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PHARMACY AND POISONS BOARD

NEWSLETTER

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Strengthening Accountability Through Performance Contracting

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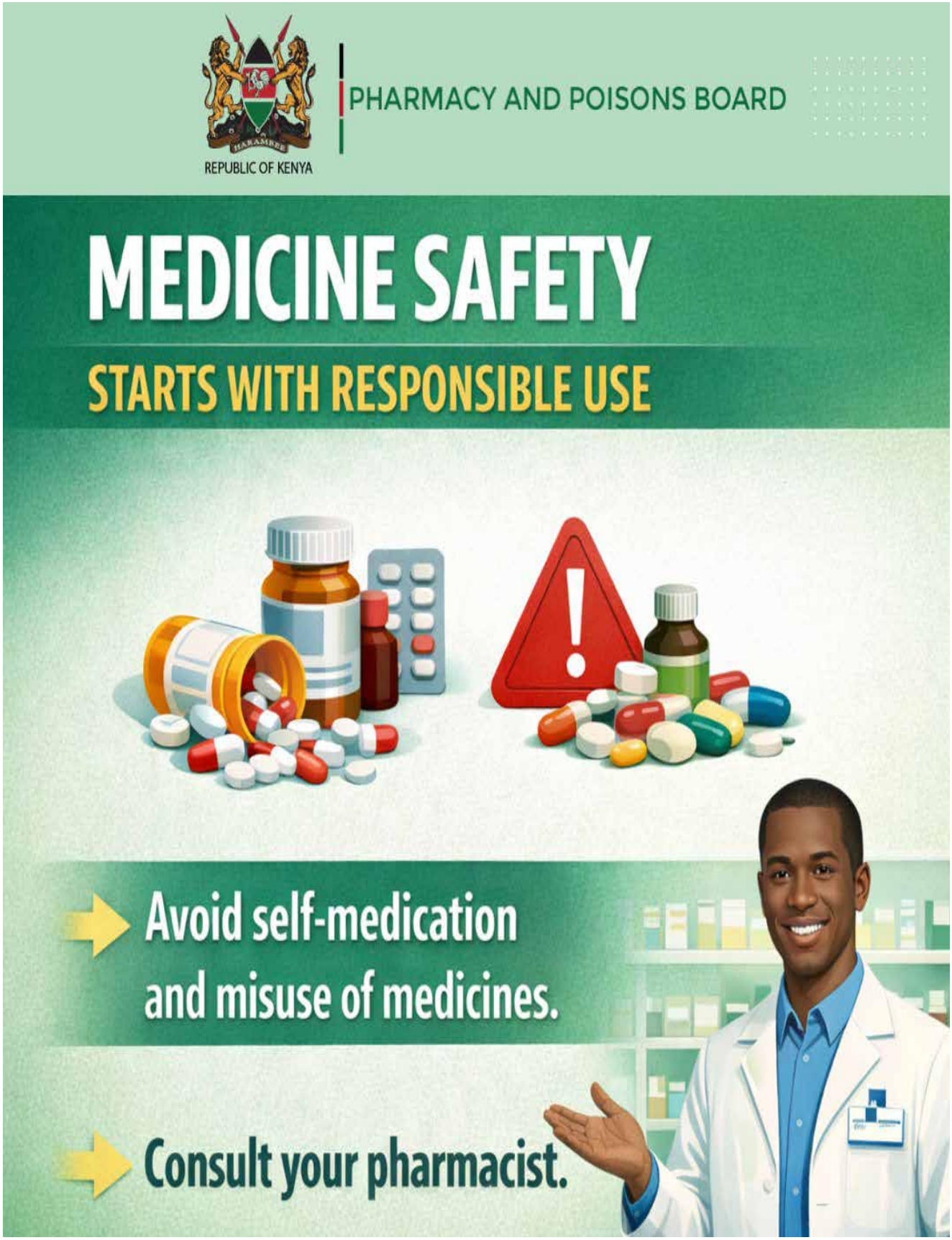
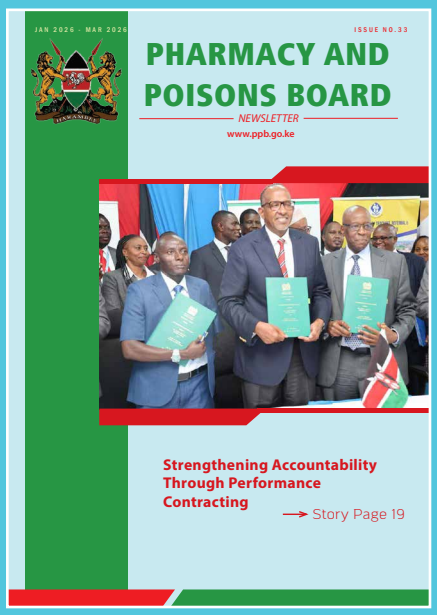


Ensuring quality, safe and efficacious health products and technologies in Kenya



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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

Be part of our growth

Welcome to Issue 33 of the Pharmacy and Poisons Board (PPB) Newsletter. This edition highlights ongoing efforts to strengthen regulatory systems and enhance patient safety.

