



PHARMACY AND POISONS BOARD

NEWSLETTER

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**Pharmacy and Poisons Board
Strengthens Vaccine Safety
Monitoring** → Story Page 7



PHARMACY AND POISONS BOARD

PUBLIC ALERT ON BENYLIN PAEDIATRIC 100MLs COUGH SYRUP, **BATCH NO. 329304** MANUFACTURED BY JOHNSON & JOHNSON (Pty), SOUTH AFRICA

The Pharmacy and Poisons Board (PPB) wishes to inform the public that it has received information regarding a medical product alert and recall of Benylin paediatric 100mls cough syrup **Batch No 329304**, by the National Agency for Food and Drug Administration and Control (NAFDAC) of Nigeria. This cough syrup manufactured by Johnson & Johnson (Pty), South Africa, is being recalled due to quality concerns arising from an unacceptable high level of diethylene glycol detected through laboratory analysis conducted by NAFDAC. Diethylene glycol is a contaminant which is toxic to humans when consumed and can prove fatal. Toxic effects can include abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state, and acute kidney injury which may lead to death.

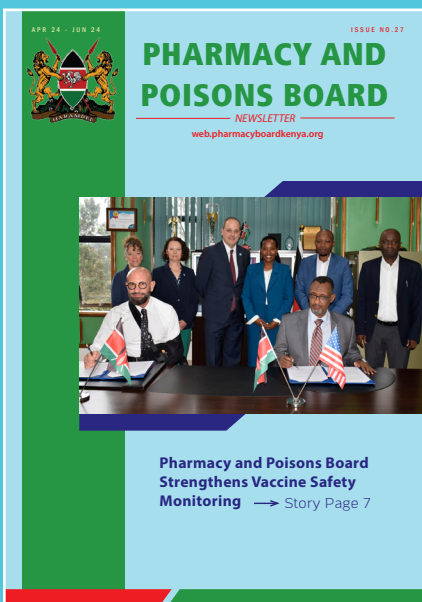
The product details is as follows;

S/N	Name of the product	Batch Number	Date of manufacture	Date of expiry
	Benylin Paediatric 100mls syrup	329304	May 2021	April 2024

Photos of the product



Following receipt of this information the PPB has immediately commenced investigations. The PPB also initiated rapid response, which includes sampling of batches of Benylin paediatric 100mls syrup that are within shelf life for the purpose of screening of the levels of Ethylene glycol and diethylene glycol.



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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

In Our 27th Edition

Welcome to the 27th edition of our newsletter. The Pharmacy and Poisons Board (PPB) is unwavering in its mission to ensure that all medicines and health products in Kenya are safe, effective and of highest quality. In this issue, we highlight the Board's efforts to boost public health.

We appreciate your continued support and collaboration.

Judy

UPCOMING EVENTS

- WHO Observed Audits
- KPA Annual Scientific Conference



PHARMACY AND POISONS BOARD

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Pharmacy and Poisons Board



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Pharmacy and Poisons Board Convene a Stakeholders' Meeting to Propel WHO ML3 Achievement



Pharmacy and Poisons Board Chief Executive Officer, Dr. F. M. Siyoi chairs a high-level meeting on WHO ML3 achievement.



On 26th March 2024, the Pharmacy and Poisons Board (PPB) convened a pivotal stakeholders' meeting chaired by the Chief Executive Officer Dr. F. M. Siyoi, marking a significant stride towards achieving World Health Organization (WHO) Maturity Level 3 (ML3).

The meeting brought together key representatives from United States Trade and Development Agency (USTDA), United States Agency for International Development (USAID- MTaps, PQM Plus, Afya-ugavi), Japan International Cooperation Agency (JICA), Bill and Melinda Gates Foundation (BMGF), United States International

Child Emergency Fund (UNICEF) and Biovax to evaluate progress and strategize for institutional advancement.

Central to the discussions were identifying crucial areas requiring governmental and stakeholder support to attain ML3 status, exploring collaborative

opportunities, and outlining a comprehensive roadmap for both achieving and sustaining ML3 maturity. Dr. Ahmed Mohamed, Director Health Products and Technologies and Dr. Wilfred Ochieng among other senior management officials attended the meeting.

These efforts underscore the PPB's commitment to enhancing regulatory frameworks and ensuring access to safe, effective, quality, and affordable medicines and vaccines nationwide. The PPB aims to achieve WHO Maturity Level 3 (ML3) by 2025 as part of its commitment to the government's broader BETA agenda, emphasizing the necessity of robust support and collaboration from stakeholders to achieve universal health coverage.



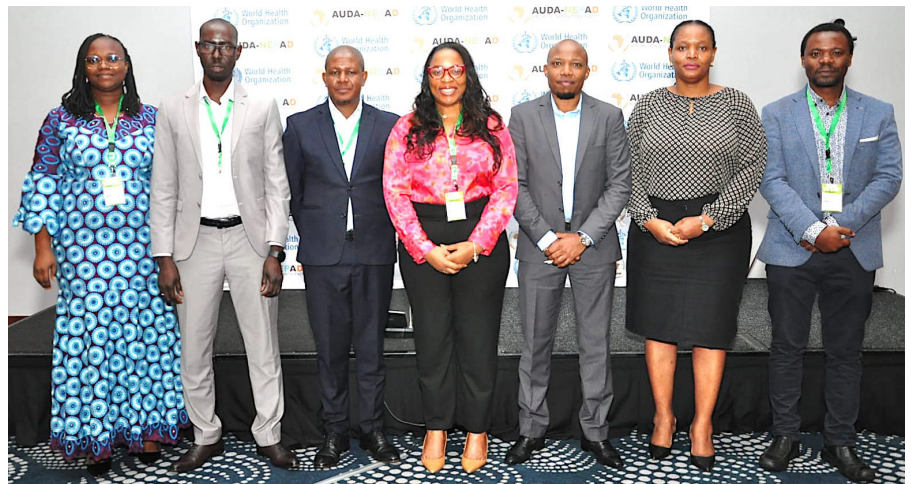
Meeting participants follow proceedings.

