Siyoi, the CEO of the Pharmacy and Poisons Board, hosted Mr. Paresh Jhurmarvala, CEO of East Africa Pharma Expo, to discuss the upcoming 7th East Africa Pharma Expo 2023. This event was scheduled to take place on October 3rd and 4th, 2023, at the Kenyatta International Convention Centre (KICC) in Nairobi, Kenya.

Dr. Siyoi, who serves as the Chief Patron of the expo, emphasized that this event provides a valuable opportunity to showcase and promote local manufacturing within the healthcare sector across the East African region.



## Pictorial...

### Exploring Collaboration with the US Drug Enforcement Administration (DEA) South Africa and US DEA Kenya



*On September 7, 2023, delegates from the United States Drug Enforcement Administration (DEA) South Africa and the US DEA Kenya paid a courteous visit to Dr. F. M. Siyoi, the Chief Executive Officer of the Pharmacy and Poisons Board. This meeting, was centered around the exploration of potential collaborative opportunities aimed at enhancing enforcement efforts in the field of drug regulation and control.*

### Zambian Delegation's Learning Tour of Medically Assisted Therapy (MAT) and Licit Control of Substances



*Dr. F. M. Siyoi, the Chief Executive Officer of the Pharmacy and Poisons Board, had the pleasure of welcoming a delegation from Zambia on September 5, 2023. This delegation was in the country to embark on a learning tour focused on Medically Assisted Therapy (MAT) and the Licit Control of Narcotics, Psychotropics, and Precursor Chemical Substances. This collaborative initiative was conducted in partnership with the Centers for Disease Control and Prevention (CDC) and Ciheb Kenya, signifying the commitment to sharing knowledge and expertise in healthcare practices.*

## Kenya Collaborates with USP to Enhance Laboratory Testing Capabilities



*PPB Chief Executive Officer, Dr. F. M. Siyoi chairs a meeting with the USP technical experts*

On the 24th of July, 2023, Dr. F. M. Siyoi, the Chief Executive Officer of the Pharmacy and Poisons Board (PPB), welcomed a team of technical experts from the United States Pharmacopeia (USP). The

primary objective of their visit was to explore opportunities for improving Kenya's laboratory testing capabilities and fortifying

its Laboratory Systems.

During the meeting, the discussion revolved around Kenya's existing testing capacities, with a keen focus on identifying areas in need of support to achieve the World Health Organization's coveted Maturity Level 3 status. As part of their visit, the USP team conducted a comprehensive assessment of the PPB laboratory to gain a deep understanding of its current capabilities. This collaboration signifies Kenya's commitment to advancing its laboratory capabilities to meet international standards and enhance its healthcare infrastructure.



*A group photo at the PPB Quality Control Laboratory*



*USP Technical experts during a meeting at Pharmacy and Poisons Board Headquarters*

## Pharmacy and Poisons Board Hosts Delegation from the World Health Organization



*Dr. F. M. Siyoi, Pharmacy and Poisons Board Chief Executive Officer at a meeting with the WHO delegation*

On August 23, 2023, a delegation from the World Health Organization (WHO), led by Dr. Abdourahmane

Diallo, WHO Country Representative, paid a visit to Dr. F. M. Siyoi, Chief Executive Officer of

the Pharmacy and Poisons Board (PPB). The primary purpose of their visit was to engage in discussions aimed at enhancing import and export processes while identifying areas for improvement.

During the visit, the WHO team expressed their appreciation for the Pharmacy and Poisons Board's





ongoing efforts in addressing stakeholder concerns. In a significant show of support, the WHO delegation pledged their commitment to collaborating with the PPB to strengthen its regulatory systems further. This meeting marks a significant milestone in fostering international partnerships to enhance healthcare and regulatory processes in Kenya.



*The World Health Organisation delegation at a meeting in Pharmacy and Poisons Board*

## South Korean Health Experts Explore Collaboration with PPB in Digital Health and System Digitization



*A group photo after the meeting with the Korean delegation*

On September 14, 2023, a delegation of digital health experts from South Korea paid a visit to the Pharmacy and Poisons Board (PPB) to explore collaborative opportunities between the two nations. Their primary mission is to enhance the digitization of health systems, with a specific focus on

improving the journey of medical products from manufacturers to consumers.

The visiting team, accompanied by health informatics officials from the Ministry of Health, received a warm welcome from Dr. Obadiah Naikuni, the PPB Director of Quality Control, who was representing the Chief

Executive Officer, Dr. F. M. Siyoi. This meeting signifies a significant step towards advancing digital health initiatives and strengthening healthcare system digitization in Kenya.