Thank you for your continued support of PPB. We value your feedback and invite your suggestions as we work to continuously improve our engagement and service to the health sector..

Editor,
Pharmacy and Poisons Board

UPCOMING EVENTS

- **World Health Organization GBT Assessment**

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

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Pharmacy and Poisons Board *@ppbkenya*

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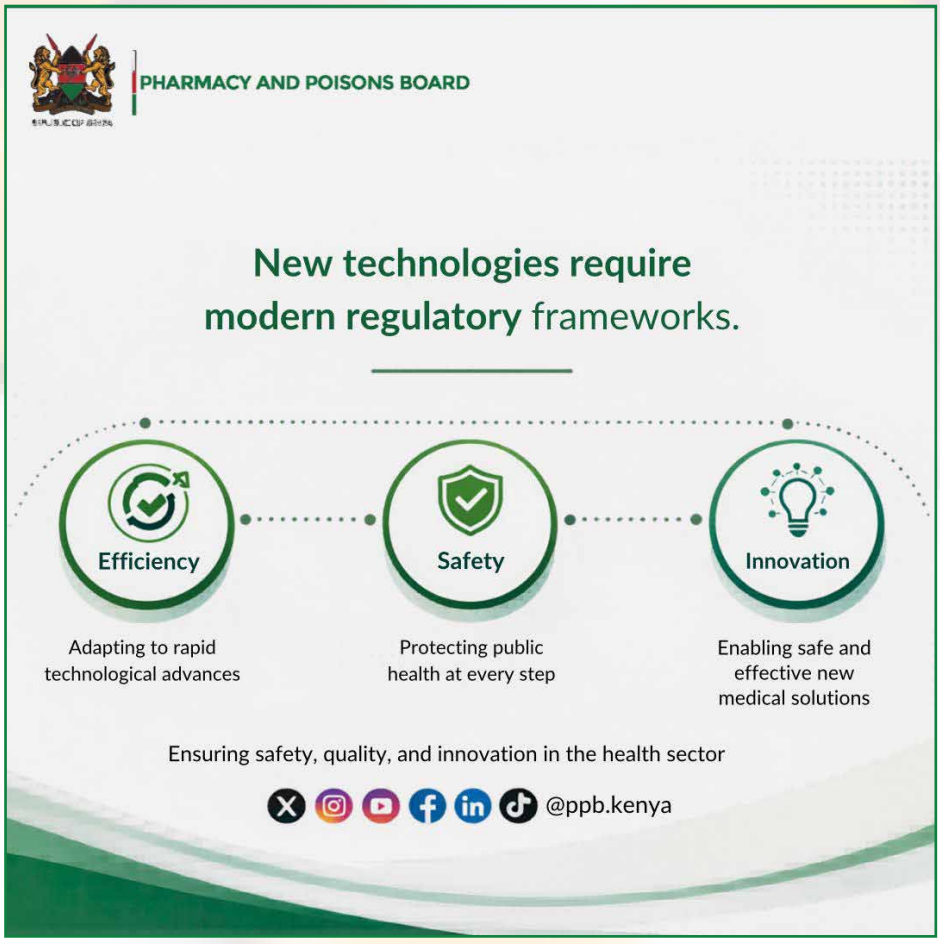

PPB Chair Calls for Strategic Reforms to Strengthen Medicines Regulation

Pharmacy and Poisons Board, Chairman, Board members, Acting CEO and senior staff pose for a group photo

The Chairman of the Pharmacy and Poisons Board (PPB), Dr. John Munyu, has called for targeted reforms to strengthen medicines regulation and enhance efficiency in oversight of health products in Kenya.

Speaking during the opening of the Board of Directors and Management Workshop in Mombasa on 9th March 2026, Dr. Munyu emphasised the need to focus on high-impact areas that improve service delivery, accountability and regulatory effectiveness.

He underscored the importance of leveraging technology to modernise regulatory processes, highlighting the role of ICT and emerging innovations such as Artificial Intelligence in improving turnaround time.

Dr. Munyu also identified human resource development as a key pillar of reform, noting that staff capacity, teamwork and professionalism remain central to institutional performance.

He further called for strengthened internal audit and risk management systems, enhanced regulatory enforcement, and strict adherence to pharmaceutical laws and standards.

"As a regulator, we have a responsibility to enforce the law. Compliance is not optional. Our focus must be on areas that deliver the greatest impact in protecting public health and ensuring order within the pharmaceutical sector," he said.

The Chair also highlighted the need to strengthen public communication, institutional rebranding and resource mobilisation to support the Board's mandate.

He reiterated the distinction between governance and operations, noting that the Board provides oversight and policy direction, while management is responsible for implementation.