Pharmacy and Poisons Board Deputy Director Appointed to Chair First Continental Heads of Medicines Registration Forum



PPB Deputy Director, Product Evaluation and Registration, Dr. Gachoki Kariuki makes his remarks during the forum.

The Pharmacy and Poisons Board (PPB) of Kenya has been honored with the chairmanship of the inaugural Continental Heads of Medicines Registration and Marketing Authorization Forum by the African Union Development Agency-NEPAD's African Medicines Regulatory Harmonization (AMRH). Dr. Kariuki Gachoki, the Deputy Director of Product Evaluation and Registration at PPB, has been appointed as Chairperson. The leadership team also includes Dr.



A group photo of the forum participants.

Chantel Noufonso from Benin as Vice Chairperson, and Mbagnick Diof from Senegal, Nazalia Macuwele from Mozambique, and Bathusi Kgosietsile from Botswana as Rapporteurs. This team was elected during the historic forum held on April 11, 2024, in Nairobi, Kenya.

This forum is set to play a vital role in implementing scientific recommendations by the Evaluation of Medicinal Products Technical Committee (EMP-TC) for human medicinal products at the continental level. Dr. Gachoki expressed his gratitude upon his appointment, committing to prioritize the well-being of African

citizens and emphasizing the importance of listening to forum members' contributions.

The leadership team aims to facilitate the adoption and translation of these continental scientific recommendations into national registration and marketing authorization processes. The forum seeks to enhance collaboration among National Regulatory Authorities, promote information exchange, and advocate for streamlined regulatory frameworks across Africa. This initiative is expected to significantly improve the efficiency and functionality of the African regulatory system for medicinal products.

Pharmacy and Poisons Board Steps Up Monitoring of Health Products Quality

The Pharmacy and Poisons Board (PPB), in collaboration with the National Pharmacovigilance and Post-marketing Surveillance (PV/PMS) technical working group, has intensified its efforts to monitor the quality of health products and technologies (HPTs). This initiative involves a national risk-based post-marketing quality survey aimed at assessing the compliance of HPTs with established quality specifications and standards.

The survey focuses on specific product categories, including:

- Cough syrups
- Herbal medicines for erectile dysfunction (ED products)
- Emergency oral contraceptives
- Depo-medroxyprogesterone (DMPA) injection
- Analgesics
- Antipsychotics



The technical working group team during a sample collection activity



Mr. Ahmed Nassir picks cold-chain samples for analysis.

- Medicines used in maternal, neonatal, and child diseases
- Non-communicable diseases
- Cancer medications

Commencing on April 22, 2024, the field exercise included data

and sample collection from pre-identified facilities across public, private, and faith-based sectors. These facilities span various tiers, such as central procurement agencies (KEMSA and MEDS), public and private hospitals, health centres, dispensaries, and pharmaceutical outlets.

Samples collected will undergo initial analysis using MiniLabs and further compendial analysis at the quality control laboratory, as per the survey protocol. The findings will inform regulatory actions by the PPB, with results and recommendations shared with relevant stakeholders through established knowledge management platforms.

The PPB urges the public to remain vigilant and report any suspected poor-quality medicines or adverse

drug reactions. Reports can be made through various channels, including the PPB's official website, mobile application (mPvERS for Android & iOS), USSD code (*271#), email (pv@pharmacyboardkenya.org), and telephone (Tel No. 0795743049).



The technical working group team during a sample collection activity.

Kenya Strengthens Ties with US FDA to Enhance Pharmaceutical Regulations



cooperative engagement, focusing on enhancing pharmaceutical regulations and safety standards in Kenya.

During their visit, the US FDA delegation also met with officials



US FDA delegates and PPB staff pose for a photo after the meeting.

In a significant move aimed at bolstering collaborations in the pharmaceutical sector, the Pharmacy and Poisons Board (PPB) of Kenya and the United States Food and Drug Administration (US FDA) have signed a Statement of Commitment. The agreement, formalized on 20th June 2024, was marked by the participation of

Mark Abdo, Associate Director for Global Policy and Strategy at the US FDA, and Dr. Ahmed Mohamed, PPB's Director of Health Products and Technologies.

This event follows a confidentiality agreement signed earlier in March 2024 between PPB and the US FDA. The agreement is designed to create new opportunities for

from the Ministry of Health, where they were received by Dr. Patrick Amoth, the Director General, representing Health Cabinet Secretary Susan Nakhumicha. Dr. Amoth underscored the government's commitment to the Bottom-up Economic Transformation agenda, highlighting health as a pivotal pillar in achieving Universal Health Coverage.



US FDA Associate Director for Global Policy and Strategy, Mark Abdoo and PPB's Director of Health Products and Technologies, Dr. Ahmed Mohamed.