*PPB's Quality Control Director, Dr. Obadiah Naikuni, Director, Pharmacy Practice Dr. Wilfred Ochieng and Dr. Ahmed Mohamed, Director, Health Products and Technologies during a meeting with the Korean delegation*

## Pharmacy and Poisons Board CEO Hosts Delegation from Japan



*PPB Chief Executive Officer, Dr. F. M. Siyoi addresses the Japanese delegation*

On July 10, 2023, Dr. F. M. Siyoi, the Chief Executive Officer of the Pharmacy and Poisons Board, had the honor of hosting a delegation from Japan. Leading the delegation was Dr. Ayano Kunimistu, a Member of the House of Representatives of Japan. The primary purpose of their visit was to engage in discussions regarding potential collaboration in clinical trials and marketing authorization between Kenya and Japan.



This crucial meeting also saw the presence of Dr. Tom Menge, who heads the Health Products and Technologies Directorate at the Ministry of Health. Additionally, representatives from the Kenya Medical Research Institute (KEMRI) were in attendance, highlighting the significance of this collaborative effort in advancing healthcare and regulatory processes.



*A group photo after the meeting*



REPUBLIC OF KENYA  
MINISTRY OF HEALTH

## PHARMACY AND POISONS BOARD

### IMPERSONATOR ALERT

**23<sup>rd</sup> August, 2023**

The Pharmacy and Poisons Board (PPB) has received concerning reports regarding an impostor named Evans Oino. This individual has been engaging in unauthorized and deceptive activities, falsely asserting as an official of the PPB.


The impostor has been using the following telephone numbers 0731475743, 0721264695, 0734780599, and 0737338369 to make calls, send text messages, and exert pressure on pharmaceutical sector stakeholders, claiming to offer assistance in obtaining PPB services.

The PPB strictly employs formal communication channels and does **NOT** initiate contact through such methods. We urge victims of such fraudulent schemes to promptly report these incidents to their local law enforcement authorities for necessary action. Alternatively, you can report such incidents to the PPB directly using the following contact details:

Email: [info@pharmacyboardkenya.org](mailto:info@pharmacyboardkenya.org) or cell phone number: +254 709 770 100

Your vigilance is vital in helping us combat such scams and protect the integrity of our interactions.

Thank you for your cooperation.

  
Dr. F. M. Siyoi

**CHIEF EXECUTIVE OFFICER**

**PHARMACY AND POISONS BOARD****PUBLIC ALERT****MANDATED RECALL OF TAMEDOL ORAL SOLUTION (PARACETAMOL ORAL SOLUTION, 120 MG/5 ML, 60 MLS) MANUFACTURED BY BIOPHARMA LTD, KENYA**

The Pharmacy and Poisons Board (PPB) has received multiple market complaints on the quality of several batches of Tamedol oral solution (Paracetamol oral solution, 120mg/5ml, 60 mls) manufactured by Biopharma LTD, Kenya. In response to these concerns, the PPB upon investigations, indeed confirmed that the product **FAILED** to meet the prescribed market authorization requirements and has initiated mandatory recall of the product by the manufacturer in line with Section 3A(i) of the Pharmacy and Poisons Act (Cap. 244).

In light of the above findings, the PPB advises all pharmaceutical outlets, healthcare facilities, healthcare professionals and members of the public to take immediate action:

- Quarantine the Product:** STOP all further distribution, sale, issuing or use of Tamedol oral solution.
- Product Returns:** Members of public are urged to return the product to their nearest healthcare facility, while healthcare facilities are instructed to return the products to their respective suppliers.

We encourage the public to remain vigilant at all times and promptly 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>,
- Mobile Application; mPvERS both android & iOS
- USSD code at \*271#
- Email [pv@pharmacyboardkenya.org](mailto:pv@pharmacyboardkenya.org),
- Telephone No. 0795743049

The PPB wishes to assure the public that we have implemented rigorous measures to guarantee that medicines supplied to the Kenyan market adhere to the requisite standards of quality, safety and efficacy.

Dr. F. M. Siyoi

**CHIEF EXECUTIVE OFFICER**

18<sup>th</sup> September 2023





REPUBLIC OF KENYA

## **Pharmacy and Poisons Board**

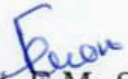
### **PUBLIC STATEMENT ON YONI PEARL**

The Pharmacy and Poisons Board (PPB) wishes to advise the general public against the use of a product known as “**Yoni Pearls**”, which may also be referred to as vaginal detox pearls, herbal tampons, cleansing pearls, or vaginal pearls.

The PPB notifies the public that “Yoni Pearls” is neither registered nor authorized for use in Kenya as required under the Pharmacy and Poisons Act (Cap 244). Therefore, their usage poses potential public health risks as the PPB cannot guarantee their quality, safety or efficacy.

In light of this, the PPB strongly advises against the distribution, supply, sale or use of the aforementioned product and any other unregistered products with similar claims.

Members of the public and healthcare providers are urged to report all suspicious health products and technologies to the Board through <https://pv.pharmacyboardkenya.org/padrs/add>, mobile application: mPvERS both android & iOS and USSD code at \*271# or Email: [pv@pharmacyboardkenya.org](mailto:pv@pharmacyboardkenya.org).

  
Dr. F.M. Siyoi  
**CHIEF EXECUTIVE OFFICER**  
**4<sup>th</sup> August, 2023**