Dr. Munyu reaffirmed the Board's commitment to attaining WHO Global Benchmarking Tool Maturity Level 3 (ML3) and noted that ongoing reviews of the performance contract and strategic plan will inform the next phase of institutional development.

During the workshop, Chief Executive Officer Dr. Ahmed Mohamed commended the Board for its continued leadership and support in driving regulatory reforms.

The five-day retreat also reviewed key policies and governance frameworks to strengthen accountability and strategic alignment. Board members present included Dr. Maurice Kodhiambo, Dr. Isha Anand, Dr. Tadudi Aly Omar, Mr. Bernard Maiyo and Ms. Serah Kisilu.

Kenya Strengthens Pharmacovigilance Through AUDA-NEPAD Partnership

Pharmacy and Poisons Board Acting chief Executive Officer, Dr. Ahmed Mohamed makes his remarks during a meeting with the Auda-Nepad team

Kenya has made notable progress in strengthening pharmacovigilance systems through ongoing collaboration between the Pharmacy and Poisons Board (PPB) and AUDA-NEPAD under the AU-3S Programme.

The partnership, anchored on a Sub-Delegation Agreement operationalised in November 2021, has enhanced safety monitoring through targeted capacity building, improved surveillance and strengthened knowledge-sharing across African regulatory authorities.

These efforts have improved coordination and technical capacity, enabling more effective detection, assessment and response to safety

Pharmacy and Poisons Board Acting Chief Executive Officer, Dr. Ahmed Mohamed meets with the AUDA-NEPAD team in his office

A group photo of the meeting participants

concerns related to medicines and other health products.

During an engagement held on 26th March 2026, Acting Chief Executive Officer Dr. Ahmed Mohamed commended AUDA-NEPAD for its continued support in advancing regulatory systems.

He reaffirmed the Board's commitment to sustaining the gains achieved and further strengthening pharmacovigilance systems to safeguard public health.

AUDA-NEPAD team during a meeting with the PPB Acting Chief Executive Officer

PPB Engages Gates MRI on Clinical Research Collaboration

The Pharmacy and Poisons Board (PPB) hosted a delegation from the Gates Medical Research Institute (Gates MRI) on 19th March 2026 to advance discussions on clinical research collaboration in Kenya.

Meeting participants pose for a group photo

Gates MRI Chief Executive Officer, Dr. Patrice Matchaba makes his remarks during the meeting

The meeting was chaired by Dr. Ali Arale on behalf of Chief Executive Officer Dr. Ahmed Mohamed and brought together the Gates MRI team led by Chief Executive Officer Dr. Patrice Matchaba.

Discussions focused on MRI's research agenda and its interest in conducting clinical trials in Kenya, with emphasis on PPB's mandate

Pharmacy and Poisons Board Acting, Director for Health Products and Technoligies Dr. Ali Arale chairs a meeting with the Gates MRI delegation

to safeguard the rights, safety and well-being of clinical trial participants.

Dr. Arale highlighted the Board's role in supporting scientific advisory

processes and collaborative regulatory frameworks to ensure research conducted in the country meets required standards of quality, safety and scientific integrity.

The engagement reaffirmed the importance of strong regulatory systems in enabling timely access to safe and effective medicines and vaccines. Participants also underscored the need to strengthen capacity at clinical trial sites to position Africa to attract a greater share of global research.

PPB Convenes Partners to Strengthen Antimicrobial Resistance Response

Pharmacy and Poisons Board Acting Chief Executive Officer, Dr. Ahmed Mohamed during the meeting

The Pharmacy and Poisons Board (PPB) convened a high-level meeting on 18th March 2026, bringing together international and regional partners to strengthen efforts in addressing antimicrobial resistance (AMR).

The meeting, chaired by Ag. Chief Executive Officer Dr. Ahmed Mohamed, included representatives from the Kenya National Public Health Institute (KNPHI) AMR Secretariat, the Swedish Medical Products Agency, the East African Community (EAC) Secretariat, and Uganda's pharmaceutical regulatory authority.

Discussions focused on reviewing Kenya's progress in tackling AMR and identifying opportunities to strengthen regulatory frameworks through enhanced collaboration and cross-border information sharing.

The engagement forms part of the HARMONEA project, funded by the European Commission through the European Medicines Agency (EMA), which aims to establish a harmonised, One Health-driven regulatory approach to antimicrobial management across EAC partner states.

Participants emphasised the growing threat of antimicrobial resistance and the need for coordinated regional action and strengthened regulatory systems to safeguard public health and preserve the effectiveness of life-saving medicines.