The collaboration between PPB and the US FDA signifies a proactive approach towards strengthening regulatory frameworks, fostering innovation, and ensuring the safety and efficacy of pharmaceutical products in Kenya. It reflects a shared commitment to advancing



Pharmacy and Poisons Board Director of Health Products and Technologies, Dr. Ahmed Mohamed during the signing of the Statement of Commitment with the United States Food and Drug Administration .

public health outcomes through international cooperation and mutual support in healthcare regulation.

Pharmacy and Poisons Board Leads Effort to Combat Illicit Trade in Health Products

The Pharmacy and Poisons Board (PPB) celebrated a significant milestone with the establishment of nine Technical Expert and Advisory Committees.

At an event held on March 20, 2024, attended by PPB Chairman Dr. Charles Githinji, Board Members, and Chief Executive Officer Dr. F. M. Siyoi, 81 members were appointed to serve on these committees.

Chairman Githinji highlighted the importance of adhering to the Manual for Technical & Expert



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



Pharmacy and Poisons Board Head of Drug Crime Investigations Unit, Mr. Dennis Otieno makes a presentation during the meeting

Advisory Committees, emphasizing the need for confidentiality and transparency in disclosing potential conflicts of interest.

Upholding professional standards and regulatory practices outlined in PPB's service charter were also emphasized during the inauguration. The establishment of these committees underscores

PPB's commitment to ensuring the safety, efficacy, and quality of medicines while upholding professional standards in the pharmacy sector.

With the expertise and dedication of committee members, PPB aims to advance regulatory excellence and safeguard public health for all Kenyans.



Stakeholders present during the meeting.

Pharmacy and Poisons Board Launches Nationwide Crackdown on Illegal Pharmaceutical Activities



On April 12, 2024, the Pharmacy and Poisons Board (PPB) initiated a comprehensive nationwide operation targeting illegal activities within the pharmaceutical sector. This decisive move, spearheaded by PPB Chief Executive Officer Dr. Fred Siyoi, aims to uphold regulatory standards and protect public health.

The operation, conducted in collaboration with multiple government agencies, inspected 400 premises and seized 200 cartons of assorted medicines. This effort aligns with 25 Presidential Directives focused on combating illicit brews, alcohol, drug, and substance abuse, emphasizing compliance with Good Distribution Practices.

Dr. Siyoi emphasized the Board's dedication to maintaining the integrity of the pharmaceutical industry and ensuring citizen well-being. "We will continue to work with other government agencies to eliminate illegal pharmaceutical outlets across the



Inside an illegal kiosk raided during the crackdown.

country," Dr. Siyoi declared in a press release.

To promote compliance, the PPB has published a comprehensive list of registered pharmaceutical outlets, available at PPB License Status. Dr. Siyoi urged the public

to purchase pharmaceuticals only from licensed and reputable sources.

Healthcare facilities handling pharmaceuticals are reminded to adhere to proper disposal protocols and report any suspicious activities to the PPB. Registered pharmaceutical practitioners are also advised to stay updated with regulatory provisions governing the prescription and dispensing of controlled medicines to ensure the highest standards of patient care and safety.



Closure notices displayed on illegal premises.



Pharmacy and Poisons Board Crackdown Closes 82 Pharmacies for Noncompliance



Enforcement officer during a crackdown on illegal premises.

In a robust effort to eliminate illegal pharmaceutical operations, the Pharmacy and Poisons Board (PPB) has shut down 82 pharmacies across Nairobi, Central, and North Eastern regions for violating various regulations. This operation, led by Kaluai Julius, Head of Enforcement and Surveillance, began on April 14, 2024, and has resulted in the apprehension of 36 individuals involved in these illicit activities,

with prosecutions initiated against 7 in Nairobi, 19 in Central Kenya, and 10 in the Upper Eastern Region.

Since its commencement, the operation has also led to the seizure of 88 boxes of assorted health products and technologies. The diligent efforts of regulatory inspectors, officers from the National Police Service, and other government administrative agencies have been crucial in maintaining the integrity of the pharmaceutical supply chain and safeguarding public health.

During the exercise Mr. Kaluai emphasized the importance of purchasing pharmaceuticals only from licensed and reputable sources. He urged the public to exercise caution, particularly against chemists operating without proper identification and unregistered medicines, which may pose significant health risks.

To further enhance compliance and adherence, the PPB has released a list of registered pharmaceutical outlets, accessible online at PPB License Status. The public is



cartons of seized medicines during the crackdown.

encouraged to verify the legitimacy of pharmaceutical establishments and promptly report any suspicious activities.

This ongoing operation underscores the PPB's unwavering commitment to protecting the public from the dangers posed by illegal pharmaceutical activities, reinforcing their dedication to ensuring safety, quality, and efficacy in medical products and health technologies.

Pharmacy and Poisons Board Uncovers Illegal Drug Distribution Network in Kajiado



Pharmacy and Poisons Board Drug Inspectors during an audit of pharmacies in Kajiado.

The Pharmacy and Poisons Board (PPB), the National Drug Regulatory Authority within the Ministry of Health, has exposed a network involved in the pilferage of government medical stores in Kajiado County. This operation, executed in collaboration with the National Police Service on May 13, 2024, targeted illegal entities dispensing medications without the necessary licenses from the PPB.

The investigation was launched following reports of medicine

shortages in public healthcare facilities. The inquiry uncovered individuals engaged in the theft and illegal distribution of essential medicines. These stolen pharmaceuticals were found in unlicensed chemists, posing serious health risks to the public.

Several individuals have been arrested, and the confiscated medicines will serve as evidence in prosecution. Those found guilty will face stringent penalties under the penal code and other applicable laws.

“The discovery of this syndicate highlights the urgent need for stringent enforcement of pharmaceutical regulations,” said Julius Kaluai, speaking on behalf of the Chief Executive Office of the PPB. “Those found guilty will face severe penalties under the penal code and other applicable laws.”



In addition to this operation, the Board’s routine enforcement and surveillance efforts have resulted in the seizure of 150 cartons of assorted health products and technologies. Thirty-five offenders have been arrested, and 50 premises have been shut down for regulatory violations.

“Our ongoing efforts are crucial in safeguarding public health,” Kaluai stated. “We have released a list of registered pharmaceutical outlets on our

website and advise the public to purchase medicines only from licensed and reputable sources.” Kaluai also warned, “The public should be cautious of chemists operating without names and unregistered medicines, which may not meet regulatory standards and could pose health risks. We encourage anyone with information about illegal pharmaceutical activities to report through our confidential hotline or email.”

The Board also reminds healthcare facilities to apply online for the disposal of pharmaceutical waste or contact PPB regional officers. Registered pharmaceutical practitioners are urged to stay updated with regulatory provisions and comply with labeling requirements as documented under the Pharmacy and Poisons Act [CAP 244].

Pharmacy and Poisons Board Chairman Engages FKPM to Propel Kenya’s Pharmaceutical Sector



On April 23, 2024, Dr. Charles Githinji, Chairman of the Pharmacy and Poisons Board (PPB), met with representatives from the Federation of Kenya Pharmaceutical Manufacturers (FKPM). The meeting focused on strategies to enhance Kenya’s pharmaceutical production, support Universal Health Coverage, and advance

pharmaceutical industrial growth in alignment with the Kenya Kwanza Government’s economic transformation agenda (BETA).

Key attendees included Dr. F. M. Siyoi, PPB’s Chief Executive Officer, senior management members, and Dr. Nihal Shah representing the FKPM chairman. Discussions emphasized the importance of

Pharmacy and Poisons Board Chairman, Dr. Charles Githinji makes his remarks during the meeting.

collaborative efforts to bolster the local pharmaceutical sector, ensuring it meets both national health goals and contributes to economic development.



Federation of Kenya Pharmaceutical Manufacturers representatives present during the meeting.

Pharmacy and Poisons Board CEO Attends Launch of HEPRR Program



Health Cabinet Secretary, Susan Nakhumicha launches the HEPRR Program.

On May 15, 2024, the World Bank-funded Health Emergency Preparedness, Response, and Resilience (HEPRR) Program was launched by the Cabinet Secretary

for Health, Nakhumicha S. Wafula. Representing the Pharmacy and Poisons Board (PPB), Chief Executive Officer Dr. Fred Siyoi and Director of Corporate Services Dr. Anthony

Toriotich were in attendance.

The HEPRR Program aims to bolster health emergency preparedness and resilience across East, Central, and Southern Africa. Phase one will be implemented in Ethiopia, Kenya, and Sao Tome and Principe, with Phase two targeting Burundi, Rwanda, the Democratic Republic of Congo, Somalia, Malawi, and Zambia. This initiative underscores a significant step towards enhancing regional health security and response capabilities.



Pharmacy and Poisons Board CEO Hosts World Bank Delegation to Enhance Regulatory Capacities



On May 17, 2024, Dr. F. M. Siyoi, Chief Executive Officer of the Pharmacy and Poisons Board (PPB), hosted a delegation from

the World Bank. This meeting followed the recent launch of the Health Emergency Preparedness, Response, and Resilience (HEPRR)

Program by Health Cabinet Secretary Nakhumicha S. Wafula.

The discussions centered on PPB's mandate and its ongoing efforts to enhance regulatory capacities, aiming to achieve the World Health Organization's Maturity Level 3. Potential collaborations were also explored to strengthen regulatory frameworks and address common pharmaceutical sector challenges.

Attendees included representatives from Sao Tome and Principe,



Pharmacy and Poisons Board Chief Executive Officer, Dr. F. M. Siyoi chairs a meeting with the World Bank delegation.

the East, Central and Southern Africa Health Community (ECSA), and PPB's Director of Corporate

Burundi, the Democratic Republic of Congo, the Intergovernmental Authority on Development (IGAD),



The World Bank delegates during the meeting.



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

Services, Dr. Anthony Toroitich, and Director of Quality Control, Dr. Wanza Katatha.

Pharmacy and Poisons Board Joins Health CS Susan Nakhumicha in Tree Planting Initiative



Health Cabinet Secretary Susan Nakhumicha during the Tree Planting exercise at Chepkalit, West Pokot.

A delegation from the Pharmacy and Poisons Board, led by Dr. Kibet Chebeo, Head of the North Rift Region, participated in a tree planting exercise alongside Health Cabinet Secretary Susan Nakhumicha and Principal Secretary Mary Muthoni in Chepkalit.

The collaborative effort aims to combat the adverse impacts of climate change and support the government's directive to increase forest cover by planting 15 billion trees by 2032.



Dr. Kibet Chebeo, Head North Rift Region plants a tree in Chepkalit, West Pokot County.

Let's unite in our commitment to a greener future!



Pharmacy and Poisons Board team during the Tree Planting Exercise.



PPB CEO Welcomes Hyatt Biotech Delegation to Discuss Medicines Regulation



Pharmacy and Poisons Board Chief Executive Officer, Dr. F. M. Siyoi chairs a meeting with the Hyatt Biotech team.