Meeting participants during the engagement session

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PHARMACY AND POISONS BOARD

ENSURING QUALITY, SAFE AND EFFICACIOUS HEALTH PRODUCTS AND TECHNOLOGIES IN KENYA

PUBLIC UPDATE

Message from the Board Chairman - Dr. John Munyu, MBS

Strategic Oversight Driving Regulatory Excellence

The Pharmacy and Poisons Board ("the Board") commends the progress made across the regulatory value chain, which reinforces confidence in the national system for assuring the quality, safety and efficacy of health products and technologies (HPTs). These achievements illustrate the impact of strengthened oversight, enhanced quality control, and digital transformation in advancing a transparent and accountable regulatory framework.

They further affirm the Board's commitment to attaining **WHO Global Benchmarking Tool Maturity Level 3 (ML3)**, supporting Universal Health Coverage, and nurturing a strong, compliant local pharmaceutical manufacturing sector. The Board of Directors will continue to provide strategic direction and governance to sustain these gains and safeguard public health.

Dr. John Munyu, MBS, Chairman Pharmacy and Poisons Board

Message from the Ag. Chief Executive Officer - Dr Ahmed I. Mohamed

Advancing Regulatory Innovation and Operational Excellence

Dr. Ahmed Mohamed - Acting Chief Executive Officer, Pharmacy and Poisons Board

The Board's achievements reflect deliberate and sustained efforts to strengthen regulatory systems that assure the quality, safety and efficacy of HPTs in Kenya. They demonstrate our commitment to building a responsive, technology-driven and risk-based regulatory environment that supports timely access to quality health products while safeguarding public health.

In line with the Board's strategic priorities, we continue to advance regulatory innovation, strengthen institutional capacity and enhance collaboration with national, regional and global partners. These efforts support our progress towards attaining **WHO Global Benchmarking Tool Maturity Level 3**, while reinforcing regulatory efficiency, transparency and public confidence in Kenya's medicines regulatory system.

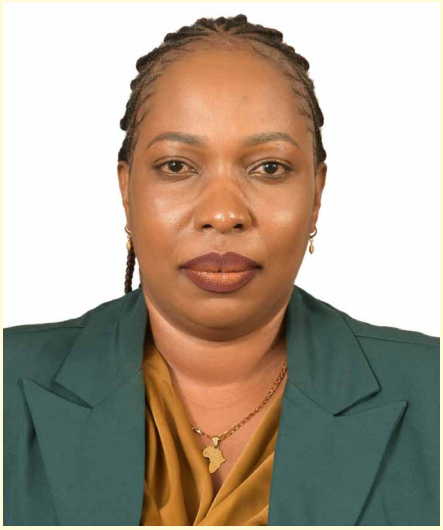
Board Members

Dr. Nancy Njeru- Board Member

Dr. Maurice Kodhiambo - Board Member

Dr. Isha Anand - Board Member

Dr. Tadudi Aly Omar - Board Member



Ms. Serah Kisilu - Board Member

Mr. Benard Maiyo - Board Member

Ms. Florence Ngungu - Board Member

Pharmacy and Poisons Board: Mandate and Regulatory Role

The Board is mandated by Cap 244 of the Laws of Kenya to protect and promote public health by regulating the pharmacy profession and ensuring access to quality, safe, and effective ("HPTs").

The Board assures the quality, safety and efficacy of HPTs through lifecycle oversight that includes control of clinical trials, inspection of manufacturing, storage and distribution channels, product assessment and registration, laboratory testing, post-market surveillance, regulation of imports and exports, control of promotion and advertising, and consumer education.

Pharmacy and Poisons Board Makes Strides in Product Evaluation and Registration

The Board has made significant progress in strengthening the evaluation and registration of HPTs to ensure that medicines, vaccines, medical devices, herbal products and blood products available in Kenya are safe, effective and of assured quality, in line with its mandate under Cap 244 of the Laws of Kenya.

A key milestone has been the implementation of mandatory Bioequivalence requirements for generic medicines, ensuring that these products demonstrate therapeutic equivalence to innovator medicines. This measure enhances public confidence in generic medicines, improves patient safety and aligns Kenya's regulatory framework with international best practices.

The Board has also reinforced post-authorization oversight through enforcement of the mandatory five-year renewal of registered medicines, ensuring that products on the market continue to meet updated standards of quality, safety and effectiveness.

To improve efficiency and consistency in regulatory decision-making, the Board introduced an Artificial Intelligence-powered proof-of-concept tool to support screening of new and renewal applications by verifying dossier completeness and compliance, thereby shortening review timelines and strengthening overall regulatory performance.

The Emergency Use Authorization pathway has been strengthened to facilitate timely access to safe and effective essential HPTs during public health emergencies such as COVID-19 and mpox outbreaks.

In response to emerging digital health innovations, we have developed comprehensive guidelines for the evaluation of Software in Medical Devices and Software as a Medical Device enhancing oversight of technology-driven medical products.

In addition, the Board has strengthened oversight of medicinal or therapeutic cosmetics by introducing a pre-authorization assessment process that transitions products from simple listing to full registration, ensuring thorough scientific evaluation before market entry.