Dr. F. M. Siyoi, Chief Executive Officer of the Pharmacy and Poisons Board (PPB), hosted a delegation from Hyatt Biotech, led by Dr. Thurania Kaugiria, Technical Advisor at the Office of The President, on April 24, 2024. The purpose of the visit was to gain insights into



A tour of the Pharmacy and Poisons Board Quality Control Laboratory.



Dr. Anthony Toroitich and Dr. Thurania Kaugiria during the meeting.

Kenya's regulatory framework for medicines in alignment with the government's Universal Health Coverage agenda.

As part of the visit, the delegation toured the PPB's Quality Control Laboratory to observe firsthand the testing capacity and capabilities of the board.

This engagement underscores PPB's commitment to fostering collaboration and dialogue with stakeholders to ensure the quality, safety, and efficacy of medicines for all Kenyans.

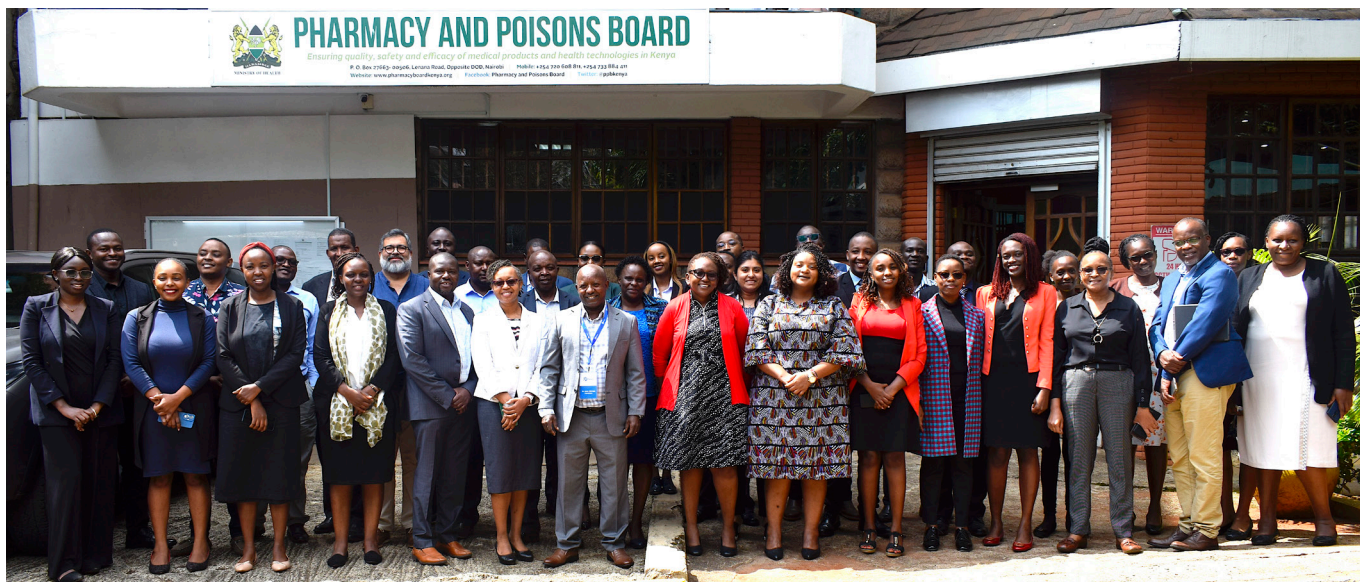
Enhancing Regulatory Systems and Bioequivalence Study by the Pharmacy and Poisons Board

The Pharmacy and Poisons Board (PPB) is advancing its regulatory capabilities with a comprehensive five-year strategic plan (2020-2025). This initiative aims to establish the PPB as a center of excellence in regulating the pharmacy profession, health products, and technologies.

A critical component of Kenya's regulatory framework involves ensuring bioequivalence (BE) for Multisource Drug Products (MSDPs), including locally manufactured generic medicines. To bolster this effort, the PPB, with funding from the Bill and Melinda Gates Foundation, has engaged



Health Ministry's Director of Health Products and Technologies, Dr. Tom Menge (Center) during the meeting.



A group photo of the participants after the meeting.

Penam Ltd, a consulting firm, to conduct a feasibility study and risk assessment. This study is pivotal in assessing the viability and potential risks associated with implementing mandatory BE requirements for locally manufactured pharmaceutical products.

On 31st May 2024, stakeholders convened for an inception meeting to outline the study's objectives. Dr. Tom Menge, Director of Health Products and Technologies at the Ministry of Health, commended the PPB and Penam Ltd for this initiative. He underscored the



Participants follow proceedings during the meeting.

significance of including locally manufactured pharmaceutical products in the essential medicine list and expressed gratitude to the Bill and Melinda Gates Foundation for their support through the Supporting Health Initiative (SHI).

Key stakeholders from various sectors participated in the meeting, including representatives from the Ministry of Health, Ministry of Investment, Trade and Industry-State Departments of Industry, National Quality Control Laboratory, Kenyatta National Hospital, Kenya Medical Supplies Agency, County Pharmacists, National Tuberculosis, Leprosy and Lung Disease Programme, USAID-Management Science for Health, Promoting the Quality of Medicines Plus (PQM+) Program &



Management Science for Health, Kenya Biovax, academia, Federation of Kenya Pharmaceutical Manufacturers, Pharmaceutical Society of Kenya, Kenya Medical Research Institute, and PharmaQ.

This collaborative effort underscores Kenya's commitment to enhancing regulatory standards and ensuring the quality and efficacy of pharmaceutical products through rigorous bioequivalence assessments, thereby safeguarding public health and supporting local pharmaceutical manufacturing capabilities.

Public Health PS Inaugurates National Quality Control Laboratory Board

The official inauguration of the newly appointed National Quality Control Laboratory (NQCL) Board of Management on 7th June 2024 marks a significant milestone in upholding the highest standards of quality and safety for health products in Kenya.

Presiding over the ceremony at the Pharmacy and Poisons

Board (PPB), Ms. Mary Muthoni Muriuki, Principal Secretary of the State Department for Public and Professional Standards, emphasized the pivotal role of NQCL in ensuring health products meet rigorous safety standards set by the PPB. She urged the NQCL leadership to enhance laboratory testing capabilities to align with



PS Mary Muthoni pose for a photo with the newly inaugurated NQCL board.



PS Mary Muthoni, poses for a group photo with the Pharmacy and Poisons Board Chairman, board members, CEO and NQCL CEO.



Principal Secretary of the State Department for Public Health and Professional Standards, Ms. Mary Muthoni flanked by the Pharmacy and Poisons Board Chairman, Dr. Charles Githinji and CEO, Dr. F. M. Siyoi at PPB.



Principal Secretary of the State Department for Public Health and Professional Standards, Ms. Mary Muthoni makes her remarks during the inauguration ceremony.



Pharmacy and Poisons Chairman, Dr. Charles Githinji makes his remarks during the inauguration ceremony.

He called upon the board to establish new benchmarks in quality control, upholding the highest standards of trust, quality, and reliability.

The event was attended by officials from the Ministry of Health, PPB board members and top management, as well as the leadership of NQCL and its newly inaugurated board of management. This collective commitment underscores Kenya's dedication to advancing regulatory standards and ensuring the safety and efficacy of health products for all its citizens.



the World Health Organization's Global Benchmarking Tool.

Ms. Muthoni also challenged the newly appointed board to implement strategies for measuring productivity, aimed at enhancing efficiency in health service delivery. She commended the PPB management for their diligence in appointing the NQCL board and encouraged continued support for effective mandate execution.

Dr. Charles Githinji, Chairman of the Pharmacy and Poisons Board,

lauded NQCL for its critical role in safeguarding public health and contributing to Kenya's national economy. He expressed confidence in the expertise, vision, and leadership of the new board members, expecting them to propel NQCL to new heights.

With Kenya targeting WHO Maturity Level 3 by 2025, Dr. Githinji urged the board to navigate evolving regulatory landscapes and address complex health product challenges through innovation and excellence.

Pharmacy and Poisons Board Cracks Down on Illegal Pharmaceutical Activities in Rift Valley

The Pharmacy and Poisons Board has launched a vigorous crackdown on illegal pharmaceutical activities in the Rift Valley region, resulting in substantial progress towards curbing illicit practices and safeguarding public health.

Between June 3rd and June 7th, 2024, in collaboration with the National Police Service, the Board executed operations that led to over 30 arrests and the seizure of 120 cartons of assorted pharmaceuticals. Furthermore,

more than 100 unlicensed chemists have been shut down as part of these efforts to ensure the safety and efficacy of medical products and health technologies.

Dr. F. M. Siyoi, CEO of the Pharmacy and Poisons Board, emphasized



and unlicensed pharmaceutical distribution channels. Through meticulous surveillance and intelligence gathering, the Board dismantled several criminal enterprises involved in the illicit pharmaceutical trade.

the grave threat posed by illicit pharmaceuticals to public health and safety. He underscored the Board's unwavering commitment to eradicating illegal activities that endanger consumer well-being.

The operations specifically targeted practices such as the unauthorized sale of prescription medications, fraudulent activities involving government drugs,

Those arrested face charges related to the illegal distribution, sale, and possession of pharmaceuticals, with robust support and collaboration from the office of the Director of Public Prosecutions to ensure thorough legal proceedings.

The closure of over 100 rogue pharmacies is expected to disrupt the illicit supply chain significantly, thereby preventing further harm to the public. The Pharmacy and Poisons Board reiterated its commitment to ongoing monitoring and enforcement across the pharmaceutical industry to guarantee that only safe and legitimate medications reach consumers.



Dr. Siyoi urged consumers to exercise caution when purchasing pharmaceuticals, emphasizing the importance of obtaining medications exclusively from licensed and reputable sources.

Established under the Pharmacy and Poisons Act Cap 244 Laws of Kenya, the Pharmacy and Poisons Board continues to fulfill its crucial role as the National Drug Regulatory Authority. It upholds rigorous standards to regulate the practice of pharmacy and ensures the safety, quality, and efficacy of medical products and health technologies nationwide.

Pharmacy and Poisons Board CEO Hosts Operation African Star to Combat Illicit Trade in HPTs



Pharmacy and Poisons Board Chief Executive Officer, Dr. F. M. Siyoi poses for a group photo with the meeting participants.

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

Dr. F. M. Siyoi, Chief Executive Officer of the Pharmacy and Poisons Board, convened a crucial meeting on June 10, 2024, with Operation African Star to devise

collaborative strategies aimed at combating the illicit trade in health products, pharmaceutical preparations, medical devices, and equipment across Africa.

Operation African Star, established in 2023, serves as a pivotal informal steering group dedicated to enhancing global public health outcomes. Its membership includes esteemed organizations such as



Representatives from the US FDA, INCB among others during the meeting.

the European Commission (EC), Interpol, Organisation for Economic Cooperation and Development (OECD), and the World Health Organization (WHO).