These milestones highlight ongoing efforts to modernise product evaluation and registration processes, enhance regulatory efficiency and keep the public informed on measures taken to ensure access to quality, safe and effective HPTs in Kenya.

Pharmacy and Poisons Board Records Major Gains in Regulating Professionals and Safeguarding Public Health

The Board has recorded notable progress in regulating pharmacy professionals and safeguarding public health through enhanced licensing systems, transparency measures and workforce development initiatives.

Through the adoption of the Regulatory Human Resource Information System (RHRIS), the Board has upscaled the registration and licensing for pharmacists and pharmaceutical technologists, boosting efficiency, revenue collection and financial accountability as well as reducing licence approval timelines.

To enhance transparency and public trust, all licences now feature QR codes for instant verification via mobile devices, deterring fake licences and protecting patient safety. Real-time licensing data

for practitioners and pharmaceutical outlets is publicly accessible online, and licence suspensions and revocations are displayed on the website- web.pharmacyboardkenya.org

The Board continues to strengthen Kenya's pharmaceutical workforce through strategic regulatory oversight and professional development initiatives. Annually, over 15,000 pharmacists and pharmaceutical technologists are licensed after fulfilling Continuing Professional Development requirements, ensuring practitioners remain current with evolving healthcare demands. Additionally, more than 2,000 new practitioners are assessed for registration or enrolment each year, reflecting a robust pipeline of talent entering the profession.

To uphold quality training standards, the Board has accredited 26 institutions offering diploma in pharmaceutical technology and nine universities offering pharmacy degrees. In a move to expand advanced patient care, the Board has initiated the recognition of specialist pharmacists, enabling practitioners to deliver specialized services that improve health outcomes across Kenya.

This ensures a well-trained workforce ready to meet evolving healthcare needs, demonstrating our commitment to innovation, transparency, and competence assurance. These efforts directly support the Universal Health Coverage agenda and guarantee that Kenyans receive quality pharmaceutical services.

Pharmacy and Poisons Board Advances Compliance and Quality Assurance Across Pharmaceutical Supply Chain

Assorted medicines seized during a crackdown activity in Nairobi county

The Board has enhanced regulatory compliance aimed at safeguarding public health through improved inspection programmes, digital innovation and support for local manufacturing, to reinforce oversight across the entire pharmaceutical supply chain.

A major milestone has been the enhanced on risk-based nationwide inspection of wholesalers for compliance with Good Storage and Distribution Practices (GSDP) framework. Conducted from December 2025 to 15th February 2026, the exercise ensured that storage, handling and distribution conditions for medicines meet established regulatory standards, preserving product quality and protecting public health.

To improve efficiency and accountability in inspections, the Board has developed a new online inspection tool. The digital platform enables real-time data capture, streamlined reporting and improved monitoring of compliance across distribution channels, strengthening transparency and regulatory responsiveness.

The Board has also played a pivotal role in advancing local pharmaceutical production by supporting the establishment of ten new manufacturers of HPTs in Kenya, currently at various stages of set-up, while continuing routine inspections of existing local manufacturers to ensure adherence to current Good Manufacturing Practice standards.

Further enhancing regulatory agility, the Board has implemented reliance pathways for determining company compliance with current Good Manufacturing Practice requirements. This approach leverages credible regulatory decisions and international benchmarks to expedite assessments while maintaining rigorous quality assurance.

These achievements underscore our commitment to robust regulatory oversight, promotion of local manufacturing and assurance that medicines and health products in the Kenyan market consistently meet the highest standards of quality, safety and efficacy.

Strengthening Quality Control Capacity at Pharmacy and Poisons Board

The Board has considerably enhanced its capacity to ensure that only quality, safe and efficacious health products are available in the Kenyan market. Strategic investments in laboratory

Dr. Lorna Wangari explains how Near Infrared technology works at the Pharmacy and Poisons Board Quality Control Laboratory

The Pharmacy and Poisons Board Quality Control Laboratory

infrastructure, rapid screening technologies and international quality assurance programmes have strengthened regulatory oversight and post-market surveillance.

The laboratory has acquired high-end analytical equipment to support full compendial testing in line with international pharmacopoeial standards. These include four High Performance Liquid Chromatography systems, a Gas Chromatography system, dissolution testers, friability, hardness and disintegration testers, Atomic Absorption Spectrometer, UV-Visible spectrometers, automatic titrator, Karl Fischer titrator and high-precision analytical balances. This equipment enables comprehensive testing of medicines to assure quality, safety and efficacy.

To improve detection of substandard and falsified medical products, the Board has deployed rapid screening technologies including Minilab kits at ports of entry and regional offices, handheld Raman spectrometers and Near Infrared spectrometers for real-time field analysis. These tools have enhanced early detection and timely regulatory response.

Testing coverage remains high, with 98 per cent of all medicines received since 2017 (3,405 out of 3,463 samples) analysed at the laboratory. Identified substandard or falsified products are documented through Certificates of Analysis to guide regulatory action by the Quality, Safety and Efficacy and Committee.

The quality control laboratory also participates in international and regional quality assurance initiatives, including EDQM proficiency testing, interlaboratory comparisons with WHO-prequalified ISO 17025 laboratories, regional testing of antimalarials and antibiotics, and specialised vaccine quality control training in East Africa. These engagements ensure alignment with global best practices and continuous strengthening of laboratory competence.

Overall, the acquisition of advanced equipment, deployment of rapid screening technologies and sustained international collaboration have significantly strengthened the Board's capacity to safeguard the quality of health products in Kenya. Continued investment in infrastructure, skills and partnerships will remain critical to sustaining regulatory excellence and protecting public health.

PPB Strengthens Surveillance and Safety Systems to Protect Public Health

The Board has intensified regulatory oversight across the health products lifecycle, recording notable progress in post-marketing surveillance, pharmacovigilance, clinical trials regulation and medicines information management.

Pharmacy and Poisons Board officers conduct Post Marketing Surveillance activity

In 2025/26 financial year, the Board conducted two active post-marketing quality surveillance surveys covering antibiotics, analgesics, emergency contraceptives and Maternal, Neonatal and Child Health products. A total of 483 samples underwent compendial testing, achieving over 90 per cent compliance, with all non-compliant products promptly recalled. The Board also received 426 reports of suspected poor-quality medicines nationwide, leading to 45 recalls and demonstrating a strengthened surveillance system capable of rapidly detecting and removing substandard products from the market.

To enhance monitoring, the Board deployed Near Infrared (NIR) screening technology for faster, cost-effective screening of a wider range of medicines. With support from the Global Fund and the Gates Foundation, the Board developed the Post Marketing Surveillance Information Management

System, a digital platform that streamlines receipt, evaluation and response to medicine quality complaints, improving efficiency and responsiveness.

Through pharmacovigilance, the Board strengthened medicine and vaccine safety monitoring by piloting the Adverse Events Following Immunization Toolkit across selected facilities increased reporting by 800 per cent, from 10 to 80 reports. Overall, 1,880 Individual Case Safety Reports were received and evaluated, reflecting an active national safety monitoring system. Capacity building remained central, with 436 healthcare providers trained on pharmacovigilance practices, serious adverse event investigations and reporting obligations. Expert committees — the Pharmacovigilance Experts Review and Advisory and the National Vaccine Safety and Advisory Committee — conducted causality assessments for 46 cases, providing critical recommendations. The Board also partnered with five key institutions, including the National Vaccines and Immunization Programme and KEMRI, to strengthen nationwide safety monitoring.

Clinical trials regulation continued to reflect Kenya's growing research environment. During the year, the Board reviewed 33 new clinical trial applications, ensuring timely approvals while maintaining rigorous ethical and scientific standards. To safeguard participants and uphold data integrity, 22 risk-based Good Clinical Practice inspections were conducted across trial sites and related entities. Additionally, 14 inspectors completed a five-day coached audit programme with World Health Organization experts to enhance inspection capacity and harmonise regulatory standards.

In FY 2025/2026, 467 applications were screened in Q1 and 606 in Q2, while approvals rose from 494 to 615, a notable improved efficiency in the regulatory processes. Queried applications declined from 601 in Q1 to 480 in Q2, indicating better submission quality and compliance. The Board undertook one post-marketing surveillance activity in Q1 to monitor HPTs safety and compliance.

These achievements underscore the Board's strengthened regulatory systems and commitment to ensuring the safety, quality and efficacy of medicines in Kenya through enhanced surveillance, robust safety monitoring and efficient application review processes.

Digital Transformation Strengthening Medicines Regulation at PPB

The Board is enhancing medicines regulation through strategic investment in ICT systems that support efficient service delivery, real-time decision-making and public safety. These platforms provide end-user support, digital services for stakeholders and guidance on emerging technologies such as Artificial Intelligence and the Internet of Things.

Key milestones include the Practice System, which enables over 15,000 practitioners to renew licences online, and the Premises and Inspections System that captures GPS-tagged inspection data for more than 7,700 premises, improving transparency and regulatory oversight. The Product Retention System, hosting over 9,100 approved products, ensures rigorous review of medicines, while Pharmacovigilance and Clinical Trials systems support safety reporting and monitoring of research protocols.

The Board also utilises the National Electronic Single Window System to streamline import and export approvals and the National Drug System to control licit movement of controlled substances. Public access to regulatory information has been expanded through mobile applications, USSD short codes, and the EShot alert platform for targeted safety communications.

Document security has been strengthened through QR-coded licences and GPS-based geolocation tagging, enhancing authenticity and compliance monitoring. Internally, enterprise solutions such as the Alfresco Document Management System and ABN GENESIS ERP have improved records management, finance, procurement and administrative efficiency, supported by a secure Data Centre infrastructure.