Originally initiated by the Pharmacy and Poisons Board and the National Drug Authority (NDA) of Uganda, Operation African Star focuses on intercepting illicit medicines distributed through postal services

and airport environments.

During the meeting, it was announced that the European Commission's European Anti-Fraud Office (OLAF) will provide critical support in detecting shipments related to the European Union, leveraging its extensive global network of postal operators.

Phase 1 of the operation involves key stakeholders such as the Pharmacy and Poisons Board, Kenya Airports Authority, Kenya Revenue Authority, Home Office-UK, Immigration, International Narcotics Control Board (INCB), Postal Corporation of Kenya, United States Agency for International Development (USAID), Office of Inspector General, United States Customs and Border Protection, and the Kenya Intelligence Service.



Pharmacy and Poisons Board Head of Drug Crime Investigations, Mr. Dennis Odero makes a presentation during the meeting.

The collaborative efforts aim to strengthen surveillance and enforcement mechanisms to curb the illegal trafficking of health products, safeguarding public health and ensuring that only safe and legitimate medical products reach consumers in Africa and beyond.

Pharmacy and Poisons Board Chairman Urges Pharmacists to Lead Healthcare Transformation



Pharmacy and Poisons Board board member, Dr. Richard Muthoka addresses conference participants on behalf of the Chairman, Dr. Charles Githinji.

highlighted the expanding responsibilities of pharmacists in direct patient care and their significant impact on healthcare outcomes nationwide.

In his address, read by Dr. Richard Muthoka, PPB Board Member, Dr. Githinji underscored the critical need for pharmacists to actively engage in policy development. He emphasized the importance of stringent regulatory measures to ensure the safety and effectiveness of pharmaceutical products, particularly in addressing challenges posed by unqualified



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

Dr. Charles G. Githinji, Chairman of the Pharmacy and Poisons Board (PPB), delivered a keynote address at the 2024 PSK-ISPE International Scientific Conference, emphasizing the pivotal role of pharmacists in reshaping healthcare policies and practices. Themed "Pharmacists Transforming Policy, Practice, and Patient Care," the conference



Pharmacy and Poisons Board panelists during the conference.



A group photo of the Pharmacy and Poisons Board team.

practitioners. Dr. Githinji called for collaborative efforts among stakeholders to uphold professional standards and combat malpractices effectively.

Highlighting Kenya's commitment to advancing healthcare through initiatives like the Strategic Health Agenda (SHA) and Strategic Health Investment Plan (SHIF), Dr. Githinji unveiled the PPB's initiative to integrate its systems with the digital health superhighway. This strategic move aims to enhance connectivity and information sharing among

healthcare providers, potentially optimizing patient care and granting pharmacists better access to critical data.

Looking forward, Dr. Githinji stressed the transformative potential of digital health technologies, highlighting AI and big data as pivotal tools to elevate service delivery and healthcare outcomes. He urged pharmacists to embrace these innovations proactively to meet evolving healthcare demands effectively.

The conference concluded with



Pharmacy and Poisons Board Chief Executive Officer, Dr. F. M. Siyoi receives a gift during the PSK conference.

a strong call for continuous professional development among pharmacists, emphasizing the importance of staying updated with cutting-edge research and best practices. Dr. Githinji reaffirmed the profession's dedication to driving positive change in healthcare, ensuring that pharmacists' essential contributions are recognized and valued across the sector.

Pharmacy and Poisons Board Conducts Media Sensitization Workshop on Medicine Safety and Regulatory Oversight



Participants group photo after the workshop.

The Pharmacy and Poisons Board (PPB), in collaboration with the USAID Medicines, Technologies,

and Pharmaceutical Services (MTaPS) program, hosted a media sensitization workshop to

emphasize the critical role of the media in promoting medicine safety and regulatory oversight. The workshop, held on April 17, 2024,



Pharmacy and Poisons Board Director of Corporate Services, addresses media training participants at Panafric Hotel, Nairobi.



Pharmacy and Poisons Deputy Director of Product Safety, Dr. Christabel Khaemba, makes her remarks during the workshop.

aimed to educate journalists on the importance of pharmacovigilance and post-marketing surveillance.

Dr. Anthony Toroitich, Deputy Director of Product Safety at PPB, underscored the necessity of regular media engagement to keep the public informed about pharmaceutical developments, such as medicine recalls and adverse drug reactions. He highlighted the media's role in accurately

disseminating information to ensure public awareness and safety. Dr. Ndinda Kusu, MTaPS Country Director, discussed the program's initiatives to strengthen regulatory systems and ensure the quality and safety of medical products and technologies. She emphasized



MTaPS Country Director, Dr. Ndinda Kusu during the workshop.



A workshop participant makes an inquiry during the workshop.

that this workshop was crucial in dispelling misinformation about medicine safety and highlighting the PPB's ongoing efforts to monitor and ensure the safety of medical products and technologies available in the market.

The workshop provided journalists with essential knowledge and tools to report responsibly on issues related to medicine safety, thereby contributing to better-informed public health decisions.

Pharmacy and Poisons Board Administers Professional Examinations



Candidates undertake their professional exams at KICC, Nairobi.

From 17th to 21st June 2024, the Pharmacy and Poisons Board conducted its professional examinations at six exam centers nationwide. The exams attracted a total of approximately 1,300 students aspiring to advance in their pharmaceutical careers.

The Pharmacy and Poisons Board extends its best wishes to all candidates who participated in the examinations. As they await their results, the Board encourages them to maintain focus and positivity in their professional journey. The successful completion of these

exams marks a significant milestone in their pursuit of excellence in the field of pharmacy.

The Board remains committed to upholding high standards in pharmaceutical education and certification, ensuring that qualified professionals contribute effectively to healthcare delivery in Kenya.



Pharmacy and Poisons Board Strengthens Vaccine Safety Monitoring



Vaccine experts during a meeting at Pharmacy and Poisons Board headquarters.

On 31st May 2024, the Pharmacy and Poisons Board (PPB) of Kenya spearheaded efforts to enhance vaccine safety monitoring with a strategic meeting focused on implementing the adverse event following immunization (AEFI) toolkit. This initiative, aimed at overcoming existing barriers in vaccine safety monitoring, aims to bolster the detection and reporting of adverse events by healthcare professionals (HCPs).

The meeting, supported by the Centers for Disease Control and Prevention (CDC), brought together a consortium of experts including representatives from the PPB, the National Vaccines and Immunization Programme (NVIP),

and the African Collaborating Centre for Pharmacovigilance (ACC) based in Ghana. The collaborative effort underscores Kenya’s commitment to ensuring the safety and efficacy of vaccines through rigorous monitoring and surveillance mechanisms.

The AEFI toolkit is anticipated to streamline reporting processes, facilitate timely responses to adverse events, and strengthen the overall vaccine safety infrastructure

in Kenya. By leveraging international partnerships and expertise, the PPB aims to optimize public health outcomes and build confidence in immunization programs across the country.

This strategic initiative reflects Kenya’s proactive approach in healthcare, emphasizing continuous improvement in vaccine safety standards and aligning with global best practices in pharmacovigilance. The PPB remains dedicated to safeguarding public health by fostering robust monitoring systems and ensuring that vaccines administered meet stringent safety criteria.



Participants pose for a group photo after the meeting.

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

National Assembly Health Committee Collaborates with Pharmacy and Poisons Board to Strengthen Pharmaceutical Sector



The National Assembly Health Committee Chair, Hon. (Dr) Robert Pukose (center) during the meeting.

The National Assembly's Departmental Committee on Health, led by Chair Hon. (Dr.) Robert Pukose, convened a fact-finding mission to the Pharmacy and Poisons Board (PPB) on April 22, 2024. The purpose was to gather insights and address pertinent issues within the pharmaceutical sector. Welcomed by Chairman Dr. Charles Githinji, Board members, CEO Dr. F. M Siyoi, and senior management, discussions centered on enhancing PPB's authority, budget allocation, staff recruitment, clinical trials, and legal framework refinement.

Dr. Pukose and team commended PPB's vigilant pharmacovigilance system, ensuring the circulation of

only quality products in the country. Chairman Githinji emphasized the ongoing crackdown on unlicensed pharmacies, initiated earlier in the year, aiming for operational maturity level 3. PPB urged the committee to expedite the establishment of the Kenya Drug Authority (KDA) to effectively separate practice from products.



Pharmacy and Poisons Board Chairman, Dr. Charles Githinji makes his remarks during the meeting.

PPB's CEO, Dr. Siyoi, underscored the Board's role in promoting local manufacturing, refining regulatory frameworks, and serving as a Regional Centre of Excellence for Pharmacovigilance in Africa. Additionally, PPB has set up and activated 10 regional offices and 11 ports of entry to enhance its operational reach and efficiency.



Pharmacy and Poisons Board Chief Executive Officer, Dr. F. M. Siyoi during a meeting with the National Assembly Health Committee.



A tour of the Pharmacy and Poisons Board Quality Control Laboratory.



REPUBLIC OF KENYA
MINISTRY OF HEALTH
Pharmacy and Poisons Board

**PUBLIC NOTICE ON FALSIFIED BATCH OF HERCEPTIN 440MG
(TRASTUZUMAB 440MG) PRODUCT BATCH NO. C5830083
MANUFACTURED IN GERMANY BY: ROCHE PRODUCTS LTD**

The Pharmacy and Poisons Board (PPB) wishes to alert the public about a suspicious batch of falsified **Herceptin 440mg** (*Trastuzumab 440mg*) product that has been detected in the market. The product batch is CLAIMED to be manufactured in Germany by: Roche Products Ltd, bearing the Batch number **C5830083**, **Mfg. Date: 12/2021**, **Exp. Date: 11/2024**.

The public is notified that this specific product batch number **C5830083** is a confirmed counterfeit. It is not authorized to be in the market and is a falsified product in view of the falsified contents, packaging and labelling aspects which have been confirmed by the brand owner.

Consequently, the PPB cautions the public against the use, supply, sale or distribution of the product batch number **C5830083** as their safety, quality and efficacy CANNOT be assured.

Further, the PPB in collaboration with government investigative agencies has instituted legal and regulatory actions against individuals suspected to be perpetrating the illegal activities in contravention of the Pharmacy and Poisons Act (Cap. 244).

The PPB has initiated a rapid response and heightened surveillance of the market to ensure that safety and public health is protected. We would like to assure the public that PPB has established robust market surveillance and control system that continuously monitor the quality and safety of medical products in the Kenyan market.

We urge members of the public and healthcare providers to report and volunteer information on suspicious activities that may be related to such

acts of falsification as well as 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: pv@ppb.go.ke • Telephone: +254 795 743 049

F. M. Siyoi

Dr. F. M. Siyoi

CHIEF EXECUTIVE OFFICER

11th May 2024

Photos