Looking ahead, the Board is developing the Pharmaceutical Regulatory Information Management System (PRIMS) to integrate all regulatory functions, alongside a real-time Data Access Dashboard and an Artificial Intelligence proof of concept to accelerate approvals and strengthen safety monitoring. Anchored by a comprehensive ICT Policy aligned to Vision 2030, these initiatives position the Board as a digitally enabled regulator committed to ensuring the quality, safety and efficacy of HPTs in Kenya.

Strengthening Accountability Through Performance Contracting

Health Cabinet Secretary Hon. Aden Duale signs the Financial Year 2025-2026 Performance Contract with the PPB Chairman Dr. John Munyu and Board Member, Mr. Benard Maiyo

The Pharmacy and Poisons Board (PPB) has reaffirmed its commitment to accountability and efficient service delivery following the signing of its Performance Contract for the Financial Year 2025/2026.

The contract was signed on 2nd March 2026 by Board Chair Dr. John Munyu, MBS, and Acting Chief Executive Officer Dr. Ahmed Mohamed during the Ministry of Health's performance contracting session for SAGAs and regulatory bodies, held at the Kenya Medical Research Institute (KEMRI) in Nairobi.

The ceremony was presided over by Cabinet Secretary for Health,

Health Canibet Secretary Hon. Aden Duale, PPB Chairman Dr. John Munyu and board Member, Mr. Benard Maiyo display the signed Performance Contract

Hon. Aden Duale, covering the performance period from 1st July 2025 to 30th June 2026.

The new performance cycle aligns PPB's regulatory priorities with ongoing health sector reforms, cascading targets across all levels of the organisation and strengthening results-based leadership anchored on transparency, integrity and prudent use of public resources.

Key priorities for FY2025/2026 include strengthening regulatory oversight of medicines and health products, enhancing pharmacovigilance and post-market surveillance, advancing digital regulatory services, and improving access to safe, quality and efficacious medical products in support of Universal Health Coverage.

The signing was attended by Principal Secretaries Hon. Ahmed Abdisalan Ibrahim (National Government Coordination), Dr. Ouma Oluga (Medical Services), and Ms. Mary Muthoni (Public Health and Professional Standards), Director-General for Health Dr. Patrick Amoth, Ministry Directors, technical heads, Chief Executive Officers of State Corporations and regulatory agencies, and PPB Board Member Mr. Benard Maiyo.

Health Cabinet Secretary Hon. Aden Duale poses for a group photo during the PC signing

Driving Quality Systems Towards WHO Maturity Level 3

Pharmacy and Poisons Board Acting Chief Executive Officer, Dr. Ahmed Mohamed makes his remarks during the Management Review Meeting

Pharmacy and Poisons Board top management follow proceeding during the meeting

The Pharmacy and Poisons Board conducted its FY 2025/2026 Management Review Meeting on 2nd February 2026 to assess the effectiveness of its Quality Management System and align operations with its strategic direction and WHO Global Benchmarking Tool Maturity Level 3 (ML3) requirements.

The meeting was opened by Acting Chief Executive Officer Dr. Ahmed Mohamed, who emphasised the need to strengthen systems performance beyond compliance and embed quality through standardised and automated processes.

He highlighted the importance of addressing ISO 9001:2015 non-conformities, improving coordination across departments, and reinforcing a culture of continuous improvement.

Dr. Ahmed also underscored the role of performance management in driving results, noting the need for clear key performance indicators, data-driven decision-making, prudent resource utilisation, and sustained systems automation.

The review supports ongoing efforts to strengthen regulatory systems and advance the Board's journey towards achieving WHO Maturity Level 3 status.

Advancing Regulatory Excellence at KIICO 2026

Dr. Gedion Too and Dr. Emmanuel Devi at the PPB exhibition booth

The Pharmacy and Poisons Board (PPB) participated in the Kenya International Investment Conference (KIICO 2026) held from 25th to 27th March 2026, showcasing its regulatory mandate, key initiatives, and contributions to strengthening Kenya's health sector.

Held under the theme "Unlocking Investment Opportunities to Drive Kenya's Transformation," the conference provided a platform for PPB to engage with investors and stakeholders, highlighting its services and exploring opportunities for collaboration to advance healthcare standards.

During the conference, Acting Chief Executive Officer Dr. Ahmed Mohamed reaffirmed the Board's commitment to safeguarding public health through regulatory excellence, noting that PPB

Pharmacy and Poisons Board Acting Chief Executive Officer, Dr. Ahmed Mohamed, Dr. Sarah Chesaro and Dr. Gedion Too during the KIICO 2026 Conference

continues to foster an enabling environment for innovation while ensuring the safety, quality and efficacy of medical products.

He underscored the critical role of regulatory institutions in supporting both public health outcomes and the growth and competitiveness of the pharmaceutical sector.

Dr. Ahmed also emphasised the importance of strategic partnerships in strengthening regulatory systems and driving sustainable growth within the health sector.

REPUBLIC OF KENYA

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

REGULATORY UPDATE

IMPLEMENTATION OF MARKET AUTHORIZATION RENEWALS, IMPORTATIONS AND REGULATORY INSPECTIONS

The Pharmacy and Poisons Board ("the Board") is mandated under the Pharmacy and Poisons Act, CAP 244 Laws of Kenya to protect and promote public health by ensuring access to quality, safe, and efficacious Health Products and Technologies ("HPTs").

Regulatory Requirements for HPTs

1. Section 3A(c) of CAP 244 mandates the Board to grant, vary, renew or withdraw marketing authorization for HPTs, subject to prescribed conditions.
2. Rule 4(1) of the the Pharmacy and Poisons (*Registration of Health Products and Technologies) Rules, 2022*, requires that any person intending to import, manufacture, or distribute a HPT must obtain prior registration of the product from the Board.
3. Further, Rule 10(1) of the same Rules provides that a certificate of registration or renewal issued by the Board shall be valid for a period of five (5) years from the date of issuance.
4. Accordingly, any HPT whose Marketing Authorization expires without submission of a renewal application ceases to have lawful registration status and is ineligible for importation, manufacture, or distribution in Kenya.
5. In line with these statutory provisions, the Board required all Marketing Authorization Holders with expired or expiring registrations to submit renewal applications by 31st December 2025.
6. As at 1st February 2026, 78% of the 9,551 HPTs that were retained and in circulation in 2025 either hold valid Marketing Authorizations or have submitted renewal applications currently under regulatory review, a demonstration of strong industry participation in the compliance framework.
7. The remaining 22% of HPTs whose renewal applications were not submitted by the stipulated deadline are therefore non-compliant with the statutory and regulatory requirements.
8. These non-compliant HPTs are required to undergo fresh registration in accordance with the applicable regulatory procedures.
9. The Board further notifies stakeholders that, as at 1st February 2026, all submitted renewal applications have been screened for completeness. Applications have either progressed to technical evaluation or been issued with requests for additional information to assure continued product Quality, Safety, and Efficacy.
10. Stakeholders issued with screening queries are required to submit responses, noting that the Board will complete screening phase within sixty (60) working days from the date of submission.

Importation of HPTs

1. Rule 3 of the Pharmacy and Poisons Rules, 2022, prohibits importation of any HPT into Kenya without a valid import License issued by the Board.

2. To ensure continuity of access to essential HPTs in Kenya, all applications that were submitted before the expiration of the period indicated in Rule 10(1) and regulatory notices (and successfully screened) may apply for import License.
3. The Board will continue to prioritize evaluation of renewal applications based on public health risk, therapeutic importance, and alignment with national public health programmes, including HPTs supporting chronic disease management.

GMP Certification Status and Inspection Scheduling

1. As part of its risk-proportionate regulatory oversight, the Board has continued to allow regulatory consideration of manufacturing sites with recently lapsed GMP certification where there is documented historical compliance, absence of reported quality defects and product recalls.
2. GMP inspections are conducted based on risk prioritization, product criticality, and public health impact, in accordance with national regulatory requirements and international best practices.
3. In furtherance of these risk mitigation measures, the Board has extended GMP certification status for several eligible manufacturing sites.

Stakeholder Engagement

1. The Board conducts regular stakeholder engagements to address emerging challenges, facilitate effective information sharing and promote compliance.
2. In this regard, the Board has scheduled a stakeholder engagement session on 4th March 2026, at 10.00 a.m., to discuss matters pertaining to the Pharmaceutical Industry.

The Board remains committed to protecting and safeguarding public health, and will continue to provide the necessary technical guidance to support sustained regulatory compliance.

Dr. Ahmed I. Mohamed
Ag. CHIEF EXECUTIVE OFFICER
5th February 2026

HOW TO IDENTIFY A LICENSED PHARMACY

1 Verify Online

Check if the pharmacy is registered on the PPB **verification platform**

2 Ask the Professional

Speak to the pharmacist or pharmaceutical technologist on duty.

3 Protect Your Health

Always buy medicines from **registered pharmacies** only.

practice.pharmacyboardkenya.org

Pharmacy and Poisons Board – Ensuring Safe Medicines in Kenya

#SafeMedicines #PatientSafety #PPB #KenyaHealth

REPUBLIC OF KENYA

PHARMACY AND POISONS BOARD

STOP ANTIMICROBIAL RESISTANCE!

You can help prevent AMR by:

- ✓ Using antibiotics only when prescribed
- ✓ Completing your full treatment
- ✓ Never sharing or using leftover antibiotics
- ✓ Practicing good hygiene & vaccination to prevent infections
- ✓ Avoiding self-medication & over-the-counter antimicrobials
- ✓ Disposing of antimicrobials safely

YOUR ACTIONS TODAY PROTECT FUTURE GENERATIONS!